

EXELIXIS INC  
Form 10-K  
February 22, 2012  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)**

**OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended: December 30, 2011

**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)

Edgar Filing: EXELIXIS INC - Form 10-K

Delaware  
(State or Other Jurisdiction of

04-3257395  
(I.R.S. Employer

Incorporation or Organization)

210 East Grand Ave.

Identification Number)

South San Francisco, CA 94080

(Address of Principal Executive Offices) (Zip Code)

(650) 837-7000

(Registrant's Telephone Number, including Area Code)

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  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

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

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

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

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

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: \$1,153,817,690 (Based on the closing sales price of the registrant's common stock on that date. Excludes an aggregate of 3,148,842 shares of the registrant's common stock held by persons who were directors and/or executive officers of the registrant at July 1, 2011 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 15, 2012, there were 148,420,470 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 April 28, 2012, in connection with the registrant's 2012 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.**

**FORM 10-K**

**INDEX**

	<b>Page</b>
<b><u>PART I</u></b>	
Item 1. <u>Business</u>	3
Item 1A. <u>Risk Factors</u>	17
Item 1B. <u>Unresolved Staff Comments</u>	37
Item 2. <u>Properties</u>	37
Item 3. <u>Legal Proceedings</u>	37
Item 4. <u>Mine Safety Disclosures</u>	37
<b><u>PART II</u></b>	
Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	38
Item 6. <u>Selected Financial Data</u>	40
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	42
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	64
Item 8. <u>Financial Statements and Supplementary Data</u>	65
Item 9. <u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	102
Item 9A. <u>Controls and Procedures</u>	102
Item 9B. <u>Other Information</u>	104
<b><u>PART III</u></b>	
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	105
Item 11. <u>Executive Compensation</u>	105
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	105
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	107
Item 14. <u>Principal Accounting Fees and Services</u>	107
<b><u>PART IV</u></b>	
Item 15. <u>Exhibits and Financial Statement Schedules</u>	108
<u>SIGNATURES</u>	109

**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, should, would, could, estimate, predict, potential, 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.*

*Exelixis has adopted a 52- or 53-week fiscal year that ends on the Friday closest to December 31<sup>st</sup>. Fiscal year 2009, a 52-week year, ended on January 1, 2010, fiscal year 2010, a 52-week year, ended on December 31, 2010, and fiscal year 2011, a 52-week year, ended on December 30, 2011. Fiscal year 2012, a 52-week year, will end on December 28, 2012. For convenience, references in this report as of and for the fiscal years ended January 1, 2010, December 31, 2010 and December 30, 2011 are indicated on a calendar year basis, ended December 31, 2009, 2010 and 2011, respectively.*

**ITEM 1. BUSINESS****Overview**

We are a biotechnology company committed to developing small molecule therapies for the treatment of cancer. We are focusing our proprietary resources and development efforts exclusively on cabozantinib, or XL184, our most advanced product candidate, in order to maximize the therapeutic and commercial potential of this compound. We believe cabozantinib has the potential to be a high-quality, broadly-active, differentiated pharmaceutical product that can make a meaningful difference in the lives of patients. We have also established a portfolio of other novel compounds that we believe have the potential to address serious unmet medical needs, many of which are being advanced by partners as part of collaborations.

**Cabozantinib**

Cabozantinib inhibits MET, VEGFR2 and RET, proteins that are key drivers of tumor growth, vascularization and/or metastasis. Cabozantinib has shown novel and differentiated activity in multiple cancer indications. The current clinical program for cabozantinib is focused on the treatment of metastatic castration-resistant prostate cancer, or CRPC, and medullary thyroid cancer but also includes the evaluation of other tumor types. Exelixis has implemented a strategy to investigate cabozantinib in a comprehensive development program for CRPC to potentially generate a product that could effectively compete in the CRPC marketplace. Two phase 3 pivotal trials, COMET-1 (Cabozantinib MET Inhibition CRPC Efficacy Trial-1, formerly known as XL184-307) and COMET-2 (Cabozantinib MET Inhibition CRPC Efficacy Trial-2, formerly known as XL184-306), were designed to provide an opportunity to commercially differentiate cabozantinib as an oncology agent with a potentially beneficial impact on overall survival, pain palliation and narcotic usage. We expect to initiate the COMET-1 trial with an overall survival endpoint in the first half of 2012. We initiated the COMET-2 trial with a pain palliation endpoint in December 2011. We also initiated a rolling submission of a new drug application, or NDA, for cabozantinib in medullary thyroid cancer in December 2011 following our October

---

## **Table of Contents**

2011 announcement of the top-line results of the primary endpoint of our ongoing phase 3 clinical trial of cabozantinib as a potential treatment for medullary thyroid cancer, known as the EXAM trial (Efficacy of XL184 (Cabozantinib) in Advanced Medullary Thyroid Cancer).

We expect to expand the cabozantinib development program to other solid tumor indications, based on encouraging interim data that have emerged from the randomized discontinuation trial, or RDT, investigating cabozantinib in nine distinct tumor types, as well as other clinical trials. Objective tumor responses have been observed in patients treated with cabozantinib in 12 of 13 individual tumor types investigated to date, reflecting the broad potential clinical activity and commercial opportunity of this new product candidate. Interim data suggest that cabozantinib has shown novel activity against bone and soft tissue lesions in patients with CRPC. We have also observed resolution of metastatic bone lesions on bone scan in patients with metastatic breast cancer, renal cell carcinoma, thyroid cancer and melanoma. Interim data from the CRPC cohort of the RDT reported at the American Society of Clinical Oncology Annual Meeting in June 2011 demonstrated that in addition to improvement of bone lesions on bone scan observed in the majority (75%) of patients, 67% of patients with bone metastases and bone pain at baseline also experienced alleviation of pain. This observation has been corroborated in a non-randomized expansion cohort, or NRE, of CRPC patients in the RDT, which collected prospectively defined patient reported outcomes on pain and narcotic use. Interim data from the NRE reported at the AACR-NCI-EORTC Symposium on Molecular Targets and Cancer Therapeutics in November 2011 demonstrated that 48% of CRPC patients with moderate to severe pain in the NRE experienced durable pain reduction greater than or equal to 30%. The median best pain reduction was 46%. In addition, these interim data indicated that 56% of CRPC patients in the NRE with moderate to severe bone pain and on narcotics at baseline were able to reduce or discontinue narcotic medication. Lower starting doses of cabozantinib are being evaluated through a dose-ranging study in CRPC patients conducted through an investigator sponsored trial, or IST. Preliminary data from the IST demonstrate that a daily dose of 40 mg resulted in a rate of bone scan responses similar to that of a 100 mg daily dose used in the RDT and was associated with improved tolerability compared with the higher dose. In addition, preliminary data from a cohort of CRPC patients in the NRE treated at a daily dose of 40 mg demonstrate pain palliation responses consistent with observations at the 100 mg daily dose.

It is a priority for us to generate additional data from the RDT as well as other ongoing exploratory clinical trials for cabozantinib in a broad range of tumor types, including ovarian cancer, melanoma, breast cancer, non-small cell lung cancer, hepatocellular cancer, renal cell carcinoma and differentiated thyroid cancer, to support further prioritization of our clinical and commercial options. In November 2011, we entered into a Cooperative Research and Development Agreement, or CRADA, with the National Cancer Institute's Cancer Therapy Evaluation Program, or CTEP, for further evaluation of cabozantinib across multiple tumor types and in combination with other anti-tumor agents in a cost-effective manner for Exelixis. We believe that cabozantinib's clinical profile is compelling and will allow commercial differentiation, assuming regulatory approval.

### **EXAM Phase 3 Clinical Trial in Medullary Thyroid Cancer**

Cabozantinib is being studied in an ongoing global phase 3 registration trial in medullary thyroid cancer known as the EXAM trial. In October 2011, we announced the top-line results of the primary endpoint of the EXAM trial. The trial met its primary endpoint of improving progression-free survival compared with placebo and substantially exceeded the threshold of a 75% increase in progression-free survival originally assumed when the trial was designed. Cabozantinib significantly improved median progression-free survival by 7.2 months compared with placebo. The median progression-free survival on the cabozantinib arm was 11.2 months versus 4.0 months on the placebo arm: hazard ratio 0.28 (95% CI 0.19, 0.40),  $p < 0.0001$ . We intend to report data from the EXAM trial at an upcoming medical conference in 2012. In December 2011, we initiated a rolling submission of an NDA for cabozantinib in medullary thyroid cancer, and we expect to complete the NDA filing in the first half of 2012. Cabozantinib is eligible for a rolling submission as a result of the United States Food and Drug Administration, or FDA, granting cabozantinib in medullary thyroid cancer Fast Track designation, which often results in a drug being considered appropriate to receive a priority review. Assuming priority review, we currently anticipate a potential approval of our NDA by the FDA by the end of 2012.

---

## **Table of Contents**

The EXAM trial was initiated in 2008 following agreement between the FDA and us on the trial design through the FDA's Special Protocol Assessment, or SPA, process. In January 2011, the FDA granted orphan drug designation to cabozantinib for the treatment of follicular, medullary, and anaplastic thyroid carcinoma and metastatic or locally advanced papillary thyroid cancer. Orphan drug status is granted to treatments for diseases that affect fewer than 200,000 people in the United States and provides the benefits of potential market exclusivity for the orphan-designated product for the orphan-designated indication for seven years, tax credits of up to 50% of the qualified clinical trial expenses and a waiver of FDA application user fees.

### **Phase 3 Clinical Trials in Castration-Resistant Prostate Cancer**

Our comprehensive CRPC development program is centered around our COMET-1 trial, which we plan to initiate in the first half of 2012, and our COMET-2 trial, which was initiated in December 2011, each of which is described below. We are also exploring other potential pivotal trials in the prostate cancer indication.

**COMET-1 Trial Design.** The primary endpoint of the COMET-1 trial will be overall survival. The double-blind trial will be conducted in patients with castration-resistant prostate cancer with bone metastases who have failed prior docetaxel and abiraterone or MDV3100 therapies. Patients will be randomized in a 2:1 ratio to receive cabozantinib at 60 mg daily or prednisone. The trial is expected to be executed globally and at non-overlapping sites with the COMET-2 trial.

**COMET-2 Trial Design.** The double-blind COMET-2 trial is designed to enroll 246 patients with castration-resistant prostate cancer that is metastatic to the bone, who are suffering from moderate to severe bone pain despite optimized narcotic medication, and who have failed prior docetaxel and abiraterone or MDV3100 therapies. The trial will be conducted in English-speaking regions, including the United States, Canada and the United Kingdom. Patients will be randomized 1:1 to receive either cabozantinib or mitoxantrone/prednisone. Alleviation of bone pain will be the primary endpoint and will be measured by comparing the percentage of patients in the two treatment arms who achieve a pain response at Week 6 that is confirmed at Week 12. The trial design assumes that 25% of patients in the cabozantinib arm will have a pain response while 8% of patients in the mitoxantrone/prednisone arm will have a pain response. Prior to randomization, patients will undergo a period during which their pain medication is optimized using one long acting narcotic medication and one immediate release narcotic medication. This optimization follows a standard approach defined in the National Comprehensive Cancer Network guidelines. Patients in the cabozantinib arm will be dosed at 60 mg per day until the patient no longer receives clinical benefit. The definition of a responder with respect to the bone pain endpoint is a greater than or equal to 30% decrease from baseline in the average of the daily worst pain intensity collected over seven days in Week 6 and confirmed in Week 12, with neither a concomitant increase in average daily dose of any narcotic pain medication, nor addition of any new narcotic pain medication. Overall survival will be a secondary endpoint of the COMET-2 trial. The trial will be deemed successful if the primary endpoint of statistically significant pain improvement is met and the overall survival analysis does not show an adverse impact on overall survival in the cabozantinib arm. We originally submitted the proposed clinical protocol for the COMET-2 trial to the FDA in June 2011 with a request for a SPA but were not able to reach a timely agreement with the FDA under a SPA on the proposed study design and analysis.

### **Strategy**

Our strategy is to aggressively advance cabozantinib through development toward commercialization. In doing so, we will pursue a pragmatic development plan focused on those cancer indications where we believe cabozantinib has the greatest therapeutic and commercial potential. We are aggressively managing our expenses to preserve our cash resources and ensure we are appropriately dedicating those resources towards successfully executing our strategy.

---

## **Table of Contents**

Consistent with our decision to focus on cabozantinib and aggressively manage our expenses, we have discontinued development efforts with respect to our remaining unpartnered compounds and programs, and are considering collaborations or other external opportunities for further development of these compounds and programs.

### **Collaborations**

We have established collaborations with leading pharmaceutical and biotechnology companies, including Bristol-Myers Squibb Company, or Bristol-Myers Squibb, Sanofi, Genentech, Inc. (a wholly owned member of the Roche Group), GlaxoSmithKline, 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 out-licensed compounds or programs to a partner for further development and commercialization, generally have no further unfunded cost obligations related to such compounds or programs and may be entitled to receive research funding, milestones and royalties or a share of profits from commercialization. Several of the out-licensed compounds are in multiple phase 2 studies and could potentially be of significant value to us if their development progresses successfully. With respect to our partnered compounds, we are eligible to receive potential milestone payments under our collaborations totaling approximately \$3.1 billion in the aggregate on a non-risk adjusted basis, of which 10% are related to clinical development milestones, 44% are related to regulatory milestones and 46% are related to commercial milestones.

#### ***Bristol-Myers Squibb***

*TGR5 License Agreement.* In October 2010, we entered into a global license agreement with Bristol-Myers Squibb pursuant to which we granted to Bristol-Myers Squibb a license to our small-molecule TGR5 agonist program, including rights to the program's lead compound, XL475, as well as potential backups. The license agreement became effective in November 2010 following clearance under the Hart-Scott-Rodino Antitrust Improvement Act of 1976, as amended. The license agreement was amended and restated in April 2011 in connection with an assignment of patents to one of our wholly-owned subsidiaries.

Under the license agreement, Bristol-Myers Squibb received a worldwide exclusive license to XL475 and sole control and responsibility for all research, development, commercial and manufacturing activities. In November 2010 we received a nonrefundable upfront cash payment of \$35.0 million from Bristol-Myers Squibb. Additionally, for each product developed by Bristol-Myers Squibb under the license, we will be eligible to receive development and regulatory milestones of up to \$250.0 million in the aggregate and commercial milestones of up to \$150.0 million in the aggregate, as well as royalties on commercial sales of any such products.

Bristol-Myers Squibb may at any time, upon specified prior notice to us, terminate the license on a product-by-product and country-by-country basis. In addition, either party may terminate the license 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 from Bristol-Myers Squibb a license to develop and commercialize such product in the related country. Such license would be royalty-free if the agreement is terminated by Bristol-Myers Squibb at will, or royalty-bearing if the agreement is terminated by us for Bristol-Myers Squibb's uncured material breach. In the event of termination by Bristol-Myers Squibb for our uncured material breach, Bristol-Myers Squibb would retain the right to such product and we would receive reduced royalties from Bristol-Myers Squibb on commercial sales of such product.

*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



---

**Table of Contents**

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 development and regulatory milestones of up to \$255.0 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 one of our wholly-owned subsidiaries.

Under the terms of the collaboration agreement, we will be 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 will end on the earlier to occur of (i) July 8, 2013 if a compound has not satisfied certain specified criteria by such time or (ii) the date when such compound satisfied the next level of specified criteria, whichever is earlier. Following the collaborative research period, Bristol-Myers Squibb will 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.

*2008 Cancer Collaboration.* In December 2008, we entered into a worldwide collaboration with Bristol-Myers Squibb for cabozantinib and XL281 (BMS-908662), a RAF inhibitor. Upon effectiveness of the collaboration agreement in December 2008, Bristol-Myers Squibb made a nonrefundable upfront cash payment of \$195.0 million for the development and commercialization rights to both programs. The agreement required Bristol-Myers Squibb to make additional license payments to us of \$45.0 million, which were received during 2009.

On July 8, 2011, we and one of our wholly-owned subsidiaries received written notification from Bristol-Myers Squibb of its decision to terminate the collaboration agreement on a worldwide basis as to XL281. The termination was made pursuant to the terms of the collaboration agreement and became effective on October 8, 2011. Bristol-Myers Squibb informed us that the termination was based upon Bristol-Myers Squibb's review of XL281 in the context of Bristol-Myers Squibb's overall research and development priorities and pipeline products. Upon the effectiveness of the termination, Bristol-Myers Squibb's license relating to XL281 terminated, and rights to XL281 reverted to us. We also received, subject to certain terms and conditions, licenses from Bristol-Myers Squibb to research, develop and commercialize XL281. We have discontinued activities related to XL281 and do not currently expect to further research, develop or commercialize XL281.

On June 18, 2010, we regained full rights to develop and commercialize cabozantinib under the collaboration agreement following receipt of notice from Bristol-Myers Squibb of its decision to terminate the collaboration agreement, solely as to cabozantinib, on a worldwide basis. Bristol-Myers Squibb informed us that the termination was based upon its review of cabozantinib in the context of Bristol-Myers Squibb's overall research and development priorities and pipeline products. On June 28, 2010, in connection with the termination, we received a \$17.0 million transition payment from Bristol-Myers Squibb in satisfaction of its obligations under the collaboration agreement to continue to fund its share of development costs for cabozantinib for a period of three months following the notice of termination. As a result of the termination, Bristol-Myers Squibb's license

---

**Table of Contents**

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.

*2007 Cancer Collaboration.* In December 2006, we entered into a worldwide collaboration with Bristol-Myers Squibb, which became effective in January 2007, to discover, develop and commercialize novel targeted therapies for the treatment of cancer. We were responsible for discovery and preclinical development of small molecule drug candidates directed against mutually selected targets. In January 2007, Bristol-Myers Squibb made an upfront payment of \$60.0 million to us for which we granted Bristol-Myers Squibb the right to select up to three investigational new drug, or IND, candidates from six future Exelixis compounds.

For each IND candidate selected, we were entitled to receive a \$20.0 million selection milestone from Bristol-Myers Squibb. Once selected, Bristol-Myers Squibb became responsible for leading the further development and commercialization of the selected IND candidates. In addition, we had the right to opt in to co-promote the selected IND candidates, in which case we would equally share all development costs and profits in the United States. In January 2008 and November 2008, Bristol-Myers Squibb exercised its option under the collaboration to develop and commercialize XL139 (BMS-833923), a Hedgehog inhibitor, and XL413 (BMS-863233), a CDC7 inhibitor, respectively. Under the terms of the collaboration agreement, the selection of XL139 and XL413 by Bristol-Myers Squibb entitled us to milestone payments of \$20.0 million each, which we received in February 2008 and December 2008, respectively. In addition, we exercised our option under the collaboration agreement to co-develop and co-commercialize each of XL139 and XL413 in the United States. However, in September 2010, we and Bristol-Myers Squibb terminated the XL413 program due to an unfavorable pharmacological profile observed in phase 1 clinical evaluation. Additionally, in connection with an amendment to the collaboration which became effective in November 2010, we exercised our right to opt-out of further co-development of XL139 in consideration for a cash payment of \$20.0 million. The collaboration agreement was amended and restated in April 2011 in connection with an assignment of patents to one of our wholly-owned subsidiaries. We have no further responsibility for conducting new activities or funding new development or commercialization activities with respect to XL139 and will therefore no longer be eligible to share profits on sales of any commercialized products under the collaboration. We will continue to be eligible to receive regulatory and commercial milestones of up to \$260.0 million as well as double-digit royalties on any future sales of any products commercialized under the collaboration. As a result of the November 2010 amendment to the collaboration, the research term has ended, and we have no further obligation to deliver to Bristol-Myers Squibb a third IND candidate under the collaboration.

Bristol-Myers Squibb may, upon notice to us, terminate the agreement as to any product containing or comprising the selected candidate. In the event of such termination election, Bristol-Myers Squibb's license relating to such product would terminate and revert to us, and we would receive, subject to certain terms and conditions, licenses from Bristol-Myers Squibb to research, develop and commercialize certain collaboration compounds that were discovered.

*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. 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. The collaboration agreement was amended and restated in April 2011 in connection with an assignment of patents to one of our wholly-owned subsidiaries.

---

**Table of Contents**

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 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 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 for achieving a development milestone.

***Sanofi***

In May 2009, we entered into a global license agreement with Sanofi for XL147 (SAR245408) and XL765 (SAR245409), leading inhibitors of phosphoinositide-3 kinase, or PI3K, and a broad collaboration for the discovery of inhibitors of 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 receive 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 XL147 and XL765, which are in phase 1, phase 1b/2 and phase 2 clinical trials, and has sole responsibility for all subsequent clinical, regulatory, commercial and manufacturing activities. Sanofi is responsible for funding all development activities with respect to XL147 and XL765, including our activities. Following the effectiveness of the license agreement, we conducted the majority of the clinical trials for XL147 and XL765 at the expense of Sanofi. As provided for under the license agreement, however, the parties transitioned all development activities for these compounds to Sanofi in 2011.

We will be eligible to receive development, regulatory and commercial milestones under the license agreement of \$745 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 XL147 or 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 and Sanofi entered into an agreement 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 milestone 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.

---

**Table of Contents**

***Genentech***

In December 2006, we entered into a worldwide co-development agreement with Genentech for the development and commercialization of XL518, a small-molecule inhibitor of MEK. 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 an IND for XL518.

Under the terms of the co-development agreement, we were responsible for developing XL518 through the end of a phase 1 clinical trial, and Genentech had the option to co-develop XL518, 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. We were responsible for the phase 1 clinical trial until the point that a maximum tolerated dose, or MTD, was determined. After MTD was achieved, we granted to Genentech an exclusive worldwide revenue-bearing license to XL518 in March 2009 and Genentech is responsible for completing the phase 1 clinical trial and subsequent clinical development. We received an additional \$7.0 million milestone payment in March 2010 under the terms of this agreement. Genentech is responsible for all further development costs of XL518 and we will share equally in the U.S. commercialization costs. On an annual basis, we are entitled to an initial equal share of U.S. profits and losses, which will decrease as sales increase, and we are also entitled to royalties on non-U.S. sales. We also have the option to co-promote in the United States. Genentech has the right to terminate the agreement without cause at any time. 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.

***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. 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 XL880 (foretinib), 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.

The \$85.0 million loan we received from GlaxoSmithKline was repayable in three annual installments. We paid the final installment of principal and accrued interest under the loan in shares of our common stock on October 27, 2011 and GlaxoSmithKline subsequently released its related security interest in certain of our patents.

---

## **Table of Contents**

### ***Merck***

In December 2011, we entered into an agreement with Merck pursuant to which we granted Merck an exclusive worldwide license to our PI3K-d program, including XL499 and other related compounds. Pursuant to the terms of the agreement, Merck will have 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 potential development and regulatory milestone payments for multiple indications of up to \$239.0 million. We will also be eligible to receive combined sales performance milestones and royalties on net-sales of products emerging from the agreement. Milestones 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 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. 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 a compound developed under the collaboration and are eligible to receive additional development, regulatory and commercialization milestones of up to \$150.5 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.

### **Potential Collaboration Candidates**

Consistent with our decision to focus on cabozantinib and aggressively manage our expenses, we have discontinued development efforts with respect to our remaining unpartnered compounds and programs, and are considering collaborations or other external opportunities for further development of these compounds and programs.

---

## **Table of Contents**

### **Manufacturing and Raw Materials**

We do not have manufacturing capabilities necessary to enable us to produce materials for our clinical trials. Raw materials and supplies required for the production of our product candidates are generally available from multiple suppliers. However, in some instances materials are available only from one supplier. In those cases where raw materials are only available through one supplier, we manage supplies, to the extent feasible, by ordering raw materials in advance of scheduled needs. However, clinical trial schedules may be delayed due to interruptions of raw material supplies. To date, we have entered into arrangements with two different suppliers for the production of cabozantinib.

### **Government Regulation**

*The following section contains some general background information regarding the regulatory environment and processes affecting our industry and is designed to illustrate in general terms the nature of our business and the potential impact of government regulations on our business. It is not intended to be comprehensive or complete. Depending on specific circumstances, the information below may or may not apply to us or any of our product candidates. In addition, the information is not necessarily a description of activities that we have undertaken in the past or will undertake in the future. The regulatory context in which we operate is complex and constantly changing.*

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 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; and

FDA approval of an NDA for commercial marketing, or NDA supplement, for an 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 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.

---

## **Table of Contents**

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 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. 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 which 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

## **Table of Contents**

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. We cannot be certain that we or our present or future suppliers will be able to comply with the GMP regulations and other FDA regulatory requirements. If our present or future suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, require us to recall a drug from distribution, or withdraw approval of the NDA for that drug.

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 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 manufacturer's communications on the subject of off-label use.

The FDA's policies may change and additional government regulations may be enacted which could prevent or delay regulatory approval of our product candidates or approval of new diseases for our product candidates. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

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 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 (PDUFA) application fee, and upon approval, the potential for seven years of market exclusivity for the orphan-designated product for the orphan-designated indication.

## **Competition**

There are many companies focused on the development of small molecules and antibodies for cancer. Our 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 potential competitors have significantly more financial, technical and other resources than we do, which may allow them to have a competitive advantage.

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

efficacy, safety and reliability of our product candidates;

timing and scope of regulatory approval;

the speed at which we develop product candidates;

our ability to complete preclinical testing and clinical development and obtain regulatory approvals for product candidates;

our ability to manufacture and sell commercial quantities of a product to the market;

our ability to successfully commercialize our products and secure reimbursement in approved indications;

product acceptance by physicians and other health care providers;



quality and breadth of our technology;

skills of our employees and our ability to recruit and retain skilled employees;

---

## **Table of Contents**

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 our lead product candidate, 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.

Any products that we may develop or discover are likely to be in highly competitive markets. We are aware of products in research or development by our competitors that are intended to treat all of the diseases we are targeting, and any of these products may compete with our drug candidates. Our competitors may succeed in developing their products before we do, obtaining approvals from the FDA or other regulatory agencies for their products more rapidly than we do, or developing products that are more effective than our products. These products or technologies might render our technology obsolete or noncompetitive. There may also be drug candidates of which we are not aware at an earlier stage of development that may compete with our drug candidates. In addition, any drug candidate that we successfully develop may compete with existing therapies that have long histories of use, such as chemotherapy and radiation treatments in cancer indications. Examples of potential competition for cabozantinib include: AstraZeneca's RET, VEGFR and EGFR inhibitor, vandetanib; Algeta's development-stage alpha-pharmaceutical, Alpharadin (Radium-223); other VEGF pathway inhibitors, including Genentech's bevacizumab; and other MET inhibitors, including Pfizer's crizotinib, ArQule's tivantinib (ARQ197), GlaxoSmithKline's foretinib (XL880) and Genentech's Met MAb. We anticipate that cabozantinib would compete with any of these potential products on the basis of the factors described above.

### **Research and Development Expenses**

Research and development expenses consist primarily of personnel expenses, laboratory supplies, consulting and facilities costs. Research and development expenses were \$156.8 million for the year ended December 31, 2011, compared to \$210.7 million for the year ended December 31, 2010 and \$234.7 million for the year ended December 31, 2009.

### **Revenues from Significant Collaborators**

In 2011, we derived 59% and 39% of our revenues from Bristol-Myers Squibb and Sanofi, respectively. The Company operates in one operating segment and has 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 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.

---

## **Table of Contents**

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 which, 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 which, 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 which, if issued, are anticipated to expire between 2023 and 2030.

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.

While trade secret protection is an essential element of our business and we have taken security measures to protect our proprietary information and trade secrets, we cannot give assurance that our unpatented proprietary technology will afford us significant commercial protection. We seek to protect our trade secrets by entering into confidentiality agreements with third parties, employees and consultants. Our employees and consultants are also required to sign agreements obligating them to assign to us their interests in intellectual property arising from their work for us. All employees sign an agreement not to engage in any conflicting employment or activity during their employment with us and not to disclose or misuse our confidential information. However, it is possible that these agreements may be breached or invalidated, and if so, there may not be an adequate corrective remedy available. Accordingly, we cannot ensure that employees, consultants or third parties will not breach the confidentiality provisions in our contracts, infringe or misappropriate our trade secrets and other proprietary rights or that measures we are taking to protect our proprietary rights will be adequate.

In the future, third parties may file claims asserting that our technologies or products infringe on their intellectual property. We cannot predict whether third parties will assert such claims against us or against the licensors of technology licensed to us, or whether those claims will harm our business. If we are forced to defend ourselves against such claims, whether they are with or without merit and whether they are resolved in favor of, or against, our licensors or us, we may face costly litigation and the diversion of management's attention and resources. As a result of such disputes, we may have to develop costly non-infringing technology or enter into licensing agreements. These agreements, if necessary, may be unavailable on terms acceptable to us, or at all.

## **Employees**

As of December 31, 2011, we had 200 full-time employees worldwide, 79 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 were incorporated in Delaware in November 1994 as Exelixis Pharmaceuticals, Inc., and we changed our name to Exelixis, Inc. in February 2000.

---

## **Table of Contents**

We maintain a site on the worldwide web at [www.exelixis.com](http://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](http://www.sec.gov).

### **ITEM 1A. RISK FACTORS**

*In addition to the factors discussed elsewhere in this report and our other reports filed with the SEC, 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 would be forced to delay, reduce or eliminate our product development programs or commercialization efforts and we may breach our financial covenants.*

We will need to raise additional capital to:

fund our operations and clinical trials;

continue our research and development efforts; and

commercialize our product candidates, if any such candidates receive regulatory approval for commercial sale.

As of December 31, 2011, we had \$283.7 million in cash and cash equivalents, marketable securities and long-term investments, which included restricted cash and investments of \$4.2 million and approximately \$85.3 million of cash and cash equivalents and marketable securities that we are required to maintain on deposit with Silicon Valley Bank or one of its affiliates pursuant to covenants in our loan and security agreement with Silicon Valley Bank. In February 2012, we raised approximately \$65 million in net proceeds from a public offering of our common stock. We anticipate that our current cash and cash equivalents, marketable securities, long-term investments and funding that we expect to receive from existing collaborators, together with the anticipated proceeds from this offering, will enable us to maintain our operations for a period of at least 12 months following the filing date of this report. However, our future capital requirements will be substantial, and we will need to raise additional capital in the future. Our capital requirements will depend on many factors, and we may need to use available capital resources and raise additional capital significantly earlier than we currently anticipate. These factors include:

the cabozantinib development program. We are focusing our proprietary resources and development efforts on cabozantinib, our most advanced product candidate, which is being studied in a variety of tumor types, with the goal of rapidly commercializing the compound. Cabozantinib is being evaluated in a broad development program encompassing multiple cancer indications. The current clinical program for cabozantinib is focused on the treatment of metastatic castration-resistant prostate cancer and medullary thyroid cancer and will be expanded to other solid tumor indications, based on

---

**Table of Contents**

encouraging interim data that have emerged from the RDT investigating cabozantinib in nine distinct tumor types and other clinical trials. In October 2011, we announced that our phase 3 clinical trial of cabozantinib in medullary thyroid cancer met its primary endpoint, and, in December 2011, the FDA granted us permission to initiate a rolling submission of an NDA for cabozantinib in medullary thyroid cancer. We initiated the submission in December 2011 by submitting to the FDA key parts of the NDA, including the preclinical information, and we expect to complete the NDA filing in the first half of 2012. Assuming priority review and approval of our NDA by the FDA, we currently anticipate a potential commercial launch of cabozantinib for the treatment of medullary thyroid cancer in the second half of 2012. In December 2011, we initiated our first phase 3 pivotal trial of cabozantinib in patients with metastatic castration-resistant prostate cancer using an endpoint of pain reduction (COMET-2). We also plan to initiate a phase 3 pivotal trial in metastatic castration-resistant prostate cancer patients with an overall survival endpoint (COMET-1) in the first half of 2012 as part of our comprehensive development plan for cabozantinib in castration-resistant prostate cancer. We are also planning other potential pivotal trials in prostate cancer. Our development and commercialization plans for cabozantinib are dependent on the extent of our available financial resources. There can be no assurance that we will have sufficient financial resources independently or through other arrangements to fund the trials that are currently planned or in process, to fund other clinical trials that we may desire to initiate in the future or to fund commercialization efforts. If adequate funds are not available, we may be required to delay, discontinue or elect not to pursue one or more trials or commercialization efforts for cabozantinib;

repayment of the notes under our note purchase agreement with Deerfield On June 2, 2010, we entered into a note purchase agreement with entities affiliated with Deerfield Management Company, L.P., or Deerfield, pursuant to which, on July 1, 2010, we sold to Deerfield an aggregate of \$124.0 million initial principal amount of our secured convertible notes, due June 2015, for an aggregate purchase price of \$80.0 million, less closing fees and expenses. The outstanding principal amount of the notes bears interest in the annual amount of \$6.0 million, payable quarterly in arrears. We will be required to make mandatory prepayments on the notes on an annual basis in 2013, 2014 and 2015 equal to 15% of specified payments from our collaborative arrangements received during the prior fiscal year, subject to a maximum annual prepayment amount of \$27.5 million and, for payments due in January 2013 and 2014, a minimum prepayment amount of \$10.0 million. We may also prepay all or a portion (not less than \$5.0 million) of the principal amount of the notes at an optional prepayment price based on a discounted principal amount (during the first three years of the term, subject to a prepayment premium) determined as of the date of prepayment, plus accrued and unpaid interest, plus in the case of a prepayment of the full principal amount of the notes (other than prepayments upon the occurrence of specified transactions relating to a change of control or a substantial sale of assets), all accrued interest that would have accrued between the date of such prepayment and the next anniversary of the note purchase agreement. In lieu of making any optional or mandatory prepayment in cash, subject to specified limitations, we have the right to convert all or a portion of the principal amount of the notes into, or satisfy all or any portion of the optional prepayment amounts or mandatory prepayment amounts (other than the first \$10.0 million of mandatory prepayments required in 2013 and 2014) with, shares of our common stock. Additionally, in lieu of making any payment of accrued and unpaid interest in respect of the notes in cash, subject to specified 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. In the event the market price for our common stock is depressed or we do not have a sufficient number of authorized but unissued shares, we may not be able to convert the principal amount of the notes or satisfy our payment obligations in full using shares of our common stock due to restrictions in the agreement on the number of shares we may issue. In addition, the issuance of shares of our common stock to convert the notes or satisfy our payment obligations may result in significant dilution to our stockholders. As a result, we may need to obtain additional funding to satisfy our repayment obligations. There can be no assurance

**Table of Contents**

that we will have sufficient funds to repay the notes or satisfy our payment obligations under the note purchase agreement when due or that we will comply with the conditions to our ability to convert the principal amount of the notes into or satisfy our payment obligations with shares of our common stock;

repayment of our loan from Silicon Valley Bank On June 2, 2010, we amended our loan and security agreement with Silicon Valley Bank to provide for a new seven-year term loan in an 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. In accordance with the terms of the loan and security agreement, we are also required to maintain on deposit an amount equal to at least 100% of the outstanding principal balance of the term loan at all times as support for our obligations under the loan and security agreement. As a result, the proceeds of the term loan cannot be used to satisfy our other obligations without causing a default under our loan and security agreement with Silicon Valley Bank;

the level of payments received under existing collaboration agreements, licensing agreements and other arrangements;

the degree to which we conduct funded development activity on behalf of partners to whom we have out-licensed compounds;

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 and marketable securities that serve as collateral for bank lines of credit;

future clinical trial results;

our need to expand our product and clinical development efforts;

our ability to share the costs of our clinical development efforts with third parties;

the cost and timing of regulatory approvals;

the cost of clinical and research supplies of our product candidates;

the effect of competing technological and market developments;

the filing, maintenance, prosecution, defense and enforcement of patent claims and other intellectual property rights; and

the cost of any acquisitions of or investments in businesses, products and technologies.

We may seek to raise funds through the sale of equity or debt securities or through external borrowings. In addition, we may enter into additional strategic partnerships, collaborative arrangements or other strategic transactions. It is unclear whether any such partnership, arrangement or transaction will occur, on satisfactory terms or at all, or what the timing and nature of such a partnership, arrangement or transaction may be. The sale of equity or convertible debt securities in the future may be dilutive to our stockholders, and debt-financing arrangements may require us to pledge certain assets and enter into covenants that would restrict certain business

---

**Table of Contents**

activities or our ability to incur further indebtedness, and may contain other terms that are not favorable to our stockholders or us. If we are unable to obtain adequate funds on reasonable terms, we may be required to curtail operations significantly or obtain funds by entering into financing, supply or collaboration agreements on unattractive terms or we may be required to relinquish rights to technology or product candidates or to grant licenses on terms that are unfavorable to us.

We may need to obtain additional funding in order to stay in compliance with financial covenants contained in agreements with third parties. The terms of our debt owed to Deerfield and Silicon Valley Bank each contain covenants requiring us to maintain specified cash balances or working capital. The failure to comply with these covenants could result in an acceleration of the underlying debt obligations. If we cannot raise additional capital in order 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 net losses since inception through 2010. As of December 31, 2011, we had an accumulated deficit of \$1.1 billion. For the fiscal year ended December 31, 2011, we recorded net income of \$75.7 million, primarily due to the revenue recognized as a result of the acceleration of deferred license revenue related to the early termination of our collaboration agreement with Bristol-Myers Squibb for XL281 in October 2011 and the wind-down in December 2011 of our PI3K discovery collaboration agreement with Sanofi. Notwithstanding our net income for the fiscal year ended December 31, 2011, we anticipate further net losses and negative operating cash flow for the foreseeable future. We have not yet completed the development, including obtaining regulatory approval, of cabozantinib or any other product candidates and, consequently, have not generated revenues from the sale of pharmaceutical products. We have derived substantially all of our revenues to date from collaborative research and development agreements. Revenues from research and development collaborations depend upon continuation of the collaborations, research funding, the achievement of milestones and royalties we earn from any future products developed from the collaborative research. If we are unable to successfully achieve milestones, our collaborators fail to develop successful products or research funding we receive from collaborators decreases, we will not earn the revenues contemplated under such collaborative agreements. The amount of our net losses will depend, in part, on the rate of growth, if any, in our license and contract revenues and on the level of our expenses. These losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Our research and development expenditures and general and administrative expenses have exceeded our revenues through 2010, and we expect to spend significant additional amounts to fund the development 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. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

***We may not realize the expected benefits of our initiatives to control costs.***

Managing costs is a key element of our business strategy. Consistent with this element of our strategy, during 2010, we implemented two restructuring plans that resulted in an overall reduction in our workforce by 386 employees. In March 2011, we implemented an additional restructuring plan that resulted in further terminations in 2011. Taking into consideration employees who have since been recalled, there has been an aggregate reduction in headcount from the 2010 and 2011 restructuring plans of 402 employees. We anticipate that we will incur additional restructuring charges through the end of 2017 in connection with the implementation of these restructuring plans.

As part of our restructuring plans, in 2011 we entered into two sublease agreements for portions of one of our buildings in South San Francisco, California. We are still assessing our ability to sublease portions of our



## **Table of Contents**

facilities in light of the workforce reduction as well as the potential for sublease income. Estimates for sublease income 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. If we are able to vacate portions of our facilities, we would need to continue to update our estimate of the lease exit costs in our financial statements until we were able to negotiate an exit to the lease or negotiate a sublease for the remaining term of the lease.

If we experience excessive unanticipated inefficiencies or incremental costs in connection with restructuring activities, such as unanticipated inefficiencies caused by reducing headcount, 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 downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents, short-term investments or long-term investments since December 30, 2011, 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.

### **Risks Related to Development of Cabozantinib**

#### ***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 intend to dedicate all of our proprietary resources to advance cabozantinib as aggressively as feasible. Our ability to realize the value of our investment is contingent on, among other things, successful clinical development, regulatory approval and market acceptance of cabozantinib. If we encounter difficulties in the development of cabozantinib due to any of the factors discussed in this Risk Factors section or otherwise, or we do not receive regulatory approval and are unable to commercialize cabozantinib, we will not have the resources necessary to continue our business in its current form.

---

## **Table of Contents**

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

Clinical trials are inherently risky and may reveal that our product candidates are ineffective or have unacceptable toxicity or other side effects that may significantly decrease the likelihood of regulatory approval.

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, including:

cabozantinib may not prove to be efficacious or may cause, or potentially cause, harmful side effects;

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

regulators or institutional review boards may withhold authorization of, 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 or our ability to generate revenues from cabozantinib 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, including those identified based on our discussions with the FDA. 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. For example, as discussed in *Risks Related to Regulatory Approval of Cabozantinib* 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 this product candidate, we were not able to reach a timely agreement with the FDA under a SPA on the proposed design and analyses of the COMET-2 trial.

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 as a product candidate. 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 that ultimately participate in the clinical trial;

the duration of patient follow-up that is appropriate in view of the results;

the number of clinical sites included in the trials; and

the length of time required to enroll suitable patient subjects.

---

**Table of Contents**

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.***

We do not have the ability to independently conduct clinical trials for cabozantinib, and we rely on third parties we do not control such as contract research organizations, 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 the 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 successfully commercialize cabozantinib.

***We lack the capability to manufacture compounds for clinical trials and rely on third parties to manufacture cabozantinib, and we may be unable to obtain required material in a timely manner, at an acceptable cost or at a quality level required to receive regulatory approval.***

We do not have the manufacturing capabilities or experience necessary to enable us to produce materials for our clinical trials. We rely on collaborators and third-party contractors to produce cabozantinib for clinical testing. These suppliers must comply with applicable regulatory requirements, including the FDA's current Good Manufacturing Practices, or GMP. Our current and anticipated future dependence upon these third-party manufacturers may adversely affect our future profit margins and our ability to develop and commercialize cabozantinib on a timely and competitive basis. These manufacturers 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 timelines and applicable regulatory requirements. We may not be able to maintain or renew our existing third-party manufacturing arrangements, or enter into new arrangements, on acceptable terms, or at all. Our third-party manufacturers could terminate or decline to renew our manufacturing 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 may be delayed. Delays in preclinical or clinical testing could delay the initiation of clinical trials.

Our third-party manufacturers may not be able to comply with the GMP regulations, other applicable FDA regulatory requirements or similar regulations applicable outside of the United States. Additionally, if we are required to enter into new supply arrangements, we may not be able to obtain approval from the FDA of any alternate 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 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 affect on our business.

***Materials necessary to manufacture cabozantinib may not be available on commercially reasonable terms, or at all, which may delay its development and commercialization.***

Some of the materials necessary for the manufacture of cabozantinib may, from time to time, be available either in limited quantities, or from a limited number of manufacturers, or both. Our contract manufacturers need to obtain these materials for our clinical trials and, potentially, for commercial distribution when and if we obtain

---

## **Table of Contents**

marketing approval for cabozantinib. Suppliers may not sell us these materials at the time we need them or on commercially reasonable terms. If we are unable to obtain the materials needed to conduct our clinical trials, product testing and potential regulatory approval could be delayed, adversely affecting our ability to develop cabozantinib. Similarly, if we are unable to obtain critical manufacturing materials after regulatory approval has been obtained, the commercial launch of cabozantinib could be delayed or there could be a shortage in supply, which could materially affect our ability to generate revenues from sales of cabozantinib. If suppliers increase the price of manufacturing materials, the price for cabozantinib may increase, which may make it less competitive in the marketplace. If it becomes necessary to change suppliers for any of these materials or if any of our suppliers experience a shutdown or disruption at the facilities used to produce these materials, due to technical, regulatory or other reasons, it could harm our ability to manufacture cabozantinib.

### **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 Bristol-Myers Squibb, Sanofi, Genentech, GlaxoSmithKline, Merck and Daiichi Sankyo, for the development and ultimate commercialization of a significant number of compounds generated from our research and development efforts. We continue to 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 our compounds 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 are not able to control the amount and timing of resources that our collaborators will devote to the development or commercialization of drug candidates or to their marketing and distribution;

we may not be able to control the amount and timing of resources that our potential future collaborators may 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;

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;

## Edgar Filing: EXELIXIS INC - Form 10-K

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

---

## **Table of Contents**

collaborations may be terminated (as occurred with respect to cabozantinib and XL281, which were previously subject to our 2008 collaboration agreement with Bristol-Myers Squibb, and with respect to our 2009 discovery collaboration with Sanofi, which was terminated in December 2011) or allowed to expire, which would delay, and may increase the cost of development of, our drug candidates.

If any of these risks materialize, our product development efforts could be delayed and otherwise adversely affected, which could adversely impact our business, operating results and financial condition.

### ***If we are unable to continue current collaborations and achieve milestones or royalties, our revenues would suffer.***

We have derived substantially all of our revenues to date from collaborative research and development agreements. Revenues from research and development collaborations depend upon continuation of the collaborations, the achievement of milestones and royalties we earn from any future products developed from the collaborative research. If we are unable to successfully achieve milestones or royalties, or our collaborators fail to develop successful products, we will not earn the revenues contemplated under such collaborative agreements.

If any of these agreements is terminated early (as occurred with respect to cabozantinib and XL281, which were previously subject to our 2008 collaboration agreement with Bristol-Myers Squibb, and with respect to our 2009 discovery collaboration with Sanofi, which was terminated in December 2011), whether unilaterally or by mutual agreement, our revenues could suffer. Most of our collaboration agreements contain early termination provisions. In addition, from time to time we review and assess certain aspects of our collaborations, partnerships and agreements and may amend or terminate, either by mutual agreement or pursuant to any applicable early termination provisions, such collaborations, partnerships or agreements if we deem them to be no longer in our economic or strategic interests. We may not be able to enter into new collaboration agreements on similar or superior financial terms to offset the loss of revenues from the termination or expiration of any of our existing or recently terminated arrangements.

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

Our strategy includes the pursuit of 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 face significant competition in seeking appropriate collaborators, and these collaborations are complex and time consuming to negotiate and document. 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, particularly those drug candidates as to which we believe a broad development program is appropriate or for which we have determined not to continue to utilize our own resources to develop. As a result, our revenues, capital resources and product development efforts could be adversely affected.

## **Risks Related to Regulatory Approval of Cabozantinib**

### ***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 this product candidate.***

Cabozantinib, as well as the activities associated with the research, development and commercialization of the product candidate, 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

---

**Table of Contents**

would prevent us from commercializing this product candidate. We have not received regulatory approval to market cabozantinib in any jurisdiction and have only limited experience in preparing and filing the applications necessary to gain regulatory approvals. The process of obtaining regulatory approvals 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. Before an NDA can be submitted to the FDA, the product candidate must undergo extensive clinical trials, which can take many years and require substantial expenditures.

We are conducting our EXAM phase 3 trial of cabozantinib as a potential treatment for medullary thyroid cancer under a SPA with the FDA. A SPA is designed to facilitate the FDA's review and provide feedback on the proposed design and size of clinical trials that are intended to form the primary basis for determining a product candidate's efficacy. If agreement is reached with the FDA, a SPA agreement documents the terms and conditions under which the design of the subject trial will be adequate for submission of the efficacy and human safety portion of an NDA. However, there are circumstances under which we may not receive the benefits of a SPA, notably if the FDA subsequently identifies a substantial scientific issue essential to determining the product candidate's safety or efficacy, and we may be required to conduct significant additional development in order to obtain regulatory approval notwithstanding the SPA. Our rolling NDA based on the EXAM results may not receive priority review and may be subject to delay or lack of approval, including delay or lack of approval based on potential feedback from an FDA Advisory Committee.

In December 2011, we initiated COMET-2, our first phase 3 pivotal trial of cabozantinib in patients with metastatic castration-resistant prostate cancer, with pain response as the primary efficacy endpoint for the trial. We were not able to reach a timely agreement with the FDA under a SPA on the proposed design and analysis of the COMET-2 trial. We originally submitted the proposed protocol for this trial using primary endpoints of pain reduction and bone scan response to the FDA in June 2011 with a request for a SPA. The FDA's final response prior to our discontinuation of the SPA process, which we received in October 2011, raised the following concerns regarding the COMET-2 trial design in the context of its consideration of a SPA for the trial, among other comments:

A concern about the ability to maintain blinding of the trial due to differences in toxicity profiles between cabozantinib and mitoxantrone.

A view that the assumed magnitude of pain improvement is modest and could represent a placebo effect or be attained with less toxicity by opioid therapy.

A view that symptomatic improvement should be supported by evidence of anti-tumor activity, an acceptable safety profile and lack of survival decrement. The FDA also expressed the view that if the effect that we believe cabozantinib will have on pain is mediated by anti-tumor activity, that anti-tumor activity should translate into an improvement in overall survival.

A recommendation that if we use pain response as a primary efficacy endpoint, that we conduct two adequate and well-controlled trials to demonstrate effectiveness as, according to the FDA, a conclusion based on two persuasive studies will always be more secure. The FDA advised that for a single randomized trial to support a new drug application, the trial must be well designed, well conducted, internally consistent and provide statistically persuasive efficacy findings so that a second trial would be ethically or practically impossible to perform.

In the context of its consideration of a SPA for the COMET-2 trial, the FDA also recommended that overall survival be the primary efficacy endpoint. The final FDA response prior to our discontinuation of the SPA process stated that we could choose to conduct the trial in the absence of a SPA agreement. We elected to proceed with initiation of the COMET-2 trial and the planned COMET-1 trial, and to discontinue further attempts to secure a SPA agreement with respect to the COMET-2 trial.

Any clinical trial may fail to produce results satisfactory to the FDA. For example, the FDA could determine that the design of a clinical trial is inadequate to produce reliable results. The regulatory process also requires



## **Table of Contents**

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 (regardless of prior receipt of a SPA) or decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. For example, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of cabozantinib.

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 country 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. These agencies also may impose various civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval.

### **Risks Related to Commercialization of Cabozantinib**

*The commercial success of cabozantinib will depend upon the degree of market acceptance of the product candidate among physicians, patients, health care payors, private health insurers and the medical community.*

Our ability to commercialize cabozantinib will be highly dependent upon the extent to which the product candidate gains market acceptance among physicians; patients; health care payors, such as Medicare and Medicaid; private health insurers, including managed care organizations and group purchasing organizations, and the medical community. If cabozantinib does not achieve an adequate level of acceptance, we may not generate adequate product revenues, if at all, and we may not become profitable. The degree of market acceptance of cabozantinib, if approved for commercial sale, 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;

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 marketing and distribution support; and

sufficient third-party coverage or reimbursement.

*If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell cabozantinib, we may be unable to generate product revenues.*

## Edgar Filing: EXELIXIS INC - Form 10-K

We have no experience as a company in the sales and distribution of pharmaceutical products and do not have a sales organization. Developing a sales force could be expensive and time-consuming, could delay any product launch, including our potential launch of cabozantinib for the treatment of medullary thyroid cancer, and we may never be able to develop this capacity. To the extent that we enter into arrangements with third parties to provide sales, marketing and distribution services, our product revenues are likely to be lower than if we market

---

## **Table of Contents**

and sell cabozantinib ourselves. If we are unable to establish adequate sales, marketing and distribution capabilities, independently or with others, we may not be able to generate product revenues.

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

Our ability to commercialize cabozantinib will be highly dependent on the extent to which coverage and reimbursement for the product candidate will be available from third-party payors, including governmental payors, such as Medicare and Medicaid, and private health insurers. Many patients will not be capable of paying themselves for cabozantinib and will rely on third-party payors to pay for, or subsidize, their medical needs. If third-party payors do not provide coverage or reimbursement for cabozantinib, our revenues and prospects for profitability will suffer. In addition, even if third-party payors 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.

Another factor that may affect the pricing of drugs is proposed congressional action regarding drug reimportation into the United States. For example, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 gives discretion to the Secretary of Health and Human Services to allow drug reimportation into the United States under some circumstances from foreign countries, including countries where the drugs are sold at a lower price than in the United States. Proponents of drug reimportation may attempt to pass legislation, which would allow direct reimportation under certain circumstances. If legislation or regulations were passed allowing the reimportation of drugs, it could decrease the price we receive for cabozantinib, thereby negatively affecting our revenues and prospects for profitability.

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 payors are challenging the prices charged for medical products and services, and many third-party payors limit reimbursement for newly approved health care products. In particular, third-party payors 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 U.S. 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 our products profitably. Among policy makers and payors in the U.S. 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 U.S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, PPACA, became law in the U.S. PPACA substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Among the provisions of PPACA of greatest importance to the pharmaceutical industry are 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, beginning in 2011;

---

**Table of Contents**

an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23% and 13% of the average manufacturer price for 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 off 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, beginning in 2011;

extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, effective March 23, 2010;

expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning in April 2010 and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, thereby potentially increasing manufacturers' Medicaid rebate liability;

expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program, effective in January 2010;

new requirements to report certain financial arrangements with physicians and teaching hospitals, including reporting any transfer of value made or distributed to prescribers and other healthcare providers, effective March 30, 2013, and reporting any investment interests held by physicians and their immediate family members during the preceding calendar year;

a new requirement to annually report drug samples that manufacturers and distributors provide to physicians, effective April 1, 2012;

expansion of health care fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;

a licensure framework for follow-on biologic products; 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 United States Supreme Court has accepted petitions to hear a constitutional challenge to the PPACA in 2012. If the Supreme Court rules that the PPACA is unconstitutional, our expenditures in preparation for the PPACA could go unused, we could require new expenditures to adjust to the new competitive environment, and new legislation could later become law that could adversely affect the pharmaceutical industry.

We anticipate that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and an additional downward pressure on the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

We also cannot be certain that cabozantinib will successfully be placed on the list of drugs covered by particular health plan formularies, nor can we predict the negotiated price for cabozantinib, which will be determined by market factors. Many states have also created preferred drug lists and include drugs on those lists only when the manufacturers agree to pay a supplemental rebate. If cabozantinib is not included on these preferred drug lists, physicians may not be inclined to prescribe it to their Medicaid patients, thereby diminishing the potential market for cabozantinib.

## Edgar Filing: EXELIXIS INC - Form 10-K

As a result of the PPACA and the trend towards cost-effectiveness criteria and managed healthcare in the United States, third-party payors 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

---

**Table of Contents**

affect demand for our products by placing them 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 payors 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 payors outside of the United States for coverage and reimbursement of cabozantinib. We also anticipate pricing pressures in connection with the sale of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals.

***Our competitors may develop products and technologies that make cabozantinib obsolete.***

The biotechnology 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 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 cabozantinib could allow our competitors to bring products to market before us, which would impair our ability to commercialize cabozantinib. Our future success will depend upon our ability to maintain a competitive position with respect to technological advances. Any products that are developed through our technologies will compete in highly competitive markets. 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 marketing 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 that may compete with cabozantinib. In addition, if cabozantinib is successfully developed, it may compete with existing therapies that have long histories of use, such as chemotherapy and radiation treatments in cancer indications. Examples of potential competition for cabozantinib include AstraZeneca's RET, VEGFR and EGFR inhibitor, vandetanib, Algeta's development-stage alpha-pharmaceutical, Alpharadin (Radium-223), other VEGF pathway inhibitors, including Genentech's bevacizumab, and other MET inhibitors, including Pfizer's crizotinib, ArQule's tivantinib (ARQ197), GlaxoSmithKline's foretinib (XL880) and Genentech's Met MAb.

***We may not be able to manufacture cabozantinib in commercial quantities, which would prevent us from commercializing the product candidate.***

To date, cabozantinib has been manufactured in small quantities for preclinical and clinical trials. If cabozantinib is approved by the FDA or other regulatory agencies for commercial sale, we will need to manufacture it in larger quantities. We may not be able to successfully increase the manufacturing capacity, whether in collaboration with third-party manufacturers or on our own, for cabozantinib in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If we are unable to successfully increase the manufacturing capacity for cabozantinib, the regulatory approval or commercial launch of the product candidate may be delayed or there may be a shortage in supply. Cabozantinib requires precise, high-quality manufacturing. 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 seriously hurt our business.

---

**Table of Contents****Risks Related to Our Intellectual Property**

*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 biotechnology 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 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, there may be 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 these 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 some of our 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 and other intellectual property protection, which makes it difficult to stop infringement. We rely on trade secret protection for 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. 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.

---

## **Table of Contents**

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, other biotechnology 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. 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 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 restructuring plans that we implemented in 2010 and 2011 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 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.



---

## **Table of Contents**

***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 and harm our operating results.***

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

### **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 trial participants and the inability to commercialize any products that we may develop. These claims might be made directly by consumers, health

## **Table of Contents**

care providers, pharmaceutical companies or others selling or testing our products. We have obtained limited product liability insurance coverage for our clinical trials in the amount of \$10.0 million per occurrence and \$10.0 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. If we obtain marketing approval for cabozantinib, we intend to expand our insurance coverage to include the sale of commercial products, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. 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 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.

### **Risks Related to Our Common Stock**

*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 scope of our research and development activities;

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 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 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 plans; 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.

## **Table of Contents**

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 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 one or more of our out-licensed programs and 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;

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 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 reimbursement policies;

disposition of any of our subsidiaries, technologies or compounds; and

general market 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.

---

## **Table of Contents**

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 may depress our stock price.***

If our stockholders sell substantial amounts of our common stock (including shares issued upon the exercise of options and warrants or upon vesting of restricted stock units and shares issued under our employee stock purchase plan) in the public market, the market price of our common stock could fall. These sales also might make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate.

### ***Some of our existing stockholders can exert control over us, and their interests could conflict with the best interests of our other stockholders.***

Due to their combined stock holdings, our officers, directors and principal stockholders (stockholders holding more than 5% of our common stock), acting together, may be able to exert significant influence over all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. In addition, this concentration of ownership may delay or prevent a change in control of our company, even when a change may be in the best interests of our stockholders. In addition, the interests of these stockholders may not always coincide with our interests as a company or the interests of other stockholders. Accordingly, these stockholders could cause us to enter into transactions or agreements that would not be widely viewed as beneficial.

### ***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.***

Provisions in our corporate charter and bylaws may discourage, delay or prevent an acquisition of our company, 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.



**Table of Contents**

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

Not applicable.

**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 are comprised of six buildings and covered by four lease agreements. The first two leases covering three buildings for a total of 179,964 square feet expire in 2017, with two five-year options to extend their respective terms prior to expiration. In July 2011, we subleased 25,110 square feet of one of these buildings to Nodality, Inc. and we subleased 28,180 square feet of the same building to Threshold Pharmaceuticals, Inc. The terms of these two subleases will expire at the end of our lease term. The third lease covering two buildings for a total of 116,063 square feet expires in 2018. A fourth lease covers a portion of one building containing 71,746 square feet that commenced in May 2008 and expires in 2015. In July 2010, we subleased approximately 68,738 square feet of the building covered by the fourth lease to Onyx Pharmaceuticals, Inc. 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.



**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
<b>Year Ended December 31, 2010</b>		
Quarter ended April 2, 2010	\$ 7.53	\$ 5.77
Quarter ended July 2, 2010	\$ 7.00	\$ 3.11
Quarter ended October 1, 2010	\$ 4.29	\$ 2.86
Quarter ended December 31, 2010	\$ 9.20	\$ 3.84
<b>Year Ended December 30, 2011</b>		
Quarter ended April 1, 2011	\$ 12.82	\$ 7.10
Quarter ended July 1, 2011	\$ 12.61	\$ 8.03
Quarter ended September 30, 2011	\$ 9.24	\$ 5.45
Quarter ended December 30, 2011	\$ 8.25	\$ 3.94

On February 15, 2012, the last reported sale price on the NASDAQ Global Select Market for our common stock was \$5.80 per share.

**Holders**

As of February 15, 2012, there were approximately 546 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 the company under the Securities Act of 1933, as amended.

The following graph compares, for the five year period ended December 31, 2011, 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 Biotech Index. The graph assumes that \$100 was invested on December 31, 2006 in each of the common stock of the company, the NASDAQ Market Index and the NASDAQ Biotech Index and assumes reinvestment of any dividends. The stock price performance on the following graph is not necessarily indicative of future stock price performance.

	12/31/06	03/31/07	06/30/07	09/30/07	12/31/07	03/31/08	06/30/08
Exelixis, Inc.	100	110	134	118	96	75	56
NASDAQ Market Index	100	100	108	112	111	94	96
NASDAQ Biotech Index	100	97	101	107	106	96	100

  

	09/30/08	12/31/08	03/31/09	06/30/09	09/30/09	12/31/09	03/31/10
Exelixis, Inc.	70	58	54	52	67	82	74
NASDAQ Market Index	90	68	67	74	85	94	99
NASDAQ Biotech Index	108	93	84	91	102	106	119

  

	06/30/10	09/30/10	12/31/10	03/31/11	06/30/11	09/30/11	12/31/11
Exelixis, Inc.	39	44	91	127	102	61	53
NASDAQ Market Index	87	98	109	115	117	100	108
NASDAQ Biotech Index	99	112	122	131	140	121	136

**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, 2011 and 2010 and for each of the three years in the period ended December 31, 2011 are derived from audited consolidated financial statements included elsewhere 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.

	2011	Year Ended December 31,			2007
		2010	2009	2008	
(In thousands, except per share data)					
<b>Consolidated Statement of Operations Data:</b>					
Total revenues	\$ 289,636	\$ 185,045	\$ 151,759	\$ 117,859	\$ 113,470
Operating expenses:					
Research and development	156,836	210,678	234,702	257,390	225,375
General and administrative	33,129	33,020	34,382	36,892	44,940
Collaboration cost sharing			4,582		
Amortization of intangible assets					202
Restructuring charge	10,136	32,744		2,890	
<b>Total operating expenses</b>	<b>200,101</b>	<b>276,442</b>	<b>273,666</b>	<b>297,172</b>	<b>270,517</b>
Income (loss) from operations	89,535	(91,397)	(121,907)	(179,313)	(157,047)
Total other income (expense)(1)	(12,543)	(1,005)	(18,936)	3,743	46,025
Consolidated income (loss) before taxes	76,992	(92,402)	(140,843)	(175,570)	(111,022)
Tax (provision) benefit	(1,295)	72	1,286		
Consolidated net income (loss)	75,697	(92,330)	(139,557)	(175,570)	(111,022)
Loss attributable to noncontrolling interest			4,337	12,716	24,641
Net income (loss) attributable to Exelixis, Inc.	\$ 75,697	\$ (92,330)	\$ (135,220)	\$ (162,854)	\$ (86,381)
Net income (loss) per share, basic, attributable to Exelixis, Inc.	\$ .60	\$ (0.85)	\$ (1.26)	\$ (1.54)	\$ (0.87)
Net income (loss) per share, diluted, attributable to Exelixis, Inc.	\$ .58	\$ (0.85)	\$ (1.26)	\$ (1.54)	\$ (0.87)
Shares used in computing basic net income (loss) per share	126,018	108,522	107,073	105,498	99,147
Shares used in computing diluted net income (loss) per share	130,479	108,522	107,073	105,498	99,147

- (1) In 2007, we sold 80.1% of our former German subsidiary, Artemis Pharmaceuticals GmbH (now known as TaconicArtemis GmbH), or Artemis, and our plant trait business, and recognized a gain of \$18.1 million and \$18.8 million in other income, respectively. We exercised our option to sell our remaining 19.9% ownership in Artemis in 2011 and recognized an additional gain of \$2.2 million in other income. In 2008, 2009 and 2010, in association with the sale of our plant trait business, we recognized an additional gain on the sale of the business of \$4.5 million, \$2.1 million and \$7.2 million, respectively. In June 2009 we recorded a \$9.8 million loss upon deconsolidation of Symphony Evolution, Inc. as a result of the expiration of our purchase option. In addition, our credit facility with Deerfield expired in November 2009, resulting in our acceleration of interest expense of \$5.2 million relating to the closing fee and outstanding warrants issued in connection with the facility.

**Table of Contents**

	2011	2010	Year Ended December 31, 2009 (In thousands)	2008	2007
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents, marketable securities, investments held by Symphony Evolution, Inc. and restricted cash and investments(1)	\$ 283,720	\$ 256,377	\$ 220,993	\$ 284,185	\$ 299,530
Working capital (deficit)	136,500	(16,455)	22,882	82,028	150,898
Total assets	393,262	360,790	343,410	401,622	412,120
Long-term obligations, less current portion	193,983	186,702	57,688	97,339	130,671
Accumulated deficit	(1,106,357)	(1,182,054)	(1,089,724)	(954,504)	(791,650)
Total stockholders' equity (deficit)	90,632	(228,325)	(163,725)	(56,261)	85,511

(1) Amounts for the years ended December 31, 2008 and 2007 include \$14.7 million and \$30.9 million, respectively, in investments held by Symphony Evolution, Inc.

**Table of Contents****ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*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, should, would, could, estimate, predict, potential, 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**

We are a biotechnology company committed to developing small molecule therapies for the treatment of cancer. We are focusing our proprietary resources and development efforts exclusively on cabozantinib, or XL184, our most advanced product candidate, in order to maximize the therapeutic and commercial potential of this compound. We believe cabozantinib has the potential to be a high-quality, broadly-active, differentiated pharmaceutical product that can make a meaningful difference in the lives of patients. We have also established a portfolio of other novel compounds that we believe have the potential to address serious unmet medical needs, many of which are being advanced by partners as part of collaborations.

**Cabozantinib**

Cabozantinib inhibits MET, VEGFR2 and RET, proteins that are key drivers of tumor growth, vascularization and/or metastasis. Cabozantinib has shown novel and differentiated activity in multiple cancer indications. The current clinical program for cabozantinib is focused on the treatment of metastatic castration-resistant prostate cancer, or CRPC, and medullary thyroid cancer but also includes the evaluation of other tumor types. Exelixis has implemented a strategy to investigate cabozantinib in a comprehensive development program for CRPC to potentially generate a product that could effectively compete in the CRPC marketplace. Two phase 3 pivotal trials, COMET-1 (Cabozantinib MET Inhibition CRPC Efficacy Trial-1, formerly known as XL184-307) and COMET-2 (Cabozantinib MET Inhibition CRPC Efficacy Trial-2, formerly known as XL184-306), were designed to provide an opportunity to commercially differentiate cabozantinib as an oncology agent with a potentially beneficial impact on overall survival, pain palliation and narcotic usage. We expect to initiate the COMET-1 trial with an overall survival endpoint in the first half of 2012. We initiated the COMET-2 trial with a pain palliation endpoint in December 2011. We also initiated a rolling submission of a new drug application, or NDA, for cabozantinib in medullary thyroid cancer in December 2011 following our October 2011 announcement of the top-line results of the primary endpoint of our ongoing phase 3 clinical trial of cabozantinib as a potential treatment for medullary thyroid cancer, known as the EXAM trial (Efficacy of XL184 (Cabozantinib) in Advanced Medullary Thyroid Cancer).

We expect to expand the cabozantinib development program to other solid tumor indications, based on encouraging interim data that have emerged from the randomized discontinuation trial, or RDT, investigating cabozantinib in nine distinct tumor types, as well as other clinical trials. Objective tumor responses have been

---

## **Table of Contents**

observed in patients treated with cabozantinib in 12 of 13 individual tumor types investigated to date, reflecting the broad potential clinical activity and commercial opportunity of this new product candidate. Interim data suggest that cabozantinib has shown novel activity against bone and soft tissue lesions in patients with CRPC. We have also observed resolution of metastatic bone lesions on bone scan in patients with metastatic breast cancer, renal cell carcinoma, thyroid cancer and melanoma. Interim data from the CRPC cohort of the RDT reported at the American Society of Clinical Oncology Annual Meeting in June 2011 demonstrated that in addition to improvement of bone lesions on bone scan observed in the majority (75%) of patients, 67% of patients with bone metastases and bone pain at baseline also experienced alleviation of pain. This observation has been corroborated in a non-randomized expansion cohort, or NRE, of CRPC patients in the RDT, which collected prospectively defined patient reported outcomes on pain and narcotic use. Interim data from the NRE reported at the AACR-NCI-EORTC Symposium on Molecular Targets and Cancer Therapeutics in November 2011 demonstrated that 48% of CRPC patients with moderate to severe pain in the NRE experienced durable pain reduction greater than or equal to 30%. The median best pain reduction was 46%. In addition, these interim data indicated that 56% of CRPC patients in the NRE with moderate to severe bone pain and on narcotics at baseline were able to reduce or discontinue narcotic medication. Lower starting doses of cabozantinib are being evaluated through a dose-ranging study in CRPC patients conducted through an investigator sponsored trial, or IST. Preliminary data from the IST demonstrate that a daily dose of 40 mg resulted in a rate of bone scan responses similar to that of a 100 mg daily dose used in the RDT and was associated with improved tolerability compared with the higher dose. In addition, preliminary data from a cohort of CRPC patients in the NRE treated at a daily dose of 40 mg demonstrate pain palliation responses consistent with observations at the 100 mg daily dose.

It is a priority for us to generate additional data from the RDT as well as other ongoing exploratory clinical trials for cabozantinib in a broad range of tumor types, including ovarian cancer, melanoma, breast cancer, non-small cell lung cancer, hepatocellular cancer, renal cell carcinoma and differentiated thyroid cancer, to support further prioritization of our clinical and commercial options. In November 2011, we entered into a Cooperative Research and Development Agreement, or CRADA, with the National Cancer Institute's Cancer Therapy Evaluation Program, or CTEP, for further evaluation of cabozantinib across multiple tumor types and in combination with other anti-tumor agents in a cost-effective manner for Exelixis. We believe that cabozantinib's clinical profile is compelling and will allow commercial differentiation, assuming regulatory approval.

### **Collaborations**

We have established collaborations with leading pharmaceutical and biotechnology companies, including Bristol-Myers Squibb Company, or Bristol-Myers Squibb, Sanofi, Genentech, Inc. (a wholly owned member of the Roche Group), GlaxoSmithKline, 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 out-licensed compounds or programs to a partner for further development and commercialization, generally have no further unfunded cost obligations related to such compounds or programs and may be entitled to receive research funding, milestones and royalties or a share of profits from commercialization. Several of the out-licensed compounds are in multiple phase 2 studies and could potentially be of significant value to us if their development progresses successfully. With respect to our partnered compounds, we are eligible to receive potential milestone payments under our collaborations totaling approximately \$3.1 billion in the aggregate on a non-risk adjusted basis, of which 10% are related to clinical development milestones, 44% are related to regulatory milestones and 46% are related to commercial milestones.

### **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, often for products that fail during the research and development process. Our long-term prospects depend upon our ability, particularly with respect to cabozantinib, 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.

## **Table of Contents**

### ***Clinical Development of Cabozantinib and Other Product Candidates***

On December 11, 2008, we entered into a worldwide collaboration agreement with Bristol-Myers Squibb for cabozantinib and XL281, which was amended and restated as of April 15, 2011 by and between us and Bristol-Myers Squibb, or as amended and restated, the 2008 Agreement. Upon effectiveness of the 2008 Agreement in December 2008, Bristol-Myers Squibb made a nonrefundable upfront cash payment of \$195.0 million for the development and commercialization rights to both programs. The 2008 Agreement required Bristol-Myers Squibb to make additional license payments to us of \$45.0 million, which were received during 2009.

On June 18, 2010, we regained full rights to develop and commercialize cabozantinib under the 2008 Agreement following receipt of notice from Bristol-Myers Squibb of its decision to terminate the 2008 Agreement, solely as to cabozantinib, on a worldwide basis. Bristol-Myers Squibb informed us that the termination was based upon its review of cabozantinib in the context of Bristol-Myers Squibb's overall research and development priorities and pipeline products. On June 28, 2010, in connection with the termination, we received a \$17.0 million transition payment from Bristol-Myers Squibb in satisfaction of its obligations under the 2008 Agreement to continue to fund its share of development costs for cabozantinib for a period of three months following the notice of termination. 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.

On July 8, 2011, we and one of our wholly-owned subsidiaries received written notification from Bristol-Myers Squibb of its decision to terminate the 2008 Agreement on a worldwide basis as to XL281. The termination was made pursuant to the terms of the 2008 Agreement and became effective on October 8, 2011.

We are focusing our proprietary resources and development efforts on the development of cabozantinib. However, the product candidate may fail to show adequate safety or efficacy in clinical testing. 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 expect to incur increased expenses for the development of cabozantinib as it advances in clinical development.

With the exception of activities related to cabozantinib, we are discontinuing efforts with respect to all of our compounds and programs that are not funded by partners pursuant to collaboration agreements and are considering collaborations or other external opportunities for the continued development of these compounds and programs. We expect discovery and clinical activities under various collaborations to continue to be funded by partners until we complete our contractual obligations.

### ***Limited Sources of Revenues***

We have no pharmaceutical products that have received marketing approval, and we have generated no revenues to date from the sale of such products. We do not expect to generate revenues from the sale of pharmaceutical products in the near term and expect that all of our near-term revenues, such as research and development funding, license fees and milestone payments and royalty revenues, will be generated from collaboration agreements with our current and potential future partners. Milestones under these agreements may be tied to factors that are outside of our control, such as significant clinical or regulatory events with respect to compounds that have been licensed to our partners.

---

## **Table of Contents**

### ***Liquidity***

As of December 31, 2011, we had \$283.7 million in cash and cash equivalents, marketable securities and long-term investments, which included restricted cash and investments of \$4.2 million and approximately \$85.3 million of cash and cash equivalents and marketable securities that we are required to maintain on deposit with Silicon Valley Bank or one of its affiliates pursuant to covenants in our loan and security agreement with Silicon Valley Bank. In February 2012, we raised approximately \$65 million in net proceeds from a public offering of our common stock. We anticipate that our current cash and cash equivalents, marketable securities, long-term investments and funding that we expect to receive from existing collaborators, together with the anticipated proceeds from this offering, will enable us to maintain our operations for a period of at least 12 months following the filing date of this report. However, our future capital requirements will be substantial and depend on many factors, including the following:

the progress and scope of the development activity with respect to cabozantinib;

whether we elect to pay cash or to issue shares of our common stock in respect of any conversion of our principal, prepayments or payments of interest in connection with the secured convertible notes we issued to entities affiliated with Deerfield Management Company, L.P., or Deerfield, under a note purchase agreement;

whether we elect to prepay the amounts advanced under our loan from Silicon Valley Bank;

the level of payments received under existing collaboration agreements, licensing agreements and other arrangements;

the degree to which we conduct funded development activity on behalf of partners to whom we have out-licensed compounds; and

whether we enter into new collaboration agreements, licensing agreements or other arrangements (including, in particular with respect to cabozantinib) that provide additional capital.

Our minimum liquidity needs are also determined by financial covenants in our loan and security agreement with Silicon Valley Bank and our note purchase agreement with Deerfield, as well as other factors, which are described under **Liquidity and Capital Resources** **Cash Requirements** .

Our ability to raise additional funds may be severely impaired if any of our product candidates fails to show adequate safety or efficacy in clinical testing.

### ***Deerfield Facility***

On June 2, 2010, we entered into a note purchase agreement with Deerfield pursuant to which, on July 1, 2010, we sold to Deerfield an aggregate of \$124.0 million initial principal amount of our secured convertible notes due June 2015 for an aggregate purchase price of \$80.0 million, less closing fees and expenses of approximately \$2.0 million. The outstanding principal amount of the notes bears interest in the annual amount of \$6.0 million, payable quarterly in arrears. We will be required to make mandatory prepayments on the notes on an annual basis in 2013, 2014 and 2015 equal to 15% of certain payments from our collaborative arrangements received during the prior fiscal year, subject to a maximum annual prepayment amount of \$27.5 million and, for payments due in January 2013 and 2014, a minimum prepayment amount of \$10.0 million. We may also prepay all or a portion (not less than \$5.0 million) of the principal amount of the notes at an optional prepayment price based on a discounted principal amount (during the first three years of the term, subject to a prepayment premium) determined as of the date of prepayment, plus accrued and unpaid interest, plus in the case of a prepayment of the full principal amount of the notes (other than prepayments upon the occurrence of specified transactions relating to a change of control or a substantial sale of assets), all accrued interest that would have accrued between the date of such prepayment and the next anniversary of the note purchase agreement. In lieu of





---

**Table of Contents**

making any optional 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 notes into, or satisfy all or any portion of the optional prepayment amounts or mandatory prepayment amounts (other than the first \$10.0 million of mandatory prepayments required in 2013 and 2014) with shares of our common stock. Additionally, in lieu of making any payment of accrued and unpaid interest in respect of the 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 our company, a sale or transfer of assets in one transaction or a series of related transactions for a purchase price of more than \$400 million or a sale or transfer of more than 50% of our assets, Deerfield may require us to prepay the notes at the optional prepayment price, plus accrued and unpaid interest and any other accrued and reimbursable expenses, or the Put Price. Upon an event of default, Deerfield may declare all or a portion of the Put Price to be immediately due and payable.

We also entered into a security agreement in favor of Deerfield which provides that our obligations under the notes will be secured by substantially all of our assets except intellectual property. The note purchase agreement 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 June 2, 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. 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. 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.

***Restructuring Plans***

During 2010, we implemented two restructuring plans that resulted in an overall reduction in our workforce of 386 employees. In March 2011, we implemented an additional restructuring plan that resulted in further terminations in 2011. Taking into consideration employees who have since been recalled, there has been an aggregate reduction in headcount from the 2010 and 2011 restructuring plans of 402 employees. The restructuring plans are a consequence of our decision to focus our proprietary resources and development efforts on the late-stage development and commercialization of cabozantinib.

In connection with the 2010 and 2011 restructuring plans, we have recorded aggregate restructuring charges of \$42.9 million, of which \$20.3 million related to termination benefits and \$22.6 million related to facility-charges and the impairment of various assets. Our 2011 restructuring expense is primarily facility-related

## **Table of Contents**

charges that relate to our buildings in South San Francisco, California and take into consideration our entry into two sublease agreements for portions of a building that we entered into in July 2011 as well as charges relating to the short-term exit of the second floor of another building in December 2011. Additionally, we had asset impairment charges of \$3.7 million relating to excess equipment and other assets, partially offset by cash proceeds of \$1.7 million from the sale of such assets.

With respect to our restructuring plans, we expect to incur additional restructuring charges of \$1.9 million relating to the previously mentioned exit and sublease of our South San Francisco facilities. These charges will be recorded through the end of 2017, or the end of the building lease terms.

As of December 31, 2011, the 2010 and 2011 restructuring plans had resulted in aggregate cash expenditures of \$23.4 million net of \$1.7 million in cash received in connection with the sale of excess equipment and other assets, of which \$14.1 million was paid in 2010 and \$9.3 million was paid in 2011. We expect to pay an additional \$15.9 million, net of cash received from our subtenants, relating to facility costs. We expect these additional facility costs to be paid through 2017, or the end of our lease terms of the buildings.

The restructuring charges that we expect to incur in connection with the restructuring plans 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 restructuring plans.

## **Critical Accounting Estimates**

Our consolidated financial statements and related notes are prepared in accordance with U.S. generally accepted accounting principles which require us to make judgments, estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. We have based our estimates on historical experience and on various other 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 the following critical accounting policies reflect the more significant estimates and assumptions used in the preparation of our consolidated financial statements:

### ***Revenue Recognition***

Our revenues are derived from three primary sources: license fees, milestone payments and collaborative agreement reimbursements.

Revenues from license fees and milestone payments primarily consist of up-front 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. For example, under the 2008 Agreement with Bristol-Myers Squibb, we originally estimated our term to be through August 2013, which

---

**Table of Contents**

was the estimated term of our performance obligations for XL281. We estimated that this would be the period over which we would be obligated to perform services and therefore the appropriate term with which to ratably recognize any license fees. During the fourth quarter of 2010, this estimate was extended to April 2014 as a result of the decision with Bristol-Myers Squibb to complete additional phase 1 trial programs for XL281. On July 8, 2011, we received written notification from Bristol-Myers Squibb of its decision to terminate the 2008 Agreement in its entirety. As a result of the termination of the 2008 Agreement, the estimated research term was revised to end on October 8, 2011. Accordingly, we accelerated the remaining deferred revenue balance through the revised end of the research term and recognized \$109.9 million in revenue during the third quarter ended September 30, 2011 and the remaining \$10.4 million in revenue during the fourth quarter ended December 31, 2011. License fees are classified as license revenues in our consolidated statement of operations.

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 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 statement 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. Under the 2008 Agreement with Bristol-Myers Squibb and prior to its termination by Bristol-Myers Squibb as to cabozantinib, both parties were actively involved with compound development and certain research and development expenses were partially reimbursable to us. On an annual basis, amounts owed by Bristol-Myers Squibb to us, net of amounts reimbursable to Bristol-Myers Squibb by us for the development of cabozantinib and XL281, were recorded as collaboration reimbursement revenues. Conversely, research and development expenses would include the net settlement of amounts we owed Bristol-Myers Squibb for research and development expenses that Bristol-Myers Squibb incurred in connection with the development of cabozantinib, less amounts reimbursable to us by Bristol-Myers Squibb for the development of both cabozantinib and XL281. In annual periods when net research and development funding payments were payable to Bristol-Myers Squibb, these payments were presented as collaboration cost-sharing expenses. Reimbursements under co-development agreements were classified as collaboration reimbursement revenues, while reimbursements under other arrangements were classified as contract revenues in our consolidated statement of operations.

As a result of the termination of the 2008 Agreement with Bristol-Myers Squibb, which became effective on October 8, 2011, reimbursement payments were presented as collaboration reimbursement revenues for the period ended December 31, 2011. We do not expect to record any further collaboration cost-sharing expense or collaboration reimbursement revenues under our current collaborations. See Note 2 of the Notes to the Consolidated Financial Statements for further information on our 2008 Agreement with Bristol-Myers Squibb.

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. Multiple element revenue agreements are evaluated to determine whether the delivered item has value to the customer on a stand-alone basis and whether objective and reliable evidence of the fair value of the undelivered item exists. Deliverables in an arrangement that do not meet the separation criteria are treated as one unit of accounting for purposes of revenue recognition. Generally, the revenue recognition guidance applicable to the final deliverable is followed for the combined unit of accounting. 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. For example, in 2011, under our 2009 collaboration agreement with Sanofi for the discovery of inhibitors of phosphoinositide-3 kinase, or the 2009 Agreement, we accelerated \$53.1 million in previously deferred revenue as a result of the termination of this agreement on December 22, 2011 instead of the previously estimated research term end date of July 2013.

## **Table of Contents**

### ***Clinical Trial Accruals***

All of our clinical trials have been performed by third-party contract research organizations, or 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 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 will 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, 2011 and 2010, we recorded a reduction related to prior periods of approximately \$1.6 million and \$0.9 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.

### ***Restructuring Liability***

In connection with our 2010 and 2011 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 two of 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 of the Notes to Consolidated Financial Statements for a further discussion on our restructuring plans.

### ***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

**Table of Contents**

volatility and the expected term of the award. We have limited historical information available to support the underlying estimates of certain assumptions required to value stock options. 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 shows 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. In addition, we are required to estimate the expected forfeiture rate 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. As of December 31, 2011, \$10.7 million of total unrecognized compensation expense related to stock options was expected to be recognized over a weighted-average period of 2.8 years in addition to \$6.3 million of total unrecognized compensation expense relating to restricted stock units, which was expected to be recognized over 2.6 years. See Note 9 of the Notes to our Consolidated Financial Statements for a further discussion on stock-based compensation.

**Fiscal Year Convention**

Exelixis has adopted a 52- or 53-week fiscal year that ends on the Friday closest to December 31<sup>st</sup>. Fiscal year 2009, a 52-week year, ended on January 1, 2010, fiscal year 2010, a 52-week year, ended on December 31, 2010 and fiscal year 2011, a 52-week year, ended on December 30, 2011. For convenience, references in this report as of and for the fiscal years ended January 1, 2010, December 31, 2010 and December 30, 2011 are indicated on a calendar year basis, ended December 31, 2009, 2010 and 2011, respectively.

**Results of Operations Comparison of Years Ended December 31, 2011, 2010 and 2009****Revenues**

Total revenues by category, as compared to the prior year, were as follows (dollar amounts are presented in millions):

	Year Ended December 31,		
	2011	2010	2009
Contract revenues:			
Research and development funding	\$ 15.6	\$ 42.8	\$ 36.6
Milestones	15.5	18.4	17.6
Collaboration reimbursements	2.8	27.4	
Other contract revenue	10.2		
License revenues and amortization of upfront payments	245.5	96.4	97.6
<b>Total revenues</b>	<b>\$ 289.6</b>	<b>\$ 185.0</b>	<b>\$ 151.8</b>
Dollar increase	\$ 104.6	\$ 33.2	\$ 33.9
Percentage increase	57%	22%	29%

**Table of Contents**

Total revenues by customer, as compared to the prior year, were as follows (dollar amounts are presented in millions):

	Year Ended December 31,		
	2011	2010	2009
Bristol-Myers Squibb	\$ 171.7	\$ 91.9	\$ 81.4
Sanofi	113.9	77.6	46.9
Genentech	2.0	7.0	12.0
Merck	1.3		
GlaxoSmithKline			0.5
Daiichi Sankyo		5.0	
Boehringer Ingelheim	0.7	3.5	10.8
All other revenue sources			0.2
Total revenues	\$ 289.6	\$ 185.0	\$ 151.8
Dollar increase	\$ 104.6	\$ 33.2	\$ 33.9
Percentage increase	57%	22%	29%

The increase in revenues from 2010 to 2011 was primarily due to the acceleration of \$99.1 million in license revenue as a result of the conclusion of our 2008 Agreement with Bristol-Myers Squibb which effectively terminated on October 8, 2011. Additionally, our revenues were increased due to the acceleration of \$53.1 million in license revenue and a one-time termination fee received in January 2012 in the amount of \$15.3 million as a result of the wind-down of our 2009 Agreement with Sanofi which effectively terminated on December 22, 2011. These increases were partially offset by a decline in collaboration reimbursement revenue and research funding related to the termination of our 2008 Agreement with Bristol-Myers Squibb and the transfer of substantially all development activities pertaining to XL147 and XL765 to Sanofi under 2009 license agreement for these compounds. Furthermore, there was a decline in milestone revenue relating to the one-time payment received from Genentech of \$2.0 million in 2011 under a 2005 collaboration agreement for therapeutics directed against targets in the Notch signaling pathway compared to \$7.0 million received from Genentech in 2010 under our 2006 MEK collaboration.

The increase in revenues from 2009 to 2010 was primarily due to our collaboration agreements with Sanofi for XL147, XL765 and the discovery of inhibitors of PI3K. In addition to the increase resulting from our collaboration agreements with Sanofi, we also recognized increases in revenues of \$27.4 million due to increased collaboration cost-sharing reimbursements relating to our 2008 cancer collaboration agreement with Bristol-Myers Squibb for cabozantinib and XL281. These increases in revenues were partially offset by a reduction in license revenues relating to our 2009 collaboration with Boehringer Ingelheim and our amended 2007 cancer collaboration with Bristol-Myers Squibb, as well as the conclusion of our MEK collaboration with Genentech. In addition, we had a decline in milestone and contract revenues related to our 2007 cancer collaboration with Bristol-Myers Squibb and the completion of revenue recognition under our LXR collaboration with Bristol-Myers Squibb.

**Research and Development Expenses**

Total research and development expenses, as compared to the prior year, were as follows (dollar amounts are presented in millions):

	Year Ended December 31,		
	2011	2010	2009
Research and development expenses	\$ 156.8	\$ 210.7	\$ 234.7
Dollar decrease	\$ (53.9)	\$ (24.0)	\$ (22.7)
Percentage decrease	(26%)	(10%)	(9%)

---

**Table of Contents**

Research and development expenses consist primarily of clinical trial expenses, personnel expenses, consulting expenses, laboratory supplies, general corporate costs, stock-based compensation and depreciation. The decrease in 2011 compared to 2010, resulted primarily from the following:

**Personnel** Personnel expense, which includes salaries, bonuses, related fringe benefits, recruiting and relocation costs, decreased by \$17.8 million, or 36% primarily due to the reduction in headcount resulting from our 2010 and 2011 restructuring plans.

**Clinical Trial Costs** Clinical trial expenses, which include services performed by third-party contract research organizations and other vendors, decreased by \$9.7 million, or 11%, primarily due to the transfer of XL765 and XL147 to Sanofi, the wind-down of activities associated with XL228 and the decrease in patient activity for XL281 trials. These decreases were partially offset by an increase in clinical trial activities for cabozantinib.

**General Corporate Costs** There was a decrease of \$7.8 million, or 22%, in the allocation of general corporate costs (such as facility costs, property taxes and insurance) to research and development, primarily as a result of a decrease in personnel and the exit of facilities in San Diego and South San Francisco, as a result of our 2010 and 2011 restructuring plans, and the resulting decrease in costs to be allocated.

**Laboratory Supplies** Laboratory supplies decreased by \$6.6 million, or 78%, primarily due to the decrease in headcount and other cost cutting measures as a result of our 2010 and 2011 restructuring plans.

**Stock-Based Compensation** Stock-based compensation expense decreased by \$5.6 million, or 48%, as a result of our reduction in headcount from our 2010 and 2011 restructuring plans.

The decrease in 2010 compared to 2009 resulted primarily from the following:

**Personnel** Personnel expense, which includes salaries, bonuses, related fringe benefits, recruiting and relocation costs, decreased by \$23.4 million, or 32%, primarily due to a reduction in headcount resulting from our March 2010 restructuring plan.

**General Corporate Costs** There was a decrease of \$8.5 million, or 19%, in the allocation of general corporate costs (such as facility costs, property taxes and insurance) to research and development, primarily as a result of a decrease in personnel and the exit of facilities in San Diego and South San Francisco, as a result of our March 2010 restructuring plan, and the resulting decrease in costs to be allocated.

**Laboratory Supplies** Laboratory supplies decreased by \$7.1 million, or 46%, primarily due to the decrease in headcount and other cost cutting measures as a result of our March 2010 restructuring plan.

**Stock-Based Compensation** Stock-based compensation expense decreased by \$4.2 million, or 26%, as a result of our reduction in headcount from our March 2010 restructuring plan.

The decrease in 2010 compared to 2009 were partially offset by an increase in clinical trial expenses and a decline in cost reimbursements. Clinical trial expenses, which include services performed by third-party contract research organizations and other vendors, increased by \$17.8 million, or 27%, primarily due to increased phase 2 and phase 3 clinical trial activity for cabozantinib and increased phase 2 clinical trial activity for XL147. These increases were partially offset by reduced activities associated with SEI-related compounds, for which the arrangement ended in 2009, as well as a decline in activities associated with various other compounds. In addition, an increase in research and development funding of \$7.0 million was recognized as a reduction to research and development expenses in 2009, which primarily related to our 2007 contract



## Edgar Filing: EXELIXIS INC - Form 10-K

research agreement with Agrigenetics, Inc., or Agrigenetics, which ended in 2009. The 2010 research and development funding, which stems from our agreement with a third party relating to the sale of our cell factory business, ended in the second quarter of 2010.

**Table of Contents**

We do not track total research and development expenses separately for each of our research and development programs. We group our research and development expenses into three categories: drug discovery, development and other. Our drug discovery group utilizes a variety of high-throughput technologies to enable the rapid discovery, optimization and extensive characterization of lead compounds such that we are able to select development candidates with the best potential for further evaluation and advancement into clinical development. Drug discovery expenses relate primarily to personnel expense, lab supplies and general corporate costs. Our development group leads the development and implementation of our clinical and regulatory strategies and prioritizes disease indications in which our compounds may be studied in clinical trials. Development expenses relate primarily to clinical trial, personnel and general corporate costs. The other category primarily includes stock-based compensation expense.

In addition to reviewing the three categories of research and development expenses described above, we principally consider qualitative factors in making decisions regarding our research and development programs. Such factors include enrollment in clinical trials for our drug candidates, the results of and data from clinical trials, the potential indications for our drug candidates, the therapeutic and commercial potential for our drug candidates and competitive dynamics. We also make our research and development decisions in the context of our overall business strategy, which historically included the pursuit of commercial collaborations with major pharmaceutical and biotechnology companies for the development of our drug candidates. 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. Our strategy is to aggressively advance cabozantinib through development toward commercialization, and as a result, we expect nearly all of our future research and development expenses to relate to the clinical development of cabozantinib.

The expenditures summarized in the following table reflect total research and development expenses by category, including allocations for general and administrative expense (dollar amounts are presented in millions):

	2011	2010	2009	Inception to date(1)
Drug Discovery	\$ 17.8	\$ 54.1	\$ 88.0	\$ 456.4
Development	132.3	142.9	126.8	713.3
Other	6.7	13.7	19.9	100.8
Total	\$ 156.8	\$ 210.7	\$ 234.7	\$ 1,270.5

(1) Inception is as of January 1, 2006, the date on which we began tracking research and development expenses by category. While we do not track total research and development expenses separately for each program, beginning in fiscal 2006, we began tracking third party expenditures directly relating to each program as a way of monitoring external costs. Our third party research and development expenditures relate principally to our clinical trial and related development activities, such as preclinical and clinical studies and contract manufacturing, and represent only a portion of the costs related to each program. Third party expenditures for programs initiated prior to the beginning of fiscal 2006 have not been tracked from project inception, and therefore these expenditures from the actual inception for most of our programs are not available. We do not accumulate on a program-specific basis internal research and development expenses, such as salaries and personnel expenses, facilities overhead expenses and external costs not directly attributable to a specific project. Nevertheless, we believe that third party expenditures by program provide a reasonable estimate of the percentage of our total research and development expenses that are attributable to each such program. Under our current strategy, we are focusing our proprietary resources and development efforts exclusively on the late-stage development and commercialization of cabozantinib. As a result, for fiscal year 2011, approximately 92% of our external third party research and development expenditures were spent on this program. The expenses for the cabozantinib program were primarily included in the development category of our research and development expenses and exclude the impact of any amounts reimbursed by our partners.

**Table of Contents**

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. In general, we will incur increased research and development expenses for compounds that advance in clinical development, whereas expenses will end for compounds that do not warrant further clinical development.

We do not have reliable estimates of total costs for a particular drug candidate to reach the market. Our potential therapeutic products are subject to a lengthy and uncertain regulatory process that 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 products may fail to demonstrate safety and efficacy, which could prevent or significantly delay regulatory approval.

**General and Administrative Expenses**

Total general and administrative expenses were as follows (dollar amounts are presented in millions):

	Year Ended December 31,		
	2011	2010	2009
General and administrative expenses	\$ 33.1	\$ 33.0	\$ 34.4
Dollar increase (decrease)	\$ 0.1	\$ (1.4)	\$ (2.5)
Percentage increase (decrease)	0.3%	(4)%	(7)%

General and administrative expenses consist primarily of personnel expenses, employee stock-based compensation expense, facility costs, legal patent costs and consulting and professional expenses, such as legal and accounting fees. The increase in general and administrative expenses for 2011 as compared to 2010, was primarily due to a decrease in allocation of general corporate costs to research and development as a result of the reduction in research and development headcount headcount from our 2010 and 2011 restructuring plans, as well as an increase in marketing expenses relating to the preparation for a potential commercial launch of cabozantinib. These increases were offset by a decrease in facility, personnel and stock compensation costs relating to our 2010 and 2011 restructuring plans.

The decrease in 2010 from 2009 was primarily due to decreased personnel and facility costs related to our March 2010 restructuring, partially offset by a change in the allocation of overhead expenses as a result of our March 2010 restructuring in addition to a slight increase in patent costs.

**Collaboration Reimbursement Revenues (Cost-Sharing Expenses)**

Total collaboration reimbursement revenues (cost-sharing expenses) were as follows (dollar amounts are presented in millions):

	Year Ended December 31,		
	2011	2010	2009
Collaboration reimbursements (cost-sharing expenses)	\$ 2.8	\$ 27.4	\$ (4.6)
Dollar increase (decrease)	\$ (24.6)	\$ 32.0	\$ (4.9)
Percentage increase (decrease)	(89.8)%	Not Meaningful	Not Meaningful

**Table of Contents**

In 2011 and 2010 we had net collaboration reimbursements and recorded collaboration reimbursement revenue, and therefore no collaboration cost sharing expenses during these years. Collaboration reimbursement revenues (cost-sharing expenses) consist of research and development expenses and reimbursements related to our 2008 cancer collaboration agreement with Bristol-Myers Squibb for cabozantinib and XL281. For the year ended December 31, 2009, when net research and development expenses were payable to Bristol-Myers Squibb, these payments were presented as collaboration cost-sharing expenses resulting in operating expenses of \$4.6 million. For the year ended December 31, 2010, we received net collaboration reimbursements and recorded collaboration reimbursement revenues of \$27.4 million, which included the \$17.0 million transition payment received from Bristol-Myers Squibb upon termination of our 2008 cancer collaboration with respect to cabozantinib only. For the year ended December 31, 2011, the \$2.8 million of collaboration reimbursement revenues related to the reimbursement of costs for XL281 expenses only. As a result of the termination of the 2008 Agreement with Bristol-Myers Squibb with respect to XL281, which became effective on October 8, 2011, we do not expect to record any further collaboration cost-sharing expense or collaboration reimbursement revenues under any of our current collaborations.

**Restructuring Charge**

Total restructuring charge expenses from restructurings plans were as follows (dollar amounts are presented in millions):

	Year Ended December 31,		
	2011	2010	2009
Restructuring charge	\$ 10.1	\$ 32.7	\$
Dollar increase (decrease)	\$ (22.6)	\$ 32.7	\$ (2.9)
Percentage increase (decrease)	(69%)	Not Meaningful	Not Meaningful

As part of our ongoing efforts to manage costs and our strategy to focus our proprietary resources and development efforts on cabozantinib, we implemented two restructuring plans during 2010 that resulted in an overall reduction of our workforce by 386 employees. In March 2011, we implemented an additional restructuring plan that resulted in further terminations in 2011. Taking into consideration employees who have since been recalled, there has been an aggregate reduction in headcount from the 2010 and 2011 restructuring plans of 402 employees. The restructuring charge taken in 2010 primarily related to termination benefits for the reduction in headcount in March 2010, in addition to facility charges relating to the exit and sublease of a building, while the restructuring charge taken in 2011 related primarily to facility charges associated with the exit and sublease of portions of another building. As a result of our 2010 and 2011 restructuring plans, we expect to incur additional restructuring charges, primarily related to facility costs, through the end of 2017.

**Total Other Income (Expense), net**

Total other income (expense), net, as compared to prior years was as follows (dollar amounts are presented in millions):

	Year Ended December 31,		
	2011	2010	2009
Interest income and other, net	\$ 1.5	\$ 0.1	\$ 1.5
Interest expense	(16.3)	(9.3)	(12.7)
Gain on sale of businesses	2.3	8.2	2.1
Loss on deconsolidation of Symphony Evolution, Inc.			(9.8)
<b>Total other income (expense), net</b>	<b>\$ (12.5)</b>	<b>\$ (1.0)</b>	<b>\$ (18.9)</b>
Dollar increase (decrease)	\$ (11.5)	\$ 17.9	\$ (22.6)

**Table of Contents**

Total other income (expense), net consists primarily of interest income earned on our marketable securities and gains on sales of businesses, offset by interest expense incurred on our notes payable, bank obligations, capital lease obligations, convertible notes and loans and our credit facility. The change in total other income (expense), net for 2011 compared to 2010, was primarily due to the increased interest expense in 2011 as a result of our entry into a note purchase agreement with Deerfield in June 2010, partially offset by gains relating to the sale of our remaining 19.9% equity interest in Artemis and the sale of excess XL647 materials. In addition, in 2010, we recorded gains relating to the sale of our plant trait business and the sale of our cell factory business.

The change in total other income (expense), net for 2010 compared to 2009, resulted primarily from the recording of a \$9.8 million loss upon deconsolidation of SEI as a result of the expiration of our purchase option for SEI in June 2009 as well as an \$8.2 million gain in 2010 relating to the sale of our plant trait business and our cell factory business. In addition, interest expense declined with the termination of our facility agreement with Deerfield in November 2009 and the payment of \$37.0 million in cash to GlaxoSmithKline in October 2010 as the second of three installments of principal and accrued interest due under our loan agreement with GlaxoSmithKline. This was partially offset by increased interest expense incurred in connection with the new Deerfield facility entered into in June 2010.

**Income Tax (Provision) Benefit**

	2011	Year Ended December 31, 2010	2009
Tax (provision) benefit	\$ (1.3)	\$ 0.1	\$ 1.3
Dollar change	\$ (1.4)	\$ (1.2)	\$ 1.3
Percentage change	Not Meaningful	Not Meaningful	Not Meaningful

In 2009 and 2010, we recorded an income tax benefit as a result of the enactment of the Housing and Economy Recovery Act of 2008, which was extended through 2009 in connection with the enactment of the American Recovery and Reinvestment Tax Act of 2009. Approximately \$0.6 million of the 2011 provision relates to an adjustment of the refund received in 2009 and 2010 under these Acts after we further evaluated the qualified expenses from which the refund calculation was originally based. The remaining amount of \$0.7 million relates to a tax deferred revenue adjustment that resulted in a state tax liability due to state net operating loss carryover limitations.

**Loss attributed to noncontrolling interest**

In 2005, we licensed three of our compounds, XL647, XL784 and XL999, to SEI in return for an \$80.0 million investment for the clinical development of these compounds. As part of the agreement, we received an exclusive purchase option to acquire all of the equity of SEI, thereby allowing us to reacquire XL647, XL784 and XL999 at our sole discretion. The purchase option expired on June 9, 2009. The expiration of the purchase option triggered a reconsideration event regarding our need to consolidate SEI, a variable interest entity. Upon the expiration of the purchase option, we no longer held a variable interest in the variable interest entity. Accordingly, we deconsolidated SEI and derecognized the SEI assets, liabilities and noncontrolling interest from our financial statements. For the year ended December 31, 2009, the losses attributed to the noncontrolling interest holders was \$4.3 million. As a result of the 2009 deconsolidation, we will no longer record any further gains or losses attributable to SEI.

**Table of Contents****Liquidity and Capital Resources***Sources and Uses of Cash*

The following table summarizes our cash flow activities for the years ended December 31, 2011, 2010 and 2009 (dollar amounts are presented in thousands):

	Year Ended December 31,		
	2011	2010	2009
Consolidated net income (loss)	\$ 75,697	\$ (92,330)	\$ (139,557)
Adjustments to reconcile net income (loss) to net cash used in operating activities	29,954	33,615	44,894
Changes in operating assets and liabilities	(264,884)	(42,333)	80,072
Net cash used in operating activities	(159,233)	(101,048)	(14,591)
Net cash used in investing activities	(51,463)	(19,569)	(112,322)
Net cash provided by (used in) financing activities	187,513	131,261	(33,989)
Net (decrease) increase in cash and cash equivalents	(23,183)	10,644	(160,902)
Cash and cash equivalents, at beginning of year	97,440	86,796	247,698
Cash and cash equivalents, at end of year	\$ 74,257	\$ 97,440	\$ 86,796

To date, we have financed our operations primarily through the sale of equity, payments and loans from collaborators and banks, debt financing arrangements and equipment financing facilities. We have also financed certain of our research and development activities under our agreements with various collaborators. As of December 31, 2011, we had \$283.7 million in cash and cash equivalents, marketable securities and long-term investments, which included restricted cash and investments of \$4.2 million and approximately \$85.3 million of cash and cash equivalents and marketable securities that we are required to maintain on deposit with Silicon Valley Bank or one of its affiliates pursuant to covenants in our loan and security agreement with Silicon Valley Bank.

*Operating Activities*

Our operating activities used cash of \$159.2 million for the year ended December 31, 2011, compared to cash used of \$101.0 million for the year ended December 31, 2010 and cash used of \$14.6 million for the year ended December 31, 2009. The increase in cash used by operating activities for 2011 related primarily to a reduction of \$244.5 million in our deferred revenue balance due to the acceleration of non-cash revenue recognized as well as a reduction in collaboration reimbursements and research funding received due to the termination of the 2008 Agreement with Bristol-Myers Squibb and our 2009 Collaboration Agreement with Sanofi. In addition, there was an increase in our receivables balance relating to our collaboration agreements and a reduction in our other accrual balances due to the timing of payments made to vendors. These increases in cash used were partially offset by our consolidated net income of \$75.7 million in addition to \$32.6 million in non-cash charges relating to stock-based compensation, depreciation and amortization, accretion of implied interest under our 2010 note purchase agreement with Deerfield, impairment of assets due to our 2010 and 2011 restructuring plans, and other non-cash changes.

Our operating activities used cash of \$101.0 million for the year ended December 31, 2010, compared to \$14.6 million for the year ended December 31, 2009, and \$9.7 million for 2008. Cash used in operating activities during 2010 related primarily to our consolidated net loss of \$92.3 million, to decreases in deferred revenues of \$42.9 million, to declines in accounts payable and other accrued expenses and gains recognized in association with our transaction with Agrigenetics and for the sale of our plant trait business. These uses of cash were partially offset by non-cash charges totaling \$38.6 million relating to stock-based compensation, depreciation and

---

**Table of Contents**

amortization, accretion of implied interest under our 2010 note purchase agreement with Deerfield, and impairment of assets due to our March and December 2010 restructuring plans. In addition, we recognized a restructuring liability of \$14.3 million primarily relating to the exit from one of our South San Francisco buildings in connection with our March 2010 restructuring plan and termination benefits from our December 2010 restructuring plan, in addition to a decrease in other receivables.

Cash used in operating activities during 2009 related primarily to our consolidated net loss of \$139.6 million offset by increases in deferred revenues and other non-cash charges. The decrease in our consolidated net loss was driven by an increase in revenues primarily due to our 2009 collaboration with Sanofi relating to XL147 and XL765 and our 2008 cancer collaboration with Bristol-Myers Squibb relating to cabozantinib and XL281, in addition to an overall decrease in operating expenses. These uses of cash were primarily offset by a net increase in deferred revenue of \$85.8 million, primarily driven by receipt of an upfront cash payment of \$140.0 million related to the global license agreement and collaboration with Sanofi, partially offset by a decrease in deferred revenue from the ratable recognition of deferred revenues over the period of continuing involvement from our various collaborations. In addition, cash uses were offset by non-cash charges totaling \$45.3 million relating to stock-based compensation, depreciation and amortization, and a \$9.8 million loss that we recorded upon deconsolidation of SEI.

Prior to 2011, we have been in a net loss position and our cash used in operating activities has been primarily driven by our consolidated net loss. 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. Going forward for at least the next several years, we expect to continue to use cash for operating activities as we incur net losses associated with our research and development activities, primarily with respect to manufacturing and development expenses for cabozantinib.

*Investing Activities*

Our investing activities used cash of \$51.5 million for the year ended December 31, 2011, compared to cash used of \$19.6 million for the year ended December 31, 2010, and cash provided of \$112.3 million for 2009.

Cash used by investing activities for 2011 was primarily driven by the purchase of \$237.2 million in marketable securities partially offset by proceeds received from the maturity of marketable securities of \$124.8 million, proceeds from the sale of marketable securities before maturity of \$55.2 million and a proceeds of \$3.0 million from the sale of our 19.9% equity ownership in Artemis.

Cash used by investing activities for 2010 was primarily driven by the purchase of \$167.3 million of marketable securities and certificates of deposit. These uses of cash were partially offset by proceeds from the maturity of marketable securities of \$127.6 million in addition to the sale of investments prior to maturity of \$12.8 million and proceeds of \$9.0 million associated with our 2007 transaction with Agrigenetics and the sale of our cell factory business in 2010. The proceeds provided by the sale and maturity of our investments were used to fund our operations. Additionally, in line with our focus on managing our cash resources, purchase of property and equipment were significantly lower in 2010 and 2009 than compared to prior years.

Cash used in investing activities for 2009 was primarily driven by purchases of marketable securities of \$161.2 million. Most of the cash invested in marketable securities was generated by payments received from collaborators. These uses of cash were partially offset by proceeds from maturities of marketable securities and on sales of investments held by SEI, for a combined cash inflow of \$54.3 million used to fund our operations.

*Financing Activities*

Our financing activities provided cash of \$187.5 million for the year ended December 31, 2011, compared to cash provided of \$131.3 million for the year ended December 31, 2010, and cash used of \$34.0 million for

---

## **Table of Contents**

2009. Cash provided by our financing activities for 2011 consisted of net proceeds of \$179.4 million from the issuance of 17.3 million shares of common stock, proceeds from the exercise of stock options of \$12.4 million and the final draw down of \$2.6 million required under our Silicon Valley Bank loan agreement. These increases in cash were partially offset by cash used for principal payments on notes payable and bank obligations of \$8.6 million.

Cash provided by our financing activities for 2010 was primarily due to funds received under our loan agreement with Silicon Valley Bank, the sale of secured convertible notes to Deerfield for proceeds of \$165.0 million, proceeds from the sale of Exelixis stock under our employee stock purchase plan of \$3.1 million and proceeds from employee option exercises of \$2.7 million. These cash inflows were partially offset by principal payments on notes payable and bank obligations of \$39.6 million.

Cash used by our financing activities for 2009 was primarily due to principal payments on notes payable and bank obligations of \$43.1 million partially offset by proceeds from notes payable and bank obligations of \$5.0 million and proceeds from employee stock purchase plan purchases of \$3.8 million.

Proceeds from collaboration loans and common stock issuances 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 June 2008, we entered into the facility agreement with Deerfield for which Deerfield agreed to loan us up to \$150.0 million, subject to specified conditions. The facility agreement was terminated in November 2009, resulting in a \$5.2 million charge to interest expense relating to a cancellation fee and outstanding warrants. We did not draw on the facility agreement at any time prior to its termination. 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 our secured convertible notes for an aggregate purchase price of \$80.0 million, less closing fees and expenses of approximately \$2.0 million. See Note 7 for additional details on these agreements.

### ***Cash Requirements***

We have incurred net losses since inception. However, for the year ended December 31, 2011, we were in a net income position of \$75.7 million, primarily as a result of the acceleration of revenue recognized under our 2008 collaboration agreement with Bristol-Myers Squibb that terminated in October 2011 and under our 2009 discovery collaboration agreement with Sanofi that terminated in December 2011. Notwithstanding our net income position for the year ended December 31, 2011, we anticipate further net losses and negative operating cash flow for the foreseeable future. As of December 31, 2011, we had \$283.7 million in cash and cash equivalents, marketable securities and long-term investments, which included restricted cash and investments of \$4.2 million and approximately \$85.3 million of cash and cash equivalents and marketable securities that we are required to maintain on deposit with Silicon Valley Bank or one of its affiliates pursuant to covenants in our loan and security agreement with Silicon Valley Bank. In February 2012, we raised approximately \$65 million in net proceeds from a public offering of our common stock. We anticipate that our current cash and cash equivalents, marketable securities, long-term investments and funding that we expect to receive from existing collaborators, together with the anticipated proceeds from this offering, will enable us to maintain our operations for a period of at least 12 months following the filing date of this report. However, our future capital requirements will be substantial and will depend on many factors that may require us to use available capital resources significantly earlier than we currently anticipate. These factors include:

the cabozantinib development program We are focusing our proprietary resources and development efforts on cabozantinib, our most advanced product candidate, which is being studied in a variety of tumor types, with the goal of rapidly commercializing the compound. Cabozantinib is being evaluated in a broad development program encompassing multiple cancer indications. The current clinical



---

**Table of Contents**

program for cabozantinib is focused on the treatment of metastatic castration-resistant prostate cancer and medullary thyroid cancer and will be expanded to other solid tumor indications, based on encouraging interim data that have emerged from the RDT investigating cabozantinib in nine distinct tumor types and other clinical trials. In October 2011, we announced that our phase 3 clinical trial of cabozantinib in medullary thyroid cancer met its primary endpoint, and, in December 2011, the FDA granted us permission to initiate a rolling submission of an NDA for cabozantinib in medullary thyroid cancer. We initiated the submission in December 2011 by submitting to the FDA key parts of the NDA, including the preclinical information, and we expect to complete the NDA filing in the first half of 2012. Assuming priority review and approval of our NDA by the FDA, we currently anticipate a potential commercial launch of cabozantinib for the treatment of medullary thyroid cancer in the second half of 2012. In December 2011, we initiated our first phase 3 pivotal trial of cabozantinib in patients with metastatic castration-resistant prostate cancer using an endpoint of pain reduction (COMET-2). We also plan to initiate a phase 3 pivotal trial in metastatic castration-resistant prostate cancer patients with an overall survival endpoint (COMET-1) in the first half of 2012 as part of our comprehensive development plan for cabozantinib in castration-resistant prostate cancer. We are also planning other potential pivotal trials in prostate cancer. Our development and commercialization plans for cabozantinib are dependent on the extent of our available financial resources. There can be no assurance that we will have sufficient financial resources independently or through other arrangements to fund the trials that are currently planned or in process, to fund other clinical trials that we may desire to initiate in the future or to fund commercialization efforts. If adequate funds are not available, we may be required to delay, discontinue or elect not to pursue one or more trials or commercialization efforts for cabozantinib;

repayment of the notes under our note purchase agreement with Deerfield On June 2, 2010, we entered into a note purchase agreement with Deerfield pursuant to which, on July 1, 2010, we sold to Deerfield an aggregate of \$124.0 million initial principal amount of our secured convertible notes, due June 2015, for an aggregate purchase price of \$80.0 million, less closing fees and expenses. The outstanding principal amount of the notes bears interest in the annual amount of \$6.0 million, payable quarterly in arrears. We will be required to make mandatory prepayments on the notes on an annual basis in 2013, 2014 and 2015 equal to 15% of specified payments from our collaborative arrangements received during the prior fiscal year, subject to a maximum annual prepayment amount of \$27.5 million and, for payments due in January 2013 and 2014, a minimum prepayment amount of \$10.0 million. We may also prepay all or a portion (not less than \$5.0 million) of the principal amount of the notes at an optional prepayment price based on a discounted principal amount (during the first three years of the term, subject to a prepayment premium) determined as of the date of prepayment, plus accrued and unpaid interest, plus in the case of a prepayment of the full principal amount of the notes (other than prepayments upon the occurrence of specified transactions relating to a change of control or a substantial sale of assets), all accrued interest that would have accrued between the date of such prepayment and the next anniversary of the note purchase agreement. In lieu of making any optional or mandatory prepayment in cash, subject to specified limitations, we have the right to convert all or a portion of the principal amount of the notes into, or satisfy all or any portion of the optional prepayment amounts or mandatory prepayment amounts (other than the first \$10.0 million of mandatory prepayments required in 2013 and 2014) with, shares of our common stock. Additionally, in lieu of making any payment of accrued and unpaid interest in respect of the notes in cash, subject to specified 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. In the event the market price for our common stock is depressed or we do not have sufficient number of authorized but unissued shares, we may not be able to convert the principal amount of the notes or satisfy our payment obligations in full using shares of our common stock due to restrictions in the agreement on the number of shares we may issue. In addition, the issuance of shares of our common stock to convert the notes or satisfy our payment obligations may result in significant

**Table of Contents**

dilution to our stockholders. As a result, we may need to obtain additional funding to satisfy our repayment obligations. There can be no assurance that we will have sufficient funds to repay the notes or satisfy our payment obligations under the note purchase agreement when due or that we will comply with the conditions to our ability to convert the principal amount of the notes into or satisfy our payment obligations with shares of our common stock;

repayment of our loan from Silicon Valley Bank On June 2, 2010, we amended our loan and security agreement with Silicon Valley Bank to provide for a new seven-year term loan in an 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. In accordance with the terms of the loan and security agreement, we are also required to maintain on deposit an amount equal to at least 100% of the outstanding principal balance of the term loan at all times as support for our obligations under the loan and security agreement. As a result, the proceeds of the term loan cannot be used to satisfy our other obligations without causing a default under our loan and security agreement with Silicon Valley Bank;

the level of payments received under existing collaboration agreements, licensing agreements and other arrangements;

the degree to which we conduct funded development activity on behalf of partners to whom we have out-licensed compounds;

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 and marketable securities that serve as collateral for bank lines of credit;

future clinical trial results;

our need to expand our product and clinical development efforts;

our ability to share the costs of our clinical development efforts with third parties;

the cost and timing of regulatory approvals;

the cost of clinical and research supplies of our product candidates;

the effect of competing technological and market developments;

the filing, maintenance, prosecution, defense and enforcement of patent claims and other intellectual property rights; and

the cost of any acquisitions of or investments in businesses, products and technologies.

We may seek to raise funds through the sale of equity or debt securities or through external borrowings. In addition, we may enter into additional strategic partnerships, collaborative arrangements or other strategic transactions. It is unclear whether any such partnership, arrangement or transaction will occur, on satisfactory terms or at all, or what the timing and nature of such a partnership, arrangement or transaction may be. The sale of equity or convertible debt securities in the future may be dilutive to our stockholders, and debt-financing

**Table of Contents**

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 may contain other terms that are not favorable to our stockholders or us. If we are unable to obtain adequate funds on reasonable terms, we may be required to curtail operations significantly or obtain funds by entering into financing, supply or collaboration agreements on unattractive terms or we may be required to relinquish rights to technology or product candidates or to grant licenses on terms that are unfavorable to us.

We may need to obtain additional funding in order to stay in compliance with financial covenants contained in agreements with third parties. As described below, the terms of our debt owed to Deerfield and Silicon Valley Bank each contain covenants requiring us to maintain specified cash balances or levels of working capital:

**Deerfield** Our note purchase agreement with Deerfield contains an event of default that would be triggered if our cash and cash equivalents fall below \$20.0 million as of December 28, 2012, subject to a cure period. Upon such an event of default, Deerfield may declare all or a portion of the Put Price to be immediately due and payable. Cash and cash equivalents for purposes of our note purchase agreement includes our total cash, cash equivalents and short-term and long-term marketable securities. As of December 31, 2011, our cash and cash equivalents were \$283.7 million.

**Silicon Valley Bank** Our loan and security agreement with Silicon Valley Bank 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 cannot raise additional capital in order 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 operating leases, notes payable and licensing agreements. The following chart details our contractual obligations, including any potential accrued or accreted interest, as of December 31, 2011 (dollar amounts are presented in thousands):

Contractual Obligations(1)	Total	Payments Due by Period			
		Less than 1 year	1-3 Years	4-5 years	After 5 years
Notes payable and bank obligations	\$ 94,690	5,739	6,662	1,953	\$ 80,336
Convertible loans(1)	144,983	6,008	67,000	71,975	
Operating leases(2)	87,568	15,634	30,644	30,109	11,181
Total contractual cash obligations	\$ 327,241	\$ 27,381	\$ 104,306	\$ 104,037	\$ 91,517

(1) See Note 9 to the Notes to our Consolidated Financial Statements regarding the terms of the Deerfield financing.

(2) The operating lease payments are net of \$18.7 million to be received through 2017 in connection with our sublease for two of our South San Francisco buildings.

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



## **Table of Contents**

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 October 2009, the FASB issued ASU No. 2009-13, Revenue Recognition *Multiple Deliverable Revenue Arrangements* ( ASU 2009-13 ). ASU 2009-13 provides application guidance on whether multiple deliverables exist, how the deliverables should be separated and how the consideration should be allocated to one or more units of accounting. This update establishes a selling price hierarchy for determining the selling price of a 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. Under ASU 2009-13, we may be required to exercise considerable judgment in determining the estimated selling price of delivered items under new agreements and our revenue under new agreements may be more accelerated as compared to the prior accounting standard. We adopted this guidance beginning January 1, 2011. While it has not had a material impact on our financial statements in 2011, we expect that this adoption could have a material impact on our financial statements going forward.

In June 2011, Accounting Standards Codification Topic 220, *Comprehensive Income* was amended to increase the prominence of items reported in other comprehensive income. Accordingly, a company can present all non-owner changes in stockholders' equity either in a single continuous statement of comprehensive income or in two separate but consecutive statements. We adopted this guidance in 2011 on a retrospective basis and have determined that it did not have a material effect on our consolidated financial statements.

### **Off-Balance Sheet Arrangements**

As of December 31, 2011, we did not have any material off-balance-sheet arrangements, as defined by applicable SEC regulations.

---

**Table of Contents**

**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, 2011, we had cash and cash equivalents, marketable securities, long-term investments and restricted cash and investments of \$283.7 million. Our marketable securities and 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, 2011 and 2010, we had debt outstanding of \$181.5 million and \$208.5 million, respectively. Our payment commitments associated with these debt instruments are primarily fixed and are comprised of interest payments, principal payments, or a combination of both. The fair value of 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, 2011 and December 31, 2010. As of December 31, 2011 and December 31, 2010, 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 \$7.2 million and \$9.7 million, respectively.

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 are associated with establishing and conducting clinical trials for cabozantinib and various other compounds in our pipeline 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, 2011, approximately \$2.8 million of our clinical accrual balance was owed in foreign currencies. As of December 31, 2011, an adverse change of one percentage point in the in foreign currency exchange rates would have resulted in a net loss of \$28,000. As of December 31, 2010, an adverse change of one percentage point in the in foreign currency exchange rates would have resulted in a net loss of \$31,000. We incurred a net loss of \$0.3 million relating to our foreign currency contract that was settled in December 2011, but we have not incurred any gains or losses relating to foreign exchange fluctuations in relation to clinical trials for the fiscal year ended December 31, 2011 or December 31, 2010.

**Table of Contents**

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA  
EXELIXIS, INC.**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	66
<u>Consolidated Balance Sheets</u>	67
<u>Consolidated Statements of Operations</u>	68
<u>Consolidated Statements of Stockholders' Equity (Deficit)</u>	70
<u>Consolidated Statements of Cash Flows</u>	71
<u>Notes to Consolidated Financial Statements</u>	72



**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 December 30, 2011 and December 31, 2010, and the related consolidated statements of operations, other comprehensive income (loss), stockholders' equity (deficit) and cash flows for each of the three fiscal years in the period ended December 30, 2011. These financial statements are the responsibility of Exelixis, Inc.'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 December 30, 2011 and December 31, 2010, and the consolidated results of its operations, and its cash flows for each of the three fiscal years in the period ended December 30, 2011, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Exelixis, Inc.'s internal control over financial reporting as of December 30, 2011, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 22, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Redwood City, California

February 22, 2012

**Table of Contents****EXELIXIS, INC.****CONSOLIDATED BALANCE SHEETS**

(in thousands, except share data)

	December 31,	
	2011	2010
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 74,257	\$ 97,440
Marketable securities	120,005	65,224
Other receivables	30,190	5,896
Prepaid expenses and other current assets	4,372	14,926
<b>Total current assets</b>	<b>228,824</b>	<b>183,486</b>
Restricted cash and investments	4,199	6,399
Long-term investments	85,260	87,314
Property and equipment, net	8,506	15,811
Goodwill	63,684	63,684
Other assets	2,789	4,096
<b>Total assets</b>	<b>\$ 393,262</b>	<b>\$ 360,790</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 1,957	\$ 2,046
Accrued clinical trial liabilities	21,729	30,975
Other accrued liabilities	8,423	15,026
Accrued compensation and benefits	8,943	6,555
Current portion of notes payable and bank obligations	4,870	8,848
Current portion of convertible loans		28,900
Current portion of restructuring	4,483	7,294
Deferred revenue	41,920	100,297
<b>Total current liabilities</b>	<b>92,325</b>	<b>199,941</b>
Long-term portion of notes payable and bank obligations	85,260	87,314
Long-term portion of convertible loans	91,385	83,396
Long-term portion of restructuring	9,495	6,987
Other long-term liabilities	7,844	9,005
Deferred revenue	16,321	202,472
<b>Total liabilities</b>	<b>302,630</b>	<b>589,115</b>
Commitments (Note 13)		
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value, 10,000,000 shares authorized and no shares issued		
Common stock, \$0.001 par value; 200,000,000 shares authorized; issued and outstanding: 135,563,735 and 109,287,160 shares at December 31, 2011 and 2010, respectively	135	109
Additional paid-in-capital	1,196,992	953,608
Accumulated other comprehensive income	(138)	12
Accumulated deficit	(1,106,357)	(1,182,054)
<b>Total stockholders' equity (deficit)</b>	<b>90,632</b>	<b>(228,325)</b>

Edgar Filing: EXELIXIS INC - Form 10-K

Total liabilities and stockholders' equity (deficit)	\$ 393,262	\$ 360,790
--	------------	------------

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

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

	Year Ended December 31,		
	2011	2010	2009
<b>Revenues:</b>			
Contract	\$ 41,309	\$ 61,271	\$ 54,141
License	245,549	96,363	97,618
Collaboration reimbursement	2,778	27,411	
<b>Total revenues</b>	<b>289,636</b>	<b>185,045</b>	<b>151,759</b>
<b>Operating expenses:</b>			
Research and development	156,836	210,678	234,702
General and administrative	33,129	33,020	34,382
Collaboration cost sharing			4,582
Restructuring charge	10,136	32,744	
<b>Total operating expenses</b>	<b>200,101</b>	<b>276,442</b>	<b>273,666</b>
Income (loss) from operations	89,535	(91,397)	(121,907)
<b>Other income (expense):</b>			
Interest income and other, net	1,462	138	1,510
Interest expense	(16,259)	(9,340)	(12,672)
Gain on sale of businesses	2,254	8,197	2,052
Loss on deconsolidation of Symphony Evolution, Inc.			(9,826)
<b>Total other income (expense), net</b>	<b>(12,543)</b>	<b>(1,005)</b>	<b>(18,936)</b>
<b>Consolidated income (loss) before taxes</b>	<b>76,992</b>	<b>(92,402)</b>	<b>(140,843)</b>
Income tax (provision) benefit	(1,295)	72	1,286
<b>Consolidated net income (loss)</b>	<b>75,697</b>	<b>(92,330)</b>	<b>(139,557)</b>
Loss attributed to noncontrolling interest			4,337
<b>Net income (loss) attributable to Exelixis, Inc.</b>	<b>\$ 75,697</b>	<b>\$ (92,330)</b>	<b>\$ (135,220)</b>
Net income (loss) per share, basic, attributable to Exelixis, Inc.	\$ 0.60	\$ (0.85)	\$ (1.26)
Net income (loss) per share, diluted, attributable to Exelixis, Inc.	\$ 0.58	\$ (0.85)	\$ (1.26)
Shares used in computing basic income (loss) per share amounts	126,018	108,522	107,073
Shares used in computing diluted income (loss) per share amounts	130,479	108,522	107,073

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



**Table of Contents****EXELIXIS, INC.****STATEMENT OF OTHER COMPREHENSIVE INCOME (LOSS)****(in thousands)**

	<b>Year Ended December 31,</b>		
	<b>2011</b>	<b>2010</b>	<b>2009</b>
Consolidated net income (loss)	\$ 75,697	\$ (92,330)	\$ (139,557)
(Decrease)/increase in net unrealized gains on available-for-sale securities	(150)	(143)	155
Comprehensive income (loss)	75,547	(92,473)	(139,402)
Comprehensive loss attributable to noncontrolling interest			4,337
Comprehensive income (loss) attributable to Exelixis, Inc.	\$ 75,547	\$ (92,473)	\$ (135,065)

Accumulated other comprehensive income consisted solely of unrealized gains (losses) on available for sale securities for the periods presented.

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 Income	Accumulated Deficit	Non- Controlling Interest	Total Stockholders Equity (Deficit)
Balance at December 31, 2008	106,331,183	\$ 106	\$ 897,423	\$	\$ (954,504)	\$ 714	\$ (56,261)
Consolidated net loss					(135,220)	(4,337)	(139,557)
Change in unrealized gains on available-for-sale securities				155			155
Comprehensive loss							(139,402)
Issuance of common stock under stock plans	1,587,151	2	5,407				5,409
Deconsolidation of Symphony Evolution Inc						3,623	3,623
Stock-based compensation expense			22,906				22,906
Balance at December 31, 2009	107,918,334	108	925,736	155	(1,089,724)		(163,725)
Consolidated net loss					(92,330)		(92,330)
Change in unrealized gains on available-for-sale securities				(143)			(143)
Comprehensive loss							(92,473)
Issuance of common stock under stock plans	1,368,826	1	6,760				6,761
Stock-based compensation expense			21,112				21,112
Balance at December 31, 2010	109,287,160	109	953,608	12	(1,182,054)		(228,325)
Consolidated net income					75,697		75,697
Change in unrealized gains on available-for-sale securities				(150)			(150)
Comprehensive income (loss)							75,547
Issuance of common stock under stock plans	3,488,669	2.7	15,038				15,041
Sale of shares of common stock	17,250,000	17	179,358				179,375
Issuance of common stock for settlement of convertible loan	5,537,906	6	36,889				36,895
Stock-based compensation expense			12,099				12,099
Balance at December 31, 2011	135,563,735	\$ 135	\$ 1,196,992	\$ (138)	\$ (1,106,357)	\$	\$ 90,632

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,		
	2011	2010	2009
<b>Cash flows from operating activities:</b>			
Consolidated net income (loss)	\$ 75,697	\$ (92,330)	\$ (139,557)
<b>Adjustments to reconcile net income (loss) to net cash used in operating activities:</b>			
Depreciation and amortization	6,822	10,543	12,595
Stock-based compensation expense	12,099	21,112	22,906
Impairment of property and equipment, net of proceeds from sales	497	3,327	
Accretion of debt discount	7,989	3,596	
Gain on sale of businesses	(2,254)	(8,197)	(2,052)
Loss on deconsolidation of Symphony Evolution, Inc.			9,826
Other	4,801	3,234	1,619
<b>Changes in assets and liabilities:</b>			
Other receivables	(24,294)	5,968	(8,505)
Prepaid expenses and other current assets	10,553	(66)	(7,338)
Other assets	405	(1,807)	6,424
Accounts payable and other accrued expenses	(5,555)	(9,444)	9,008
Restructuring liability	(303)	14,281	
Other long-term liabilities	(1,162)	(8,320)	(5,294)
Deferred revenue	(244,528)	(42,945)	85,777
<b>Net cash used in operating activities</b>	<b>(159,233)</b>	<b>(101,048)</b>	<b>(14,591)</b>
<b>Cash flows from investing activities:</b>			
Purchases of investments held by Symphony Evolution, Inc.			(49)
Proceeds on sale of investments held by Symphony Evolution, Inc.			4,497
Purchases of property and equipment	(991)	(1,811)	(5,908)
Proceeds on sale of property and equipment	1,526	165	
Proceeds on sale of businesses	3,010	9,000	2,200
Decrease (increase) in restricted cash and investments	2,200	45	(2,429)
Proceeds from sale of marketable securities	55,205	12,780	766
Proceeds from maturities of marketable securities	124,800	127,569	49,767
Purchases of marketable securities	(237,213)	(167,317)	(161,166)
<b>Net cash used in investing activities</b>	<b>(51,463)</b>	<b>(19,569)</b>	<b>(112,322)</b>
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of stock, net of offering costs	179,375		
Proceeds from exercise of stock options and warrants	12,436	2,684	273
Proceeds from employee stock purchase plan	1,734	3,132	3,826
Proceeds from notes payable and bank obligations	2,589	165,008	5,002
Principal payments on notes payable and bank obligations	(8,621)	(39,563)	(43,065)
Repayments, net from deconsolidation of Symphony Evolution, Inc.			(25)
<b>Net cash provided by (used in) financing activities</b>	<b>187,513</b>	<b>131,261</b>	<b>(33,989)</b>
<b>Net (decrease) increase in cash and cash equivalents</b>	<b>(23,183)</b>	<b>10,644</b>	<b>(160,902)</b>
Cash and cash equivalents, at beginning of year	97,440	86,796	247,698



Edgar Filing: EXELIXIS INC - Form 10-K

Cash and cash equivalents, at end of year	\$ 74,257	\$ 97,440	\$ 86,796
---	-----------	-----------	-----------

Supplemental cash flow disclosure:

Cash paid for interest	\$ 6,835	\$ 11,059	\$ 10,532
------------------------	----------	-----------	-----------

Non-cash financing activity:

Issuance of common stock for settlement of convertible loan, including accrued interest	\$ 36,895	\$	\$
---	-----------	----	----

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 biotechnology company committed to developing small molecule therapies for the treatment of cancer. We are focusing our proprietary resources and development efforts exclusively on cabozantinib (XL184), our most advanced product candidate, in order to maximize the therapeutic and commercial potential of this compound. We believe cabozantinib has the potential to be a high-quality, broadly active, differentiated pharmaceutical product that can make a meaningful difference in the lives of patients. We have also established a portfolio of other novel compounds that we believe have the potential to address serious unmet medical needs, many of which are being advanced by partners as part of collaborations.

**Basis of Consolidation**

The consolidated financial statements include the accounts of Exelixis and our wholly owned subsidiaries as well as one former variable interest entity, Symphony Evolution, Inc. ( SEI ), for which we were the primary beneficiary. As of June 9, 2009, our purchase option for SEI expired and as a result, we were no longer considered to be the primary beneficiary. (Refer to Note 10). All significant intercompany balances and transactions have been eliminated.

Exelixis adopted a 52- or 53-week fiscal year that ends on the Friday closest to December 31. Fiscal year 2009, a 52-week year, ended on January 1, 2010, fiscal year 2010, a 52-week year, ended on December 31, 2010, and fiscal year 2011, a 52-week year, ended on December 30, 2011. Fiscal year 2012, a 52-week year, will end on December 28, 2012. For convenience, references in this report as of and for the fiscal years ended, January 1, 2010, December 31, 2010 and December 30, 2011 are indicated on a calendar year basis, ended December 31, 2009, 2010 and 2011, respectively.

**Segment Information:**

We operate in one business segment and we have operations solely in the United States, while some of our collaboration partners have headquarters outside of the United States. In fiscal years 2011, 2010 and 2009, 100% of our revenues were earned in the United States and all of our long-lived assets were located in the United States.

**Use of Estimates**

The preparation of the consolidated financial statements is in conformity with accounting principles generally accepted in the United States which requires management to make 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, long-lived assets, derivative instruments, accrued liabilities, and share-based compensation. We base our estimates on historical experience and on various other market-specific and other relevant assumptions that are believed 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.

**Table of Contents****Cash and Investments**

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

All marketable securities are classified as available-for-sale and are carried at fair value. We view our available-for-sale portfolio as available for use in current operations. Accordingly, we have classified certain investments as short-term marketable securities, even though the stated maturity date may be one year or more beyond the current balance sheet date. Available-for-sale securities are stated at fair value based upon quoted market prices of the securities. We have classified certain investments as cash and cash equivalents or marketable securities that collateralize loan balances; however they are not restricted to withdrawal. Funds that are used to collateralize equipment lines of credit that extend for over 12 months have been classified as long term investments, in association with the loan arrangement. Unrealized gains and losses on available-for-sale investments are reported as a separate component of stockholders' equity (deficit). Realized gains and losses, net, on available-for-sale securities are recorded in our Consolidated Statement of Operations as Interest income and other, net. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are recorded in our Consolidated Statement of Operations as Interest income and other, net.

All of our marketable securities are subject to quarterly reviews for impairment that is deemed to be other-than-temporary. An investment is considered other-than-temporarily impaired when its fair value is below its amortized cost and (1) we intend to sell the security; (2) it is more likely than not that we will be required to sell the security before recovery of its amortized cost basis or (3) the present value of expected cash flows from the investment is not expected to recover the entire amortized cost basis.

The following summarizes available-for-sale securities included in cash and cash equivalents and restricted cash and investments as of December 31, 2011 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	\$ 81,986	\$	\$	\$ 81,986
Commercial paper	29,079	2	(1)	29,080
Corporate bonds	116,068	22	(169)	115,921
U.S. Government sponsored enterprises	37,237	12		37,249
Municipal bonds	19,488		(3)	19,485
Total	\$ 283,858	\$ 36	\$ (173)	\$ 283,721

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
As reported:				
Cash equivalents	\$ 74,256	\$ 1	\$	\$ 74,257
Marketable securities	120,143	35	(173)	120,005
Restricted cash and investments	4,199			4,199
Long-term investments	85,260			85,260
Total	\$ 283,858	\$ 36	\$ (173)	\$ 283,721

**Table of Contents**

The following summarizes available-for-sale securities included in cash and cash equivalents and restricted cash and investments as of December 31, 2010 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	\$ 171,048	\$	\$	\$ 171,048
Commercial paper	19,283			19,283
Corporate bonds	36,869	18	(10)	36,877
U.S. Government sponsored enterprises	18,811	5		18,816
Municipal bonds	10,913		(1)	10,912
Total	\$ 256,924	\$ 23	\$ (11)	\$ 256,936

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
As reported:				
Cash equivalents	\$ 98,001	\$	\$ (2)	\$ 97,999
Marketable securities	65,210	23	(9)	65,224
Restricted cash and investments	6,399			6,399
Long-term investments	87,314			87,314
Total	\$ 256,924	\$ 23	\$ (11)	\$ 256,936

As of December 31, 2011, all securities that were in an unrealized loss position have been so for less than one year and the unrealized losses were not attributed to credit risk. Based on the scheduled maturities of our marketable securities, 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.

**Foreign Currency Forward Contract**

We have entered into foreign currency forward contracts to reduce our net exposure to Eurodollar currency fluctuations. On March 30, 2011, we entered into a new foreign contract for a notional amount of \$7.0 million that expired in December 2011. In December 2011, we received the \$7.0 million from the French taxing authority relating to our 2009 Sanofi Collaboration Agreement and as a result, we settled all outstanding contracts for a net loss of \$0.3 million and cash receipt of \$6.7 million. The net unrealized loss on our foreign currency forward contracts, none of which were designated as a hedge, were recorded in our Consolidated Statement of Operations as Interest income and other, net.

**Fair Value Measurements**

The fair value of our financial instruments 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). The fair value hierarchy has the following three levels:

Level 1 quoted prices in active markets for identical assets and liabilities.

Level 2 observable inputs other than quoted prices in active markets for identical assets and liabilities.

Level 3 unobservable inputs.

**Table of Contents**

Our financial instruments are valued using quoted prices in active markets or based upon other observable inputs. The following table sets forth the fair value of our financial assets that were measured on a recurring basis as of December 31, 2011 and 2010, respectively (in thousands):

As of December 31, 2011:

	Level 1	Level 2	Level 3	Total
Money market funds	\$ 81,986	\$	\$	\$ 81,986
Commercial paper		29,080		29,080
Corporate bonds		115,921		115,921
U.S. Government sponsored enterprises		37,249		37,249
Municipal bonds and variable rate demand notes		19,485		19,485
Total	\$ 81,986	\$ 201,735	\$	\$ 283,721

As of December 31, 2010:

	Level 1	Level 2	Level 3	Total
Money market funds	\$ 171,048	\$	\$	\$ 171,048
Commercial paper		19,283		19,283
Corporate bonds		36,877		36,877
U.S. Government sponsored enterprises		18,816		18,816
Municipal bonds		10,912		10,912
Foreign currency forward contract		(156)		(156)
Total	\$ 171,048	\$ 85,732	\$	\$ 256,780

We have estimated the fair value of our long-term debt instruments, where possible, using the net present value of the payments discounted at an interest rate that is consistent with our current borrowing rate for similar long-term debt. However, due to the unique structure of our 2010 financing agreement with entities affiliated with Deerfield Management Company L.P. ( Deerfield ) and the current non-liquid market in structured notes, there is no practicable method to determine the fair value of this instrument. See Note 7 for details on the structure and terms of our 2010 financing with Deerfield. The estimated fair value of our outstanding debt, excluding our 2010 financing with Deerfield, was as follows (in thousands):

	December 31, 2011	December 31, 2010
GlaxoSmithKline loan	\$	\$ 26,693
Equipment lines of credit	10,066	16,064
Silicon Valley Bank loan	77,835	77,480
Total	\$ 87,901	\$ 120,237

At December 31, 2011 and 2010, the book value of our debt outstanding, including our 2010 financing with Deerfield, was \$181.5 million and \$208.5 million, respectively. These items are described in further detail in Note 7 of the Notes to the Consolidated Financial Statements. Our payment commitments associated with these debt instruments are fixed during the corresponding terms and are comprised of interest payments, principal payments or a combination thereof. The fair value of our debt will fluctuate with movements of interest rates, increasing in periods of declining rates of interest, and declining in periods of increasing rates of interest.



**Table of Contents**

In accordance with the terms of our loan and security agreement with GlaxoSmithKline, we elected to repay the third and final installment of the loan in shares of our common stock. The shares issued in connection with this repayment were valued at \$6.66 per share, resulting in the issuance of 5,537,906 shares of our common stock to GlaxoSmithKline on October 27, 2011, as satisfaction in full of our \$36.9 million repayment obligation, including \$8.0 million in accrued interest, under the loan and security agreement.

**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

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. 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 determined that our reporting units are consistent with our operating segments. We have allocated goodwill to our reporting units based on the relative fair value of the reporting units. We also evaluate other intangibles for impairment when impairment indicators are identified.

**Long-Lived Assets**

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. Long-lived assets include property and equipment and identified intangible assets. In 2011 and 2010, we wrote down property and equipment in the amount of approximately \$0.5 million and \$3.2 million, respectively, in connection with our 2010 and 2011 restructuring plans. These amounts exclude the impact of auction proceeds of \$1.7 million subsequently received relating to the sale of these impaired assets. See Note 4 for further information on the restructuring plans.

**Concentration of Credit Risk**

Financial instruments that potentially subject us to concentrations of credit risk are primarily cash and cash equivalents, accounts receivable and investments in marketable securities. Cash equivalents and marketable securities consist of money market funds, taxable commercial paper, corporate bonds with high credit quality, U.S. government agency obligations and U.S. government sponsored enterprises. All cash and cash equivalents, and marketable securities are maintained with financial institutions that management believes are creditworthy. Other receivables are typically unsecured and are concentrated in the pharmaceutical and biotechnology industries. Accordingly, we may be exposed to credit risk generally associated with pharmaceutical and biotechnology companies. We have incurred no bad debt expense since inception.

**Table of Contents**

The following table sets forth revenues recognized under our collaboration agreements that are 10% or more of total revenues during the years ending December 31, 2011, 2010 and 2009:

<b>Collaborator</b>	<b>2011</b>	<b>2010</b>	<b>2009</b>
Bristol-Myers Squibb	59%	50%	54%
Sanofi	39%	42%	31%

**Revenue Recognition**

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 statement of operations.

We enter into corporate collaborations under which we may obtain up-front license fees, research funding, and contingent milestone payments and royalties. 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. Deliverables that do not meet these criteria are not evaluated separately for the purpose of revenue recognition. For a combined unit of accounting, non-refundable up-front fees and milestones are recognized in a manner consistent with the final deliverable, which is generally ratably over the period of the research and development obligation. Milestone payments are non-refundable and recognized as revenues over the period of the research arrangement. This typically results in a portion of the milestone being recognized at the date the milestone is achieved, which portion is equal to the applicable percentage of the research term that has elapsed at the date the milestone is achieved, and 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 continued involvement. In such circumstances, we would recognize 100% of the milestone revenues when the milestone is achieved. Milestones payments, when recognized as revenue, are classified as contract revenues in our consolidated statement of operations.

Collaborative agreement reimbursement revenues or collaboration cost-sharing expenses are recorded as earned or owed based on the performance requirements by both parties under the respective contracts. For arrangements in which we and our collaborative partner are active participants in the agreement and for which both parties are exposed to significant risks and rewards depending on the commercial success of the activity, we present payments between the parties on a net basis. On an annual basis, to the extent that net research and development funding payments are received, Exelixis will record the net cash inflow as revenue. In annual periods when the net research and development funding payments result in a payable, these amounts are presented as collaboration cost-sharing expense. Agreement reimbursements are classified as either contract revenues or collaboration reimbursement in our consolidated statement of operations, depending on the terms of the agreement.

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.

**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.



---

**Table of Contents**

Substantial portions of our preclinical studies and all of our clinical trials have been performed by 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 will 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, 2011 and 2010, we recorded a reduction related to prior periods of approximately \$1.6 million and \$0.9 million, or \$0.01 per basic and diluted share, respectively, during 2011 and 2010 to our accrued clinical trial liabilities and research and development expenses primarily related to our phase 2 and phase 3 clinical trials for cabozantinib.

**Collaboration Arrangements**

Collaborative agreement reimbursement revenues or collaboration cost-sharing expenses are recorded as earned or owed based on the performance requirements by both parties under the respective contracts. On December 11, 2008, we entered into a worldwide Collaboration Agreement with Bristol-Myers Squibb Company ( Bristol-Myers Squibb ) for the development of cabozantinib and XL281, which was amended and restated by the Amended and Restated Collaboration Agreement dated as of April 15, 2011 by and between us and Bristol-Myers Squibb (as amended and restated, the 2008 Agreement ). However, on June 18, 2010, we regained full rights to develop and commercialize cabozantinib under the 2008 Agreement following receipt of notice from Bristol-Myers Squibb of its decision to terminate the 2008 Agreement, solely as to cabozantinib, on a worldwide basis. Prior to the termination of the 2008 Agreement as to cabozantinib, both parties were actively involved with compound development and certain research and development expenses were partially reimbursable to us on a net basis by compound. On an annual basis, amounts owed by Bristol-Myers Squibb to us, net of amounts reimbursable to Bristol-Myers Squibb by us for the development of cabozantinib and XL281, were recorded as collaboration reimbursement revenues. Conversely, research and development expenses would include the net settlement of amounts we owed Bristol-Myers Squibb for research and development expenses that Bristol-Myers Squibb incurred in connection with the development of cabozantinib, less amounts reimbursable to us by Bristol-Myers Squibb for the development of both cabozantinib and XL281. On July 8, 2011, we received written notification from Bristol-Myers Squibb of its decision to terminate the 2008 Agreement in its entirety. Due to this termination, which became effective on October 8, 2011, for the year ended December 31, 2011, reimbursement payments were presented as collaboration reimbursement revenues. We do not expect to record any further collaboration cost-sharing expense or collaboration reimbursement revenues under our current collaborations. See Note 2 for further information on our 2008 cancer collaboration with Bristol-Myers Squibb.

**Net Income (Loss) Per Share**

Basic net income (loss) per share is computed by dividing the net income (loss) attributable to Exelixis, Inc. for the period by the weighted average number of shares of common stock outstanding during the period. Diluted net income (loss) 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).

**Table of Contents**

The following table sets forth a reconciliation of basic and diluted net income (loss) per share (in thousands, except per share amounts):

	Year Ended December 31,		
	2011	2010	2009
<b>Numerator:</b>			
Net income (loss)	\$ 75,697	\$ (92,330)	\$ (135,220)
<b>Denominator:</b>			
Shares used in computing basic income (loss) per share amounts	126,018	108,522	107,073
<b>Add effect of dilutive securities:</b>			
Shares issuable upon the exercise of outstanding stock options	2,064		
Shares issuable pursuant to the issuance of vested RSUs	515		
Shares issuable pursuant to the exercise of warrants	1,858		
Shares issuable upon the purchase of ESPP	24		
Shares used in computing diluted net income (loss) per common share	4,461		
Shares used in computing diluted income (loss) per share amounts	130,479	108,522	107,073
Net income (loss) per share, basic	\$ 0.60	\$ (0.85)	\$ (1.26)
Net income (loss) per share, diluted	\$ 0.58	\$ (0.85)	\$ (1.26)

The following table sets forth potential shares of common stock that are not included in the computation of diluted net loss per share because to do so would be antidilutive for the years ended December 31 2011, 2010 and 2009:

	2011(1)	2010	2009
Restricted stock units and options to purchase common stock	9,085,043	21,802,461	27,072,822
Conversion of loans		6,725,296	10,277,428
Warrants		2,250,000	3,000,000
	9,085,043	30,777,757	40,350,250

(1) The Treasury Stock method was used to calculate the dilutive and excluded antidilutive share totals for the year ended December 31, 2011.

**Foreign Currency Translation and Remeasurement**

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 foreign currency assets and liabilities were not material for the periods presented.

**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 option pricing model. We have limited historical information available to support the underlying estimates of certain assumptions required to value stock options. 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. We have elected to use the simplified method to calculate the beginning pool of excess tax benefits.

We have employee and director stock option plans that are more fully described in Note 9.

**Table of Contents****Need to Raise Additional Capital**

We have incurred net losses since inception. However, for the year ended December 31, 2011, we were in a net income position of \$75.7 million, primarily as a result of the acceleration of deferred revenue under our 2008 collaboration agreement with Bristol-Myers Squibb that terminated in October 2011 and under our 2009 discovery collaboration agreement with Sanofi that terminated in December 2011. Notwithstanding our net income position for the year ended December 31, 2011, we anticipate further net losses and negative operating cash flow for the foreseeable future. Our ultimate success depends on the outcome of our research and development activities. In February 2012, we raised approximately \$65 million in net proceeds from a public offering of our common stock. We may seek to raise funds through additional sales of equity or debt securities or through external borrowings. In addition, we may enter into additional strategic partnerships or collaborative arrangements for the development and commercialization of our compounds. If adequate funds are not available, we will be required to delay, reduce the scope of, or eliminate one or more of our development programs.

**Recent Accounting Pronouncements**

In October 2009, the FASB issued ASU No. 2009-13, Revenue Recognition *Multiple Deliverable Revenue Arrangements* ( ASU 2009-13 ). ASU 2009-13 provides application guidance on whether multiple deliverables exist, how the deliverables should be separated and how the consideration should be allocated to one or more units of accounting. This update establishes a selling price hierarchy for determining the selling price of a 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. Under ASU 2009-13, we may be required to exercise considerable judgment in determining the estimated selling price of delivered items under new agreements and our revenue under new agreements may be more accelerated as compared to the prior accounting standard. We adopted this guidance beginning January 1, 2011. While it has not had a material impact on our financial statements in 2011, we expect that this adoption could have a material impact on our financial statements going forward.

In June 2011, Accounting Standards Codification Topic 220, *Comprehensive Income* was amended to increase the prominence of items reported in other comprehensive income. Accordingly, a company can present all non-owner changes in stockholders' equity either in a single continuous statement of comprehensive income or in two separate but consecutive statements. We adopted this guidance in 2011 on a retrospective basis and have determined that it did not have a material effect on our consolidated financial statements.

**NOTE 2. RESEARCH AND COLLABORATION AGREEMENTS****Merck**

On December 21, 2011, we entered into an agreement with Merck & Co., Inc., known as MSD outside of the United States and Canada ( Merck ), pursuant to which we granted to Merck an exclusive worldwide license to our phosphoinositide-3 kinase delta ( PI3K-d ) program, including XL499 and other related compounds. Pursuant to the terms of the agreement, Merck will have sole responsibility to research, develop, and commercialize compounds from our PI3K-d program.

Merck was required to pay us an upfront cash payment of \$12.0 million in connection with the agreement, which we received on January 19, 2012. Under the terms of the agreement, we will complete the transfer of the license and associated knowledge transfer within ninety days of the effective date of the agreement and will recognize the upfront payment over the term of this technology transfer period. We will be eligible to receive potential development and regulatory milestone payments for multiple indications of up to \$239.0 million. We will also be eligible to receive combined sales performance milestones and royalties on net-sales of products emerging from the agreement. Milestones 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.

---

**Table of Contents**

Merck may at any time, upon specified prior notice to us, terminate the license. In addition, either of us 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.

**Sanofi**

On December 22, 2011, we and Sanofi entered into an agreement (the "Termination Agreement") pursuant to which the parties mutually agreed to terminate the Collaboration Agreement (the "Collaboration Agreement") dated as of May 27, 2009 and effective as of July 7, 2009 for the discovery of inhibitors of Phosphoinositide-3 Kinase (PI3K) alpha and beta. The termination of the Collaboration Agreement is effective as of the end of the day on December 22, 2011. The parties agreed to terminate the Collaboration Agreement in light of our decision in 2010 to focus our resources and development efforts on cabozantinib, our most advanced compound.

Under the Collaboration Agreement, the parties had agreed to combine efforts in establishing several pre-clinical PI3K programs and jointly share responsibility for research and preclinical activities related to isoform-selective inhibitors of PI3K- $\alpha$  and - $\beta$ . Sanofi was required to provide us with guaranteed annual research and development funding during the research term and was responsible for funding all development activities for each product following approval of the investigational new drug, or IND, application filed with the applicable regulatory authorities for such product. We were entitled to receive guaranteed research funding over three years to cover certain costs under the Collaboration Agreement. Sanofi had sole responsibility for all subsequent clinical, regulatory, commercial and manufacturing activities of any products arising from the collaboration; however, Sanofi could request that we conduct certain clinical trials at their expense. The research term under the collaboration was originally three years, although Sanofi had the right to extend the term for an additional one-year period upon prior written notice. We were eligible to receive development, regulatory and commercial milestones, as well as royalties on sales of any products commercialized under the Collaboration Agreement. The Collaboration Agreement would have automatically terminated under certain circumstances upon the expiration of the research term, in which case all licenses granted by a party to the other party would have terminated and reverted to the respective granting party, except that Sanofi would have retained the right to receive, under certain circumstances, the first opportunity to obtain a license from us to any isoform-selective PI3K inhibitor. In addition, after expiration of the research term, Sanofi had the right, upon certain prior written notice to us, to terminate the Collaboration Agreement in whole or as to particular products, in which case we would have received, subject to certain terms, conditions and obligations for us to make payments to Sanofi, exclusive licenses from Sanofi to research, develop and commercialize such products.

Pursuant to the terms of the Termination Agreement, the parties' material rights and obligations under the Collaboration Agreement have terminated, each party has released the other from any potential liabilities arising under the Collaboration Agreement prior to the termination effective date, each party retains ownership of the intellectual property that it generated under the Collaboration Agreement, and we have granted Sanofi covenants not-to-enforce with respect to certain of our intellectual property rights. The Termination Agreement required that Sanofi make a payment to us of \$15.3 million within 10 business days after the termination effective date, 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 milestone payment to the us upon the first receipt by Sanofi or its affiliate or licensee of regulatory 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. In addition, the Termination

---

## **Table of Contents**

Agreement provides that Sanofi will make a milestone payment to us upon the first compound that is subject to the covenant not-to-enforce reaching a pre-clinical event.

For purposes of recognizing up-front payments received under the Collaboration Agreement, prior to the effectiveness of the Termination Agreement, we were recognizing revenue through the end of the research term, which was estimated to be July 2013. As a result of the termination of the Collaboration Agreement, the estimated research term ended on December 22, 2011. Accordingly, we accelerated the remaining deferred revenue balance of \$53.1 million as of that date, an increase of \$0.42 per basic share or \$0.41 per diluted share, and recognized a total of \$73.6 million in revenue in the fourth fiscal quarter of 2011, relating to the up-front payment under the Collaboration Agreement and the termination payment pursuant to the Termination Agreement.

In addition to the Termination Agreement and the Collaboration Agreement, we and Sanofi remain parties to a global license agreement for the development and commercialization of XL147 (SAR245408) and XL765 (SAR245409), PI3K inhibitors that are in clinical development.

### **Bristol-Myers Squibb**

#### *TGR5 License Agreement*

In October 2010, we entered into a global license agreement with Bristol-Myers Squibb for XL475 (and any potential backups), a preclinical compound that modulates the metabolic target known as TGR5 (the TGR5 License Agreement). Pursuant to the terms of the TGR5 License Agreement, Bristol-Myers Squibb will have a worldwide exclusive license to XL475 and will have sole control and responsibility for all subsequent research, development, commercial and manufacturing activities. The TGR5 License Agreement became effective in November 2010 following clearance under the Hart-Scott-Rodino Antitrust Improvement Act of 1976, as amended. The license agreement was amended and restated in April 2011 in connection with an assignment of patents to one of our wholly-owned subsidiaries.

Under the license agreement, Bristol-Myers Squibb received a worldwide exclusive license to XL475 and sole control and responsibility for all research, development, commercial and manufacturing activities. In November 2010 we received a nonrefundable upfront cash payment of \$35.0 million from Bristol-Myers Squibb. Additionally, for each product developed by Bristol-Myers Squibb under the license, we will be eligible to receive development and regulatory milestones of up to \$250.0 million in the aggregate and commercial milestones of up to \$150.0 million in the aggregate, as well as royalties on commercial sales of any such products. As of December 31, 2011, we have recognized aggregate license revenue of \$13.6 million under this agreement.

#### *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 development and regulatory milestones of up to \$255.0 million in the aggregate and commercial 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 one of our wholly-owned subsidiaries. In July 2011, we achieved a development milestone of \$2.5 million and have recognized aggregate license and contract revenues of \$3.1 million under this agreement as of December 31, 2011.

**Table of Contents***2008 Cancer Collaboration*

In December 2008, we entered into a worldwide collaboration with Bristol-Myers Squibb for cabozantinib and XL281 (BMS-908662), a RAF inhibitor. Upon effectiveness of the 2008 Agreement in December 2008, Bristol-Myers Squibb made a nonrefundable upfront cash payment of \$195.0 million for the development and commercialization rights to both programs. The 2008 Agreement required Bristol-Myers Squibb to make additional license payments to us of \$45.0 million, which were received during 2009.

On July 8, 2011, we and one of our wholly-owned subsidiaries received written notification from Bristol-Myers Squibb of its decision to terminate the 2008 Agreement, on a worldwide basis as to XL281. The termination was made pursuant to the terms of the 2008 Agreement and became effective on October 8, 2011. Bristol-Myers Squibb informed us that the termination was based upon Bristol-Myers Squibb's review of XL281 in the context of Bristol-Myers Squibb's overall research and development priorities and pipeline products. Upon the effectiveness of the termination, Bristol-Myers Squibb's license relating to XL281 terminated, and rights to XL281 reverted to us. We also received, subject to certain terms and conditions, licenses from Bristol-Myers Squibb to research, develop and commercialize XL281. We have discontinued activities related to XL281 and do not currently expect to further research, develop or commercialize XL281.

Under the 2008 Agreement, we and Bristol-Myers Squibb originally agreed to co-develop cabozantinib and Bristol-Myers Squibb also received an exclusive worldwide license to develop and commercialize XL281. On June 18, 2010, we received a notice from Bristol-Myers Squibb of its decision to terminate the 2008 Agreement solely as to cabozantinib, on a worldwide basis, pursuant to the terms of the 2008 Agreement. We continued to carry out certain clinical trials of XL281 under the 2008 Agreement, and Bristol-Myers Squibb was responsible for funding all future development of XL281, including our activities. We were eligible for development and regulatory milestones of up to \$315.0 million on XL281, sales performance milestones of up to \$150.0 million and double-digit royalties on worldwide sales of XL281.

For purposes of recognizing upfront license fees received under the 2008 Agreement, prior to receiving the termination notification from Bristol-Myers Squibb in July 2011, we were recognizing revenue related to the upfront license fees through the estimated period of our involvement, or April 2014. As a result of the July 2011 termination, the estimated research term was revised to end on October 8, 2011. Accordingly, we accelerated the recognition of the remaining deferred revenue balance through the revised end of the research term and recognized an additional \$99.1 million in revenue, or \$0.79 per basic share or \$0.76 per diluted share, during 2011. Amounts attributable to both programs under the 2008 Agreement consisted of the following (in thousands):

	<b>Year Ended December 31,</b>		
	<b>2011</b>	<b>2010</b>	<b>2009</b>
Exelixis research and development expenses(1)	\$ 2,598	\$ 41,877	\$ 52,148
Net amount due from (owed to) collaboration partner	\$ 2,778	\$ 27,411	\$ (4,582)

(1) Total research and development expenses attributable to us include direct third party expenditures plus estimated internal personnel costs are calculated in accordance with the terms of the particular collaboration.

*2007 Cancer Collaboration*

In December 2006, we entered into a worldwide collaboration with Bristol-Myers Squibb, which became effective in January 2007, to discover, develop and commercialize novel targeted therapies for the treatment of cancer. We were responsible for discovery and preclinical development of small molecule drug candidates directed against mutually selected targets. In January 2007, Bristol-Myers Squibb made an upfront payment of \$60.0 million to us for which we granted Bristol-Myers Squibb the right to select up to three investigational new drug ( IND ) candidates from six future Exelixis compounds. We recognized the upfront payment as revenues over the estimated research term.

---

**Table of Contents**

For each IND candidate selected, we were entitled to receive a \$20.0 million selection milestone from Bristol-Myers Squibb. Once selected, Bristol-Myers Squibb became responsible for leading the further development and commercialization of the selected IND candidates. In addition, we had the right to opt in to co-promote the selected IND candidates, in which case we would equally share all development costs and profits in the United States. In January 2008 and November 2008, Bristol-Myers Squibb exercised its option under the collaboration to develop and commercialize XL139 (BMS-833923), a Hedgehog inhibitor, and XL413 (BMS-863233), a CDC7 inhibitor, respectively. Under the terms of the collaboration agreement, the selection of XL139 and XL413 by Bristol-Myers Squibb entitled us to milestone payments of \$20.0 million each, which we received in February 2008 and December 2008, respectively. In addition, we exercised our option under the collaboration agreement to co-develop and co-commercialize each of XL139 and XL413 in the United States. However, in September 2010, we and Bristol-Myers Squibb terminated the XL413 program due to an unfavorable pharmacological profile observed in phase 1 clinical evaluation. Additionally, in connection with an amendment to the collaboration which became effective in November 2010, we exercised our right to opt-out of further co-development of XL139 in consideration for a payment of \$20.0 million. The collaboration agreement was amended and restated in April 2011 in connection with an assignment of patents to one of our wholly-owned subsidiaries. We have no further responsibility for conducting new activities or funding new development or commercialization activities with respect to XL139 and will therefore no longer be eligible to share profits on sales of any commercialized products under the collaboration. We will continue to be eligible to receive regulatory and commercial milestones as well as double-digit royalties on any future sales of any products commercialized under the collaboration. As a result of the November 2010 amendment to the collaboration, the research term has ended, and we have no further obligation to deliver to Bristol-Myers Squibb a third IND candidate under the collaboration.

*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. 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 selected drug candidates selected by Bristol-Myers Squibb. The research term expired in January 2010. The collaboration agreement was amended and restated in April 2011 in connection with an assignment of patents to one of our wholly-owned subsidiaries.

Under the collaboration agreement, Bristol-Myers Squibb paid us a nonrefundable upfront 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 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 sales milestones and royalties on sales of any products commercialized under the collaboration. In connection with the extension of the collaboration through January 2009, and subsequently 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 for achieving a development milestone.



---

## **Table of Contents**

### **Genentech**

#### *MEK Collaboration*

In December 2006, we entered into a worldwide co-development agreement with Genentech for the development and commercialization of XL518, a small-molecule inhibitor of MEK. 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 an IND for XL518. Genentech paid us a milestone payment of \$7.0 million in March 2010 to maintain Genentech's licenses to XL518.

Under the terms of the co-development agreement, we were responsible for developing XL518 through the end of a phase 1 clinical trial, and Genentech had the option to co-develop XL518, 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. We were responsible for the phase 1 clinical trial until the point that a maximum tolerated dose, ( MTD ), was determined. After MTD was achieved, we granted to Genentech an exclusive worldwide revenue-bearing license to XL518 in March 2009 and Genentech is responsible for completing the phase 1 clinical trial and subsequent clinical development. We received an additional \$7.0 million milestone payment in March 2010 under the terms of this agreement. Genentech is responsible for all further development costs of XL518 and we will share equally in the U.S. commercialization costs. On an annual basis, we are entitled to an initial equal share of U.S. profits and losses, which will decrease as sales increase, and we are also entitled to royalties on non-U.S. sales. We also have the option to co-promote in the United States. Genentech has the right to terminate the agreement without cause at any time. 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.

#### *Notch Collaboration*

In May 2005, we established a collaboration agreement with Genentech to discover and develop therapeutics directed against targets in the Notch signaling pathway. Under the terms of the collaboration agreement, we granted to Genentech a license to certain intellectual property. Genentech paid us a nonrefundable upfront license payment and was obligated to provide research and development funding over the three-year research term, totaling \$16.0 million.

Under the collaboration agreement, Genentech had primary responsibility in the field of cancer for research and development activities as well as rights for commercialization of any products. In the fields of inflammatory disease and in the fields of tissue growth and repair, we had primary responsibility for research activities. In May 2008, the research term under the collaboration expired, at which time we had the option to elect to share a portion of the costs and profits associated with the development, manufacturing and commercialization of products in one of the fields. In June 2008, we elected to share a portion of the costs and profits associated with the development, manufacturing and commercialization of a therapeutic to treat tissue growth and repair. For all products under the collaboration agreement that were not elected as cost or profit sharing products, we may receive milestone and royalty payments. In June 2011, we earned an additional milestone of \$2.0 million under this agreement that was recognized in full as contract revenue.

### **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

---

**Table of Contents**

\$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. 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 XL880 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. For periods prior to the quarter ended June 30, 2008, revenues from upfront payments, premiums paid on equity purchases and milestones had been recognized assuming that the development term would be extended through the longest contractual period of October 27, 2010. However, as a result of the development term concluding on the earliest scheduled end date, the remaining deferred revenues was recognized through October 27, 2008. The change in the estimated development term increased our total revenues by \$18.5 million or \$0.17 per share for the period ended December 31, 2008.

In July 2008, we achieved proof-of-concept for cabozantinib and submitted the corresponding data report to GlaxoSmithKline. 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 GSK of a 3% royalty on net sales of any product incorporating cabozantinib. As described under Bristol-Myers Squibb 2008 Cancer Collaboration, in December 2008, we entered into a worldwide collaboration with Bristol-Myers Squibb for cabozantinib and XL281. We have discontinued development of XL820, XL228 and XL844.

The \$85.0 million loan we received from GlaxoSmithKline had an interest rate of 4.0% per annum. In accordance with the terms of our loan and security agreement, we elected to repay the third and final installment of the loan in shares of our common stock. The shares issued in connection with this repayment were valued at \$6.66 per share, resulting in the issuance of 5,537,906 shares of our common stock to GlaxoSmithKline on October 27, 2011, as satisfaction in full of our \$36.9 million repayment obligation, including \$8.0 million in accrued interest, under the loan and security agreement. GlaxoSmithKline subsequently released its related security interest in certain of our patents.

**Boehringer Ingelheim**

On May 7, 2009, we entered into a collaboration agreement with Boehringer Ingelheim International GmbH ( Boehringer Ingelheim ) to discover, develop and commercialize products that consist of agonists of the sphingosine-1-phosphate type 1 receptor ( S1P1R ), a central mediator of multiple pathways implicated in a variety of autoimmune diseases.

Under the terms of the agreement, Boehringer Ingelheim paid us a nonrefundable upfront cash payment of \$15.0 million for the development and commercialization rights to our S1P1R agonist program, and we shared responsibility for discovery activities under the collaboration with Boehringer Ingelheim. The agreement provided that the parties would each conduct research under a mutually agreed upon research plan until such time that we submitted a compound that met agreed-upon criteria, or such later time as agreed upon by the parties. The parties were responsible for their respective costs and expenses incurred in connection with performing research under the collaboration. Under the collaboration, Boehringer Ingelheim also had the right, at its own expense, to conduct additional research on S1P1R agonists outside of the scope of the research plan agreed to by the parties. The agreement further provided that Boehringer Ingelheim would receive an exclusive worldwide license to further develop, commercialize and manufacture compounds developed under the collaboration and have sole responsibility for, and bear all costs and expenses associated with, all subsequent preclinical, clinical, regulatory, commercial and manufacturing activities. In return, we would potentially receive up to \$339.0 million

**Table of Contents**

in further development, regulatory and commercial milestones and be eligible to receive royalties on worldwide sales of products commercialized under the collaboration. The upfront payment was recognized ratably over the estimated research term and recorded as license revenues from the effective date of the agreement. During the first half of 2010, the expected research term was extended from eleven months to twenty three months through March 2011, resulting in an extension of the term for revenue recognition purposes and a corresponding decrease in license revenues recognized each quarter. The agreement terminated in April 2011 and the parties have no further obligations to each other.

**Daiichi Sankyo**

In March 2006, Exelixis and Daiichi Sankyo Company Limited ( Daiichi Sankyo ) entered into a collaboration agreement for the discovery, development and commercialization of novel therapies targeted against 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. 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 a compound developed under the collaboration. 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.

**NOTE 3. DISPOSITIONS****Artemis**

On November 20, 2007 (the Taconic Closing Date ), we entered into a share sale and transfer agreement with Taconic Farms, Inc., ( Taconic ), pursuant to which Taconic acquired from us, for \$19.8 million in cash, 80.1% of the outstanding share capital in our wholly-owned subsidiary, Artemis Pharmaceuticals GmbH ( Artemis ), located in Cologne, Germany. Subsequent to the transaction, Artemis was renamed TaconicArtemis GmbH. In connection with the sale and transfer agreement. In connection with the sale and transfer agreement, we also entered into a shareholders agreement and approved amended articles of association of Artemis that govern the relationship between us and Taconic as shareholders of Artemis, particularly with respect to matters of corporate governance and the transfer of our respective ownership interests. The shareholders agreement provided that we could require Taconic to purchase our remaining 19.9% interest in Artemis between 2010 and 2015 or in the event of a change in control of Taconic, and that Taconic could require us to sell our 19.9% interest to Taconic between 2013 and 2015 or in the event of a change in control of Exelixis, in each case subject to certain conditions set forth in the shareholders agreement. On September 27, 2011, in accordance with the terms and conditions of the shareholders agreement, we exercised our right to sell our remaining 19.9% interest in Artemis to Taconic and Taconic was obligated to remit payment for such interest within 90 days. Pursuant to the terms of the shareholders agreement, in December 2011, we received \$3.0 million in consideration of our

**Table of Contents**

remaining 19.9% interest, and we recognized a gain of \$2.3 million after consideration of foreign currency and the write off of the carrying value of our investment in Artemis.

**NOTE 4. RESTRUCTURINGS**

During 2010, we implemented two restructuring plans that resulted in an overall reduction in our workforce of 386 employees. In March 2011, we implemented an additional restructuring plan that resulted in further terminations in 2011. Taking into consideration employees who have since been recalled, there has been an aggregate reduction in headcount from the 2010 and 2011 restructuring plans of 402 employees. The restructuring plans are a consequence of our decision to focus our proprietary resources and development efforts on the late-stage development and commercialization of cabozantinib.

In connection with the 2010 and 2011 restructuring plans, we have recorded aggregate restructuring charges of \$42.9 million, of which \$20.3 million related to termination benefits and \$22.6 million related to facility-charges and the impairment of various assets. Our 2011 restructuring expense is primarily facility-related charges that relate to our buildings in South San Francisco, California and take into consideration our entry into two sublease agreements for portions of a building that we entered into in July 2011 as well as charges relating to the short-term exit of the second floor of another building in December 2011. Additionally, we had asset impairment charges of \$3.7 million relating to excess equipment and other assets, partially offset by cash proceeds of \$1.7 million from the sale of such assets.

With respect to our restructuring plans, we expect to incur additional restructuring charges of \$1.9 million relating to the previously mentioned exit and sublease of our South San Francisco facilities. These charges will be recorded through the end of 2017, or the end of the building lease terms.

As of December 31, 2011, the 2010 and 2011 restructuring plans had resulted in aggregate cash expenditures of \$23.4 million net of \$1.7 million in cash received in connection with the sale of excess equipment and other assets, of which \$14.1 million was paid in 2010 and \$9.3 million was paid in 2011. We expect to pay an additional \$15.9 million, net of cash received from our subtenants, relating to facility costs. We expect these additional facility costs to be paid through 2017, or the end of our lease terms of the buildings.

The total outstanding restructuring liability is included in Current portion of restructuring and Long-term portion of restructuring on our Condensed Consolidated Balance Sheet and is based upon restructuring charges recognized as of December 31, 2011 in connection with the 2010 and 2011 restructuring plans. As of December 31, 2011, the components of these liabilities are summarized in the following table (in thousands):

	<b>Employee Severance And Other Benefits</b>	<b>Facility Charges</b>	<b>Asset Impairment</b>	<b>Legal and Other Fees</b>	<b>Total</b>
Ending accrual balance as of December 31, 2010	\$ 5,523	\$ 8,688	\$	\$ 70	\$ 14,281
Restructuring charge	2,566	8,480	(907)	(3)	10,136
Cash payments	(7,366)	(3,469)		(16)	(10,851)
Adjustments or non-cash credits including stock compensation expense	(717)	222	(619)		(1,114)
Proceeds from sale of assets			1,526		1,526
Ending accrual balance as of December 31, 2011	\$ 6	\$ 13,921	\$	\$ 51	\$ 13,978

The restructuring charges that we expect to incur in connection with the restructuring plans 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 restructuring plans.

**Table of Contents****NOTE 5. PROPERTY AND EQUIPMENT**

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

	December 31,	
	2011	2010
Laboratory equipment	\$ 28,795	\$ 43,356
Computer equipment and software	11,743	20,163
Furniture and fixtures	3,230	4,772
Leasehold improvements	15,961	21,993
Construction-in-progress	155	373
	59,884	90,657
Less accumulated depreciation and amortization	(51,378)	(74,846)
	\$ 8,506	\$ 15,811

For the years ended December 31, 2011, 2010 and 2009, we recorded depreciation expense of \$6.8 million, \$10.5 million and \$12.6 million, respectively. In 2011 and 2010, we recorded impairment charges in the amount of approximately \$0.5 million and \$3.2 million in connection with our 2010 restructuring plans, partially offset by auction proceeds of \$1.7 million.

**NOTE 6. DEERFIELD CREDIT FACILITY**

On June 4, 2008, we entered into a facility agreement with entities affiliates with Deerfield Management Company L.P. ( Deerfield ), pursuant to which Deerfield agreed to loan to us up to \$150.0 million. We had the right to draw down on the loan facility through December 4, 2009, with any amounts drawn being due on June 4, 2013. The facility agreement was terminated in November 2009. As a result of the termination, we incurred a \$5.2 million charge to interest expense relating to the write-off of deferred financing costs. We did not draw on the facility agreement at any time prior to its termination. Pursuant to the facility agreement, we paid Deerfield a one-time transaction fee of \$3.8 million, or 2.5% of the loan facility. In addition, we were obligated to pay an annual commitment fee of \$3.4 million that was payable quarterly and was recognized as interest expense as incurred. Pursuant to the facility agreement, we issued six-year warrants to Deerfield to purchase an aggregate of 1,000,000 shares of our common stock at an exercise price of \$7.40 per share.

Warrants issued upon execution of the facility agreement were assigned a value of \$3.4 million using the Black-Scholes option pricing model. The related assumptions were as follows: risk-free interest rate of 3.41%, expected life of six years, volatility of 62% and expected dividend yield of 0%.

See Note 7 regarding the 2010 Deerfield Financing.

**NOTE 7. DEBT**

Our debt consists of the following (in thousands):

	December 31,	
	2011	2010
GlaxoSmithKline convertible loans	\$ 10,130	\$ 28,900
Bank equipment lines of credit	80,000	80,000
Silicon Valley Bank Term Loan	91,385	83,396
Deerfield notes	181,515	208,458
Less: current portion	(4,870)	(37,748)

Long-term debt	\$ 176,645	\$ 170,710
----------------	------------	------------

---

**Table of Contents*****Deerfield Financing***

On June 2, 2010, we entered into a note purchase agreement with Deerfield, pursuant to which, on July 1, 2010, we sold to Deerfield an aggregate of \$124.0 million initial principal amount of our secured convertible notes due June 2015 for an aggregate purchase price of \$80.0 million, less closing fees and expenses of approximately \$2.0 million. The outstanding principal amount of the notes bears interest in the annual amount of \$6.0 million, payable quarterly in arrears. We will be required to make mandatory prepayments on the notes on an annual basis in 2013, 2014 and 2015 equal to 15% of certain revenues from our collaborative arrangements received during the prior fiscal year, subject to a maximum annual prepayment amount of \$27.5 million and, for payments due in January 2013 and 2014, a minimum prepayment amount of \$10.0 million. We may also prepay all or a portion (not less than \$5.0 million) of the principal amount of the notes at an optional prepayment price based on a discounted principal amount (during the first three years of the term, subject to a prepayment premium) determined as of the date of prepayment, plus accrued and unpaid interest, plus in the case of a prepayment of the full principal amount of the notes (other than prepayments upon the occurrence of specified transactions relating to a change of control or a substantial sale of assets), all accrued interest that would have accrued between the date of such prepayment and the next anniversary of the note purchase agreement. In lieu of making any optional 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 notes into, or satisfy all or any portion of the optional prepayment amounts or mandatory prepayment amounts (other than the first \$10.0 million of mandatory prepayments required in 2013 and 2014) with shares of our common stock. Additionally, in lieu of making any payment of accrued and unpaid interest in respect of the 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 our company, a sale or transfer of assets in one transaction or a series of related transactions for a purchase price of more than \$400 million or a sale or transfer of more than 50% of our assets, Deerfield may require us to prepay the notes at the optional prepayment price, plus accrued and unpaid interest and any other accrued and reimbursable expenses (the "Put Price"). Upon an event of default, Deerfield may declare all or a portion of the Put Price to be immediately due and payable.

We also entered into a security agreement in favor of Deerfield which provides that our obligations under the notes will be secured by substantially all of our assets except intellectual property. The note purchase agreement and the security agreement include customary representations and warranties and covenants made by us, including restrictions on the incurrence of additional indebtedness. The balance of unamortized closing fee and expenses of \$1.8 million is recorded in the accompanying consolidated balance sheet as long-term assets. The carrying value of the loan as of December 31, 2011 is \$91.4 million.

***Silicon Valley Bank Loan and Security Agreement***

In December 2004, we entered into a loan modification agreement to the loan and security agreement originally entered into in May 2002. The terms associated with the original \$16.0 million line of credit under the May 2002 agreement were not modified. The loan modification agreement provided for an additional equipment line of credit in the amount of up to \$20.0 million with a draw down period of one year. Pursuant to the terms of the modified agreement, we were required to make interest only payments through February 2006 at an annual rate of 0.70% on all outstanding advances. This equipment line of credit was fully drawn as of March 31, 2006 and was fully paid off as of March 31, 2010.

In December 2006, we entered into a second loan modification agreement to the loan and security agreement originally entered into in May 2002. The terms associated with the original line of credit under the May 2002 agreement and December 2004 loan modification agreement were not modified. The December 2006 loan modification agreement provided for an additional equipment line of credit in the amount of

---

**Table of Contents**

up to \$25.0 million with a draw down period of approximately one year. Each advance must be repaid in 48 equal, monthly installments of principal, plus accrued interest, at an annual rate of 0.85% fixed and is subject to a prepayment penalty of 1.0%. The loan facility is secured by a non-interest bearing certificate of deposit account with the bank, in an amount equal to at least 100% of the outstanding obligations under the line of credit. This equipment line of credit was fully drawn as of December 31, 2008. The outstanding obligation under the line of credit as of December 31, 2011 and 2010 was zero and \$2.9 million, respectively.

In December 2007, we entered into a third loan modification agreement to the loan and security agreement originally entered into in May 2002 with Silicon Valley Bank. The terms associated with the original line of credit under the May 2002 agreement and the subsequent loan modifications were not modified. The December 2007 loan modification agreement provides for an additional equipment line of credit in the amount of up to \$30.0 million with a draw down period of approximately 2 years (the 2007 Line of Credit). Each advance must be repaid in 48 equal, monthly installments of principal, plus accrued interest, at an annual rate of 0.75% fixed. In December 2009, we amended the agreement and extended the draw down period on the 2007 Line-of-Credit for an additional 18 months through June 2011 and increased the principal amount of the line of credit from \$30.0 million to \$33.6 million. Pursuant to the terms of the amendment, we are required to make minimum draws of \$2.5 million every 6 months through June 2011, for total additional draws of \$7.5 million. The loan facility requires security for the 2007 Line of Credit in the form of a non-interest bearing certificate of deposit account with the bank, in an amount equal to at least 100% of the outstanding obligations under the line of credit. In June 2008, we drew down \$13.6 million under this agreement, in December 2009, we drew down \$5.0 million, and we drew down an additional \$2.5 million in each of June 2010, December 2010 and June 2011 in accordance with the terms of the modified agreement. In accordance with the amended loan terms, the 2007 Line of Credit has expired and we have no further draw down obligations under the line of credit.

On June 2, 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. 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 outstanding obligation under the term loan and all other lines of credit with Silicon Valley Bank as of December 31, 2011 and December 31, 2010 was \$90.1 million and \$96.1 million, respectively. The total collateral balance as of December 31, 2011 and December 31, 2010 was \$85.3 million and \$96.9 million, respectively and is reflected in our Condensed Consolidated Balance Sheet as Cash and cash equivalents and



**Table of Contents**

Marketable securities as the deposit account is 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.

Aggregate future principal payments of our total long-term debt as of December 31, 2010 are as follows (in thousands):

<b>Year Ending December 31,(1)</b>	
2012	\$ 4,870
2013	30,670
2014	29,262
2015	69,328
2016	
Thereafter	80,000
	214,130
Less current portion	(4,870)
	\$ 209,260

(1) Amounts include principal payments associated with the accretion of the Deerfield financing and assumes the maximum earliest possible payments that could be required to be made under the agreement terms. The actual timing of payments made may differ materially.

**NOTE 8. COMMON STOCK AND WARRANTS****Sale of Shares of Common Stock**

In March 2011, we completed a public offering of 17.3 million shares of our common stock pursuant to a shelf registration statement previously filed with the SEC, which the SEC declared effective on May 8, 2009. We received approximately \$179.4 million in net proceeds from the offering after deducting the underwriting discount and related offering expenses.

In February 2012, we completed a public offering of 12.7 million shares of our common stock pursuant to a shelf registration statement previously filed with the SEC, which the SEC declared effective on May 8, 2009. We received approximately \$65 million in net proceeds from the offering after deducting the underwriting discount and related offering expenses.

**Warrants**

We have granted warrants to purchase shares of capital stock to SEI in connection with our financing transaction as described in Note 10. As of December, 31, 2011, SEI transferred the rights to all of these warrants to other parties and only 441,215 of the original 2 million warrants granted remain outstanding and exercisable.

In addition, in June 2008 we issued 1,000,000 six-year warrants to Deerfield pursuant to the facility agreement described in Note 6.

At December 31, 2011, the following warrants to purchase common stock were outstanding and exercisable:

<b>Date Issued</b>	<b>Exercise Price per Share</b>	<b>Expiration Date</b>	<b>Number of Shares</b>
June 4, 2008	\$ 7.40	June 4, 2014	1,000,000
June 10, 2009	\$ 6.05	June 10, 2014	441,215



**Table of Contents****NOTE 9. EMPLOYEE BENEFIT PLANS****Stock Option Plans**

We have several stock option plans under which we have granted incentive stock options and non-qualified stock options to employees, directors and consultants. The Board of Directors or a designated Committee of the Board is responsible for administration of our employee stock option plans and determines the term, exercise price and vesting terms of each option. Prior to 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 (five years for incentive stock options granted to holders of more than 10% of Exelixis' voting stock and 6.2 years for options issued in exchange for options cancelled under our 2009 option exchange program). On May 18, 2011, at the annual meeting of stockholders, the Exelixis, Inc. 2011 Equity Incentive Plan (the 2011 Plan) was approved and adopted as the successor plan to the Prior Plans. Stock options issued under the 2011 Plan 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.

On December 9, 2005, Exelixis' Board of Directors adopted a Change in Control and Severance Benefit Plan (the Plan) for executives and certain non-executives. Eligible Plan participants include Exelixis employees with the title of vice president and higher. If a participant's employment with Exelixis is terminated without cause during a period commencing one month before and ending thirteen months following a change in control, then the 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. Effective December 23, 2008, we amended and restated the Plan to bring it into compliance with Section 409A of the Internal Revenue Code of 1986, as amended. Effective December 1, 2010, we further amended and restated the Plan to principally bring it into compliance with other rules governing such plans.

**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 \$0.7 million, \$1.3 million, and \$2.4 million for the years ended December 31, 2011, 2010 and 2009, respectively. As of December 31, 2011, we had 2,685,200 shares available for grant under our ESPP. We issued 375,305 shares, 689,093 shares, and 1,278,336 shares of common stock during the years ended December 31, 2011, 2010, and 2009, respectively, pursuant to the ESPP at an average price per share of \$4.62, \$4.55, and \$2.99, respectively.

**Stock-Based Compensation**

We recorded and allocated employee stock-based compensation expense as follows (in thousands):

	Year Ended December 31,		
	2011	2010	2009
Research and development expense	\$ 5,935	\$ 11,535	\$ 15,708
General and administrative expense	5,459	7,931	7,109
Restructuring-related stock compensation expense	625	1,505	
Total employee stock-based compensation expense	\$ 12,019	\$ 20,971	\$ 22,817

In addition, we recognized stock-based compensation expense of \$0.1 million relating to nonemployees in each of the years ended December 31, 2011, 2010 and 2009.

**Table of Contents**

During July 2010, our former Chief Executive Officer, George A. Scangos, Ph.D., resigned as an employee of Exelixis and in connection with such resignation agreed to cancel unvested stock options exercisable for 981,302 shares of our common stock and unvested RSUs with respect to 101,050 shares of our common stock. Due to Dr. Scangos' continued services as a director of Exelixis he was entitled to retain his stock options and RSUs. Therefore, we treated the cancellation as a modification of his stock option and RSU agreements and recorded a non-cash compensation charge of approximately \$1.5 million to our consolidated statement of operations.

We use the Black-Scholes 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 share-based payments awards was estimated using the following assumptions and weighted average fair values:

	<b>Stock Options</b>		
	<b>2011</b>	<b>2010</b>	<b>2009(1)</b>
Weighted average grant-date fair value	\$ 3.5	\$ 3.60	\$ 3.61
Risk-free interest rate	1.07%	2.25%	2.25%
Dividend yield	0%	0%	0%
Volatility	70%	70%	65%
Expected life	5.5 years	5.2 years	5.4 years

  

	<b>ESPP</b>		
	<b>2011</b>	<b>2010</b>	<b>2009</b>
Weighted average grant-date fair value	\$ 2.85	\$ 1.87	\$ 1.70
Risk-free interest rate	0.11%	0.21%	0.18%
Dividend yield	0%	0%	0%
Volatility	68%	68%	64%
Expected life	6 months	6 months	2.6 months

- (1) These exclude the assumptions used to estimate the fair value of the options granted under the stock option exchange program as discussed below.

On July 7, 2009, we commenced a stock option exchange program approved by our stockholders on May 14, 2009. The exchange program was open to all eligible employees who, at the start of the exchange program, were employed by us or one of our subsidiaries and remained employed through August 5, 2009, the date that the replacement stock options were granted. As a result of the exchange, 9.9 million options were cancelled, of which 7.3 million and 2.6 million were vested and unvested, respectively. Of the 7.2 million replacement options that were granted, 5.1 million were issued in exchange for vested options and vested over a one year term, while 2.1 million options were issued in exchange for unvested options that vest over three years, with a one year cliff. In association with these grants, we recognized incremental compensation cost of approximately zero, \$0.4 million and \$0.3 million ratably over the vesting period, as of December 31, 2011, 2010, and 2009 respectively.

The fair value of replacement options issued under the option exchange was estimated using the following assumptions and resulted in the following weighted average fair values:

Weighted average fair value of awards	\$ 2.82
Risk-free interest rate	2.1%
Dividend yield	0%
Volatility	67%
Expected life	3.7 years

**Table of Contents**

A summary of all option activity was as follows for the following fiscal years ended December 31:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Options outstanding at December 31, 2008	24,141,186	\$ 9.67		
Granted	12,180,734	5.93		
Exercised	(59,763)	4.57		
Cancelled	(11,868,559)	10.39		
Options outstanding at December 31, 2009	24,393,598	\$ 7.46		
Granted	243,500	6.28		
Exercised	(495,098)	5.42		
Cancelled	(4,511,970)	7.35		
Options outstanding at December 31, 2010	19,630,030	\$ 7.52		
Granted	2,545,625	5.86		
Exercised	(2,161,804)	5.75		
Cancelled	(2,577,473)	9.79		
Options outstanding at December 31, 2011	17,436,378	\$ 7.16	4.92 years	\$ 216,760
Exercisable at December 31, 2011	13,319,848	\$ 7.54	4.31 years	\$ 166,966

At December 31, 2011, a total of 10,274,293 shares equivalents 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 2011 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, 2011. Total intrinsic value of options exercised was \$7.0 million, \$0.8 million and \$0.2 million for 2011, 2010 and 2009, respectively. Total fair value of employee options vested and expensed in 2011, 2010 and 2009 was \$8.4 million, \$16.2 million and \$20.4 million, respectively.

The following table summarizes information about stock options outstanding and exercisable at December 31, 2011:

Exercise Price Range	Number	Options Outstanding		Options Outstanding and Exercisable	
		Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number of Exercisable	Weighted Average Exercise Price
\$3.05 - \$ 5.47	1,775,716	6.71	\$ 4.87	1,164,344	\$ 4.77
\$5.50	2,140,059	6.74	5.50	0	0.00
\$5.61	21,553	7.63	5.61	11,761	5.61
\$5.63	3,329,797	3.72	5.63	3,082,881	5.63
\$5.64 - \$ 7.05	1,827,969	3.60	6.35	1,642,264	6.38
\$7.12 - \$ 7.51	2,141,795	6.55	7.28	1,289,960	7.26
\$7.56 - \$ 8.90	2,696,347	3.37	8.69	2,687,996	8.69
\$8.92 - \$ 9.50	1,764,871	4.11	9.00	1,764,871	9.00
\$9.53 - \$15.70	1,737,271	4.92	10.94	1,674,771	10.92
\$16.62	1,000	0.00	16.62	1,000	16.62
	17,436,378	4.89	\$ 7.16	13,319,848	\$ 7.54



**Table of Contents**

As of December 31, 2011, \$10.7 million of total unrecognized compensation expense related to stock options is expected to be recognized over a weighted-average period of 2.79 years. Cash received from option exercises and purchases under the ESPP in 2011 and 2010 was \$14.2 million and \$5.8 million, respectively. A summary of all RSU activity for the fiscal year ended December 31, 2011 is presented below:

	Shares	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
RSUs outstanding at December 31, 2010	2,172,431	\$ 7.31		
Awarded	356,498	6.17		
Released	(648,437)	7.43		
Forfeited	(488,801)	7.45		
Awards outstanding at December 31, 2011	1,391,691	\$ 6.92	1.48 years	\$ 6,589,665

As of December 31, 2011, \$6.3 million of total unrecognized compensation expense related to employee RSUs was expected to be recognized over a weighted-average period of 2.64 years.

**401(k) Retirement Plan**

We sponsor a 401(k) Retirement Plan whereby eligible employees may elect to contribute up to the lesser of 20% of their annual compensation or the statutorily prescribed annual limit allowable under Internal Revenue Service regulations. The 401(k) Retirement Plan permits Exelixis 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) Retirement Plan in the form of Exelixis common stock. However, beginning in January 2011, we will match 100% of the first 3% of participant contributions into the 401(k) Retirement Plan in the form of Exelixis common stock. We recorded expense of \$0.8 million, \$1.0 million and \$1.1 million related to the stock match for the years ended December 31, 2011, 2010 and 2009, respectively.

**NOTE 10. SYMPHONY EVOLUTION**

On June 9, 2005 (the *Symphony Closing Date*), we entered into a series of related agreements providing for the financing of the clinical development of XL784, XL647 and XL999 (the *Programs*). Pursuant to the agreements, Symphony Evolution, Inc. (*SEI*) invested \$80.0 million to fund the clinical development of these Programs and we licensed to SEI our intellectual property rights related to these Programs. SEI is a wholly owned subsidiary of Symphony Evolution Holdings LLC (*Holdings*), which provided \$40.0 million in funding to SEI at closing, and an additional \$40.0 million in June 2006. Pursuant to the agreements, we issued to Holdings a five-year warrant to purchase 750,000 shares of our common stock at \$8.90 per share in June 2005. We issued an additional five-year warrant to purchase 750,000 shares of our common stock at \$8.90 per share in connection with the additional \$40.0 million in funding in June 2006. As part of the agreement, we also received an exclusive purchase option to acquire all of the equity of SEI, thereby allowing us to reacquire XL647, XL784 and XL999 at our sole discretion. The purchase option expired on June 9, 2009. As a result of the expiration of the purchase option, we issued a third warrant to Symphony Evolution Holdings LLC to purchase 500,000 shares of our common stock at a price of \$6.05 per share with a five-year term.

The expiration of the purchase option triggered a reconsideration event regarding our need to consolidate SEI, a variable interest entity. Upon the expiration of the purchase option, we no longer held a variable interest in the variable interest entity. Accordingly, we deconsolidated SEI and derecognized the SEI assets, liabilities and noncontrolling interest from our financial statements. In the second quarter, we recognized a loss of \$9.8 million

**Table of Contents**

upon the deconsolidation of the variable interest entity. For the period prior to the expiration of the purchase option, we concluded that SEI was a variable interest entity for which we were the primary beneficiary. As a result, we included the financial condition and results of operations of SEI in our consolidated financial statements. Accordingly, we had deducted the losses attributable to the noncontrolling interest in SEI from our net loss in the consolidated statement of operations and we also reduced the noncontrolling interest holders' ownership interest in SEI in the consolidated balance sheet by SEI's losses. The noncontrolling interest holders' ownership in the consolidated balance sheet was \$0.7 million as of December 31, 2008. Prior to 2009, we would not allocate losses to the noncontrolling interest in SEI such that the carrying value of the noncontrolling interest would be reduced below zero. However, with the adoption of updated reporting standards for noncontrolling interests in consolidated financial statements in the first quarter of fiscal year 2009, we would allocate losses to the noncontrolling interest in SEI such that the noncontrolling interest could have a negative carrying value. For the years ended December 31, 2011, 2010, and 2009, the losses attributed to the noncontrolling interest holders were zero, zero and \$4.3 million, respectively.

**NOTE 11. INCOME TAXES**

We recorded an income tax benefit (provision) of \$(1.3) million and \$0.1 million for the periods ended December 31, 2011 and 2010, respectively. In 2009 and 2010, we recorded an income tax benefit as a result of the enactment of the Housing and Economic Recovery Act of 2008. Under this Act, corporations otherwise eligible for bonus first-year depreciation could instead elect to claim a refundable credit for R&D tax credits generated prior to 2006. This tax benefit was extended for tax year 2009 with the enactment of the American Recovery and Reinvestment Tax Act of 2009. Approximately \$0.6 million of the 2011 provision relates to an adjustment of the refund received in 2009 and 2010 under these Acts after we further evaluated the qualified expenses from which the refund calculation was originally based. The remaining amount of \$0.7 million relates to a tax deferred revenue adjustment that resulted in a state tax liability due to state net operating loss carryover limitations. As a result of these circumstances, we have revised our 2010 footnote disclosures to reflect the changes to our reported deferred tax assets as of December 31, 2010 from amounts previously reported.

Our consolidated net income (loss) includes the following components (in thousands):

	Year Ended December 31,		
	2011	2010	2009
Domestic	\$ 76,992	\$ (92,402)	\$ (140,843)
Foreign			
<b>Total</b>	<b>\$ 76,992</b>	<b>\$ (92,402)</b>	<b>\$ (140,843)</b>

A reconciliation of income taxes at the statutory federal income tax rate to net income taxes included in the accompanying consolidated statement of operations is as follows (in thousands):

	Year Ended December 31,		
	2011	2010	2009
U.S. federal taxes (benefit) at statutory rate	\$ 26,177	\$ (31,417)	\$ (47,886)
Unutilized net operating losses	(29,650)	29,636	42,954
Non-Deductible Interest	2,809		
Stock based compensation	627	1,709	2,641
State Tax Expense	660		
Other	36	72	2,291
Refundable Tax Credit	636	(72)	(1,286)
<b>Total</b>	<b>\$ 1,295</b>	<b>\$ (72)</b>	<b>\$ (1,286)</b>



**Table of Contents**

Deferred tax assets and liabilities reflect the net tax effects of net operating loss and tax credit carryforwards and temporary differences between the carrying amounts of assets and liabilities for financial reporting and the amounts used for income tax purposes.

Our deferred tax assets and liabilities consist of the following (in thousands):

	December 31,	
	2011	2010 Revised(1)
Deferred tax assets:		
Net operating loss carryforwards(1)	\$ 318,638	\$ 273,395
Tax credit carryforwards	54,726	70,566
Capitalized research and development costs	805	1,836
Deferred revenue(1)	18,400	97,935
Accruals and reserves not currently deductible	6,522	7,087
Book over tax depreciation	6,543	7,251
Amortization of deferred stock compensation non-qualified	25,865	23,145
<b>Total deferred tax assets</b>	<b>431,499</b>	<b>481,215</b>
Valuation allowance	(431,499)	(481,215)
<b>Net deferred tax assets</b>		
Deferred tax liabilities:		
<b>Net deferred taxes</b>	<b>\$</b>	<b>\$</b>

- (1) The 2010 deferred tax asset balances of net operating loss carryforwards and deferred revenue have been revised to correct an error that we identified in 2011. These revisions reflect additional revenue amounts that should have been included in income recognized for tax purposes in 2010. The revision in the 2010 deferred tax asset balances reflects a decrease in the net operating losses of \$62.8 million with a corresponding increase of the same amount in deferred revenue. There was no impact on the balance sheet or statement of operations as of or for any periods presented.

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance decreased by \$49.7 million and increased by \$25.2 million and \$52.4 million during 2011, 2010 and 2009, respectively.

At December 31, 2011, we had federal net operating loss carryforwards of approximately \$863 million, which expire in the years 2018 through 2031, and federal research and development tax credits of approximately \$66 million which expire in the years 2019 through 2029. We also had net operating loss carryforwards for California of approximately \$724 million, which expire in the years 2013 through 2031, and California research and development tax credits of approximately \$18 million which have no expiration.

Under the Internal Revenue Code and similar state provisions, certain substantial changes in our ownership could result in an annual limitation on the amount of net operating loss and credit carryforwards that can be utilized in future years to offset future taxable income. The annual limitation may result in the expiration of net operating losses and credit carryforwards before utilization.

We track the portion of our deferred tax assets attributable to stock option benefits; these amounts are no longer included in our gross or net deferred tax assets. The tax benefit of stock options total \$6 million at December 31, 2011 and will only be recorded when we realize a reduction in taxes payable.



**Table of Contents**

Accounting Standards Codification Topic 740-10 clarifies the accounting for uncertainty in income taxes by prescribing the recognition threshold a tax position is required to meet before being recognized in the financial statements. It also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

We had \$46.4 million of unrecognized tax benefits as of January 1, 2011. The following table summarizes the activity related to our unrecognized tax benefits for the year ended December 31, 2011 (in thousands):

	<b>Year Ended December 31, 2011</b>
Balance at January 1, 2011	\$ 46,381
Decrease relating to prior year provision	(9,782)
Increase relating to current year provision	2,711
Ending Balance at December 31, 2011	\$ 39,310

Included in the balance of unrecognized tax benefits as of December 31, 2011 are \$126,000 of tax benefits that, if recognized, would affect the effective tax rate. All of our deferred tax assets are subject to a valuation allowance. As of December 31, 2011, the company accrued interest of \$9,000, but no penalties, related to tax contingencies. Any tax-related interest and penalties are included in income tax expense in the consolidated statements of operations. We do not anticipate that the amount of unrecognized tax benefits existing as of December 31, 2011 will significantly decrease over the next 12 months.

We file U.S. and state income tax returns in jurisdictions with varying statutes of limitations during which such tax returns may be audited and adjusted by the relevant tax authorities. The 1995 through 2011 years generally remain subject to examination by federal and most state tax authorities to the extent of net operating losses and credits generated during these periods and are being utilized in the open tax periods. The Company's 2008, 2009 and 2010 tax years are currently under audit by the Internal Revenue Service.

**NOTE 12. COMMITMENTS****Leases**

We lease office and research space and certain equipment under operating leases that expire at various dates through the year 2018. Certain operating leases contain renewal provisions and require us to pay other expenses. In connection with the sale of our cell factory business, we assigned our lease to our Portland facility to the purchaser and as a result of our March 2010 restructuring plan, we exited certain facilities in San Diego and South San Francisco. Aggregate future minimum lease payments under our operating leases are as follows (in thousands):

<b>Year Ending December 31,</b>	<b>Operating Leases(1)</b>
2012	\$ 19,397
2013	19,130
2014	19,539
2015	19,831
2016	16,431
Thereafter	11,910
	\$ 106,238

- (1) Minimum payments have not been reduced by minimum sublease rentals of \$18.7 million due in the future under noncancelable subleases.

**Table of Contents**

The following is a summary of aggregate future minimum lease payments under operating leases at December 31, 2011 by material operating lease agreements (in thousands):

	Original Term (Expiration)	Renewal Option	Future Minimum Lease Payment
Building Lease #1&2	May 2017	2 additional periods of 5 years	\$ 60,428
Building Lease #3	July 2018	1 additional period of 5 years	29,586
Building Lease #4	December 2015	1 additional period of 3 years	16,224
Total			\$ 106,238

Rent expense under operating leases was \$21.3 million, \$28.0 million and \$21.0 million for the years ended December 31, 2011, 2010 and 2009, respectively. Rent expense under operating leases was net of sublease rentals of \$1.9 million and \$0.3 million for the years ended December 2011 and 2010, respectively. There were no sublease rentals in 2009.

**Letter of Credit and Restricted Cash**

We entered into a standby letter of credit with a bank in July 2004, which is related to a building lease, with a value of \$0.5 million at each of December 31, 2011 and 2010. We entered into two standby letters of credit with a bank in May 2007, which is related to our workers compensation insurance policy, for a combined value of \$0.8 million at each of December 2011 and 2010. As of December 31, 2011, the full amount of our three letters of credit was still available. As part of a purchasing card program with a bank we initiated during 2007, we were required to provide collateral in the form of a non-interest bearing certificate of deposit. The collateral at December 31, 2011 and 2010 was \$2.9 million and \$5.1 million, respectively, and we recorded these amounts in the accompanying Consolidated Balance Sheet as Restricted cash and investments as the securities are restricted as to withdrawal.

**Indemnification Agreements**

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.

**NOTE 13. QUARTERLY FINANCIAL DATA (UNAUDITED)**

The following tables summarize the unaudited quarterly financial data for the last two fiscal years (in thousands, except per share data):

	2011 Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
Total revenues	\$ 35,893	\$ 32,162	\$ 128,272	\$ 94,309
Income (loss) from operations	(23,730)	(18,008)	79,699	51,574
Net income (loss) attributable to Exelixis, Inc.	(27,490)	(20,975)	77,865	46,297
Basic net income (loss) per share, attributable to Exelixis, Inc.	\$ (0.24)	\$ (0.16)	\$ 0.60	\$ .35
Diluted net income (loss) per share, attributable to Exelixis, Inc.	\$ (0.24)	\$ (0.16)	\$ 0.59	\$ .35

**Table of Contents**

	2010 Quarter Ended			
	March 31,(1,4)	June 30,(2,4)	September 30,	December 31,(3)
Total revenues	\$ 42,199	\$ 47,596	\$ 54,474	\$ 40,776
Loss from operations	(47,452)	(25,631)	(4,205)	(14,109)
Net loss attributable to Exelixis, Inc.	(43,249)	(22,614)	(8,603)	(17,864)
Basic and diluted net loss per share, attributable to Exelixis, Inc.	\$ (0.40)	\$ (0.21)	\$ (0.08)	\$ (0.16)

- (1) In connection with the March 2010 restructuring plan, we recorded a charge of approximately \$16.1 million in the first quarter of 2010 primarily related to termination benefits, which includes the modification of certain stock option awards previously granted to the terminated employees. The modification accelerates the vesting of any stock options that would have vested over the period beginning from cessation of employment through August 5, 2010. Employees who were terminated in March also received an additional two months to exercise their options, for which a small charge was taken. The remainder of the charge was for the impairment of various assets and for non-cash charges relating to the closure of our facility in San Diego, California.
- (2) We recorded further restructuring expenses of approximately \$9.4 million during the second quarter of 2010 associated primarily with lease-exit costs in connection with the sublease and exit of our South San Francisco building, partially offset by a reduction in termination benefits following the recall of certain employees that were originally terminated under the restructuring plan and the continued delay in the termination of a small group of employees impacted by the restructuring plan.
- (3) In connection with the December 2010 restructuring plan, we recorded a charge of approximately \$6.9 million in the fourth quarter of 2010 primarily related to termination benefits, which includes the modification of certain stock option awards previously granted to the terminated employees. The modification allows employees who were terminated under the plan to exercise their options until September 2011. The remainder of the charge was for the impairment of various assets relating to idle equipment in our South San Francisco location.
- (4) In the second quarter of 2009, we signed an amendment to our arrangement with Agrigenetics for which we received \$1.8 million in July 2009. We received additional payments of \$2.7 million and \$4.5 million in March 2010 and May 2010 respectively and recognized these as additional gains in other income.

---

**Table of Contents**

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

Not applicable.

**ITEM 9A. CONTROLS AND PROCEDURES**

***Evaluation of Disclosure Controls and Procedures.*** Based on the evaluation of our disclosure controls and procedures (as defined under Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended) required by Rules 13a-15(b) or 15d-15(b) under the Securities Exchange Act of 1934, as amended, our Chief Executive Officer and our Chief Financial Officer have concluded that as of the end of the period covered by this report, our disclosure controls and procedures were effective.

***Limitations on the Effectiveness of Controls.*** A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our principal executive officer and principal financial officer have concluded, based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were effective to provide reasonable assurance that the objectives of our disclosure control system were met.

***Management's Report on Internal Control Over Financial Reporting.*** Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is a process designed under the supervision of our principal executive and principal financial officers to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in accordance with U.S. generally accepted accounting principles.

As of the end of our 2011 fiscal year, management conducted an assessment of the effectiveness of our internal control over financial reporting based on the framework established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this assessment, management has determined that our internal control over financial reporting as of December 31, 2011 was effective. There were no material weaknesses in internal control over financial reporting identified by management.

Our internal control over financial reporting includes policies and procedures that pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and dispositions of assets; provide reasonable assurances that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with authorizations of our management and directors; and provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

The independent registered public accounting firm Ernst & Young LLP has issued an audit report on our internal control over financial reporting, which is included below.

---

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders of Exelixis, Inc.

We have audited Exelixis, Inc.'s internal control over financial reporting as of December 30, 2011, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Exelixis, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, Exelixis, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 30, 2011, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Exelixis, Inc. as of December 30, 2011 and December 31, 2011, and the related consolidated statements of operations, other comprehensive income (loss), stockholders' equity (deficit), and cash flows for each of the three fiscal years in the period ended December 30, 2011, of Exelixis, Inc. and our report dated February 22, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Redwood City, California

February 22, 2012



**Table of Contents**

***Changes in Internal Control Over Financial Reporting.*** There were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

Not applicable

**Table of Contents**

**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The information required by this item relating to our directors and nominees, including information with respect to our audit committee, audit committee financial experts and procedures by which stockholders may recommend nominees to our board of directors, is incorporated by reference to the section entitled "Proposal 1 Election of Class I Directors" appearing in our Proxy Statement for our 2012 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission, or SEC, within 120 days after December 30, 2011, which we refer to as our 2012 Proxy Statement. The information required by this item regarding our executive officers is incorporated by reference to the section entitled "Executive Officers" appearing in our 2012 Proxy Statement. The information required by this item regarding compliance with Section 16(a) of the Securities Exchange Act of 1934, as amended, is incorporated by reference to the section entitled "Section 16(a) Beneficial Ownership Reporting Compliance" appearing in our 2012 Proxy Statement.

**Code of Ethics**

We have adopted a Code of Conduct and Ethics that applies to all of our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer. The Code of Conduct and Ethics is posted on our website at [www.exelixis.com](http://www.exelixis.com) under the caption "Investors."

We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of this Code of Conduct and Ethics by posting such information on our website, at the address and location specified above and, to the extent required by the listing standards of the NASDAQ Stock Market, by filing a Current Report on Form 8-K with the SEC, disclosing such information.

**ITEM 11. EXECUTIVE COMPENSATION**

The information required by this item is incorporated by reference to the sections entitled "Compensation of Executive Officers," "Compensation of Directors," "Compensation Committee Interlocks and Insider Participation" and "Compensation Committee Report" appearing in our 2012 Proxy Statement.

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

The information required by this item relating to security ownership of certain beneficial owners and management is incorporated by reference to the section entitled "Security Ownership of Certain Beneficial Owners and Management" appearing in our 2012 Proxy Statement.

**Table of Contents****Equity Compensation Plan Information**

The following table provides certain information about our common stock that may be issued upon the exercise of stock options and other rights under all of our existing equity compensation plans as of December 31, 2011, which consists of our 2000 Equity Incentive Plan, or the 2000 Plan, our 2000 Non-Employee Directors Stock Option Plan, or the Director Plan, our 2000 Employee Stock Purchase Plan, or the ESPP, our 2010 Inducement Award Plan, or the 2010 Plan, our 2011 Equity Incentive Plan, or the 2011 Plan, and our 401(k) Plan:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights(1) (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
<b>Equity compensation plans approved by stockholders(2):</b>	18,688,124	7.14	12,959,493
<b>Equity compensation plans not approved by stockholders(3):</b>	139,945	5.93	649,090
<b>Total</b>	<b>18,828,069</b>	<b>7.14</b>	<b>13,608,583</b>

(1) The weighted average exercise price does not take into account the shares subject to outstanding restricted stock units which have no exercise price.

(2) Represents shares of our common stock issuable pursuant to the 2000 Plan, the 2011 Plan, the Director Plan and the ESPP.

The 2000 Plan was originally adopted by our Board of Directors in January 2000 and approved by our stockholders in March 2000. The 2000 Plan was amended and restated by our Board of Directors in December 2006 to require that the exercise price for options granted pursuant to the 2000 Plan be equal to the fair market value as of the determination date. The 2000 Plan is administered by the Compensation Committee of our Board of Directors. The 2000 Plan expired in January 2010 and there are no shares available for future issuance. As of December 31, 2011, there were options outstanding to purchase 14,023,086 shares of our common stock under the 2000 Plan at a weighted average exercise price of \$7.35 per share. The weighted average exercise price does not take into account the shares subject to outstanding restricted stock units which have no exercise price. As of December 31, 2011, there were 969,793 shares reserved for issuance upon the vesting of outstanding restricted stock units under the 2000 Plan.

The Director Plan was originally adopted by our Board of Directors in January 2000 and approved by our stockholders in March 2000. The Director Plan provides for the automatic grant of options to purchase shares of common stock to non-employee directors. The Director Plan was amended by our Board of Directors in February 2004 to increase the annual option grant to each director from 5,000 shares to 10,000 shares, which amendment was approved by our stockholders in April 2004. The Director Plan was further amended by our Board of Directors in February 2008 to increase the annual option grant to each director from 10,000 shares to 15,000 shares and again in December 2010 to extend the post-termination exercise period for future granted options. Stockholder approval of these changes was not required. The Director Plan was further amended by our Board of Directors in February 2011 to reduce the number of shares available for future grant to 1,227,656 shares, which amendment became effective in May 2011 in connection with stockholder approval of the 2011 Plan. The Director Plan is administered by the Compensation Committee of our Board of Directors. As of December 31, 2011, there were 1,117,656 shares available for future issuance under the Director Plan. As of December 31, 2011, there were options outstanding to purchase 996,250 shares of our common stock under the Director Plan at a weighted average exercise price of \$8.42.

---

## **Table of Contents**

The ESPP was originally adopted by our Board of Directors in January 2000 and approved by our stockholders in March 2000. The ESPP allows for qualified employees 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 purchase period. The ESPP is implemented by one offering period during each six-month period; provided, however, our Board of Directors may alter the duration of an offering period without stockholder approval. Employees may authorize up to 15% of their compensation for the purchase of stock under the ESPP; provided, that an employee may not accrue the right to purchase stock at a rate of more than \$25,000 of the fair market value of our common stock for each calendar year in which the purchase right is outstanding. The ESPP was amended by our Board of Directors in January 2005 and February 2009, each time to increase the number of shares available for issuance under the ESPP. Each increase in the ESPP share reserve was approved by our stockholders in April 2005 and May 2009, respectively. As of December 31, 2011, there were 2,685,200 shares available for future issuance under the ESPP.

The 2011 Plan was originally adopted by our Board of Directors on February 16, 2011 and amended by the Compensation Committee on March 18, 2011, subject to stockholder approval. The 2011 Plan was approved by our stockholders in May 2011. As of December 31, 2011, there were 9,156,637 shares available for future issuance under the 2011 Plan. As of December 31, 2011, there were options outstanding to purchase 2,384,542 shares of our common stock under the 2011 Plan at a weighted average exercise price of \$5.50 per share. The weighted average exercise price does not take into account the shares subject to outstanding restricted stock units which have no exercise price. As of December 31, 2011, there were 314,453 shares reserved for issuance upon the vesting of outstanding restricted stock units under the 2011 Plan.

(3) Represents shares of our common stock issuable pursuant to the 2010 Plan and the 401(k) Plan.

In December 2009, we adopted the 2010 Plan to replace the 2000 Plan, which expired in January 2010. A total of 1,000,000 shares of our common stock were authorized for issuance under the 2010 Plan. Following stockholder approval of the 2011 Plan in May 2011, no further stock awards will be granted under the 2010 Plan. The 2010 Plan is administered by the Compensation Committee. As of December 31, 2011, there were options outstanding to purchase 32,500 shares of our common stock under the 2010 Plan at a weighted average exercise price of \$5.93. The weighted average exercise price does not take into account the shares subject to outstanding restricted stock units which have no exercise price. As of December 31, 2011, there were 107,445 shares reserved for issuance upon the vesting of outstanding restricted stock units under the 2010 Plan.

We sponsor a 401(k) Plan whereby eligible employees may elect to contribute up to the lesser of 20% 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. From 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 2011, we match 100% of the first 3% of participant contributions into the 401(k) Plan in the form of our common stock.

### **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information required by this item is incorporated by reference to the sections entitled Certain Relationships and Related Party Transactions and Proposal 1 Election of Class I Directors appearing in our 2012 Proxy Statement.

### **ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

The information required by this item is incorporated by reference to the section entitled Proposal 2 Ratification of Selection of Independent Registered Public Accounting Firm appearing in our 2012 Proxy Statement.

**Table of Contents**

**PART IV**

**ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

(a) The following documents are being filed as part of this report:

(1) The following financial statements and the Report of Independent Registered Public Accounting Firm are included in Part II, Item 8:

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	66
<u>Consolidated Balance Sheets</u>	67
<u>Consolidated Statements of Operations</u>	68
<u>Consolidated Statements of Stockholders' Equity (Deficit)</u>	70
<u>Consolidated Statements of Cash Flows</u>	71
<u>Notes to Consolidated Financial Statements</u>	72

(2) All financial statement schedules are omitted because the information is inapplicable or presented in the Notes to Consolidated Financial Statements.

(3) See Index to Exhibits at the end of this Report, which is incorporated herein by reference. The Exhibits listed in the accompanying Index to Exhibits are filed as part of this report.

**Table of Contents****SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of South San Francisco, State of California, on February 22, 2012.

EXELIXIS, INC.

By: */s/* MICHAEL M. MORRISSEY  
**Michael M. Morrissey, Ph.D.**  
**President and Chief Executive Officer**

**POWER OF ATTORNEY**

**KNOW ALL PERSONS BY THESE PRESENTS**, that each person whose signature appears below constitutes and appoints **MICHAEL M. MORRISSEY, JAMES B. BUCHER** and **FRANK KARBE**, and each or any one of them, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report on Form 10-K has been signed by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signatures	Title	Date
<i>/s/</i> MICHAEL M. MORRISSEY  <b>Michael M. Morrissey, Ph.D.</b>	Director, President and Chief Executive Officer (Principal Executive Officer)	February 22, 2012
<i>/s/</i> FRANK KARBE  <b>Frank Karbe</b>	Chief Financial Officer (Principal Financial and Accounting Officer)	February 22, 2012
<i>/s/</i> STELIOS PAPAPOPOULOS  <b>Stelios Papadopoulos, Ph.D.</b>	Chairman of the Board	February 22, 2012
<i>/s/</i> CHARLES COHEN  <b>Charles Cohen, Ph.D.</b>	Director	February 22, 2012
<i>/s/</i> CARL B. FELDBAUM  <b>Carl B. Feldbaum, Esq.</b>	Director	February 22, 2012
<i>/s/</i> ALAN M. GARBER  <b>Alan M. Garber, M.D., Ph.D.</b>	Director	February 22, 2012

Edgar Filing: EXELIXIS INC - Form 10-K

/s/ VINCENT MARCHESI

Director

February 22, 2012

**Vincent Marchesi, M.D., Ph.D.**

109

**Table of Contents**

<b>Signatures</b>	<b>Title</b>	<b>Date</b>
/s/ FRANK MCCORMICK <b>Frank McCormick, Ph.D.</b>	Director	February 22, 2012
/s/ GEORGE POSTE <b>George Poste, D.V.M., Ph.D.</b>	Director	February 22, 2012
/s/ GEORGE A. SCANGOS <b>George A. Scangos, Ph.D.</b>	Director	February 22, 2012
/s/ LANCE WILLSEY <b>Lance Willsey, M.D.</b>	Director	February 22, 2012
/s/ JACK L. WYSZOMIERSKI <b>Jack L. Wyszomierski</b>	Director	February 22, 2012



**Table of Contents****INDEX TO EXHIBITS**

Exhibit Number	Exhibit Description	Form	Incorporation by Reference		Filing Date	Filed Herewith
			File Number	Exhibit/Appendix		
3.1	Amended and Restated Certificate of Incorporation of Exelixis, Inc.	10-K	000-30235	3.1	3/10/2010	
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Exelixis, Inc.	10-K	000-30235	3.2	3/10/2010	
3.3	Amended and Restated Bylaws of Exelixis, Inc.	8-K	000-30235	3.1	12/5/2011	
4.1	Specimen Common Stock Certificate.	S-1,	333-96335	4.1	2/7/2000	
		as amended				
4.2	Form of Warrant, dated June 10, 2009, to purchase 500,000 shares of Exelixis, Inc. common stock in favor of Symphony Evolution Holdings LLC.	10-Q,	000-30235	4.4	7/30/2009	
		as amended				
4.3	Warrant Purchase Agreement, dated June 9, 2005, between Exelixis, Inc. and Symphony Evolution Holdings LLC.	10-Q	000-30235	4.4	8/5/2010	
4.4*	Form Warrant to Purchase Common Stock of Exelixis, Inc. issued to Deerfield Private Design Fund, L.P., Deerfield Private Design International, L.P., Deerfield Partners, L.P. and Deerfield International Limited	8-K	000-30235	4.9	6/9/2008	
4.5	Form of Common Stock Agreement and Warrant Certificate.	S-3,	333-158792	4.17	4/24/2009	
		as amended				
4.6	Form of Preferred Stock Agreement and Warrant Certificate.	S-3,	333-158792	4.18	4/24/2009	
		as amended				
4.7	Form of Debt Securities Warrant Agreement and Warrant Certificate.	S-3,	333-158792	4.19	4/24/2009	
		as amended				
4.8	Form of Senior Debt Indenture.	S-3,	333-158792	4.13	5/28/2009	
		as amended				
4.9	Form of Subordinated Debt Indenture.	S-3,	333-158792	4.14	5/28/2009	
		as amended				
4.10	Form of Note, dated July 1, 2010, in favor of Deerfield Private Design International, L.P.	10-Q	000-30235	10.1	8/5/2010	
				(Exhibit A-1)		
4.11	Form of Note, dated July 1, 2010, in favor of Deerfield Private Design Fund, L.P.	10-Q	000-30235	10.1	8/5/2010	
				(Exhibit A-2)		



**Table of Contents**

Exhibit Number	Exhibit Description	Form	Incorporation by Reference		Filing Date	Filed Herewith
			File Number	Exhibit/Appendix Reference		
10.1	Form of Indemnity Agreement.	S-1,	333-96335	10.1	2/7/2000	
		as amended				
10.2	2000 Equity Incentive Plan.	10-Q	000-30235	10.1	5/3/2007	
10.3	Form of Stock Option Agreement under the 2000 Equity Incentive Plan (early exercise permissible).	10-Q	000-30235	10.2	11/8/2004	
10.4	Form of Stock Option Agreement under the 2000 Equity Incentive Plan (early exercise may be restricted).	8-K	000-30235	10.1	12/15/2004	
10.5	Form of Restricted Stock Unit Agreement under the 2000 Equity Incentive Plan.	10-K	000-30235	10.6	3/10/2010	
10.6	2000 Non-Employee Directors Stock Option Plan.	10-Q	000-30235	10.1	8/4/2011	
10.7	Form of Stock Option Agreement under the 2000 Non-Employee Directors Stock Option Plan.	10-K	000-30235	10.7	2/22/2011	
10.8	2000 Employee Stock Purchase Plan.	Schedule 14A	000-30235	A	4/13/2009	
10.9	2010 Inducement Award Plan	10-K	000-30235	10.10	3/10/2010	
10.10	Form of Stock Option Agreement under the 2010 Inducement Award Plan.	10-K	000-30235	10.11	3/10/2010	
10.11	Form of Restricted Stock Unit Agreement under the 2010 Inducement Award Plan.	10-K	000-30235	10.1	5/24/2011	
10.12	2011 Equity Incentive Plan.	8-K	000-30235	10.1	5/24/2011	
10.13	Form of Stock Option Agreement under the 2011 Equity Incentive Plan	10-Q	000-30235	10.3	8/4/2011	
10.14	Form of Restricted Stock Unit Agreement under the 2011 Equity Incentive Plan	10-Q	000-30235	10.4	8/4/2011	
10.15	Exelixis, Inc. 401(k) Plan.	10-K	000-30235	10.13	3/10/2010	
10.16	Exelixis, Inc. 401(k) Plan Adoption Agreement.	10-K	000-30235	10.14	3/10/2010	
10.17	Offer Letter Agreement, dated February 3, 2000, between Michael Morrissey, Ph.D., and Exelixis, Inc.	10-Q	000-30235	10.43	8/5/2004	

**Table of Contents**

Exhibit Number	Exhibit Description	Form	Incorporation by Reference			Filed Herewith
			File Number	Exhibit/Appendix Reference	Filing Date	
10.18	Offer Letter Agreement, dated November 20, 2003, between Frank Karbe and Exelixis, Inc.	10-Q	000-30235	10.46	8/5/2004	
10.19	Offer Letter Agreement, dated March 27, 2000, between Pamela Simonton, J.D., L.L.M. and Exelixis, Inc.	10-K	000-30235	10.17	3/15/2005	
10.20	Offer Letter Agreement, dated June 20, 2006, between Exelixis, Inc. and Gisela M. Schwab, M.D.	8-K	000-30235	10.1	6/26/2006	
10.21	Offer Letter Agreement, dated October 6, 2011, between Exelixis, Inc. and J. Scott Garland.					X
10.22	Resignation Agreement dated July 22, 2010, by and between Exelixis, Inc. and George A. Scangos	10-Q	000-30235	10.1	11/4/2010	
10.23	Separation Agreement and Release, dated July 18, 2011, by and between Exelixis, Inc. and Frances K. Heller.	10-Q	000-30235	10.1	10/27/2011	
10.24	Severance/Consulting Agreement and Release, dated September 28, 2011, by and between Exelixis, Inc. and Lupe M. Rivera.	10-Q	000-30235	10.8	10/27/2011	
10.25	Compensation Information for Named Executive Officers.	8-K	000-30235	10.1	2/7/2012	
10.26	Compensation Information for Non-Employee Directors.					X
10.27	Exelixis, Inc. Change in Control and Severance Benefit Plan, as amended and restated.	10-Q	000-30235	10.2	10/27/2011	
10.28*	Product Development and Commercialization Agreement, dated as of October 28, 2002, by and between SmithKlineBeecham Corporation and Exelixis, Inc.	10-Q	000-30235	10.36	11/8/2002	
10.29*	First Amendment, dated January 10, 2005, to the Product Development and Commercialization Agreement, dated October 28, 2002, by and between SmithKlineBeecham Corporation and Exelixis, Inc.	10-K	000-30235	10.24	3/15/2005	

**Table of Contents**

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Form</b>	<b>Incorporation by Reference</b>		<b>Filing Date</b>	<b>Filed Herewith</b>
			<b>File Number</b>	<b>Exhibit/Appendix Reference</b>		
10.30*	Second Amendment, dated June 13, 2008, to the Product Development and Commercialization Agreement, dated October 28, 2002, by and between SmithKlineBeecham Corporation d/b/a GlaxoSmithKline and Exelixis, Inc.	10-Q	000-30235	10.3	8/5/2008	
10.31*	Stock Purchase and Stock Issuance Agreement, dated October 28, 2002, by and between SmithKlineBeecham Corporation and Exelixis, Inc.	10-Q	000-30235	10.37	11/8/2002	
10.32	First Amendment, dated January 10, 2005, to the Stock Purchase and Stock Issuance Agreement, dated October 28, 2002, by and between SmithKlineBeecham Corporation and Exelixis, Inc.	10-K	000-30235	10.26	3/15/2005	
10.33*	Loan and Security Agreement, dated October 28, 2002, by and between SmithKlineBeecham Corporation and Exelixis, Inc.	10-Q	000-30235	10.38	11/8/2002	
10.34	First Amendment, dated December 5, 2002, to the Loan and Security Agreement, dated October 28, 2002, by and between SmithKlineBeecham Corporation and Exelixis, Inc.	10-K	000-30235	10.30	3/10/2010	
10.35	Second Amendment, dated September 20, 2004, to the Loan and Security Agreement, dated October 28, 2002, by and between SmithKlineBeecham Corporation and Exelixis, Inc.	8-K	000-30235	10.1	9/23/2004	
10.36*	Third Amendment, dated January 10, 2005, to the Loan and Security Agreement, dated October 28, 2002, by and between SmithKlineBeecham Corporation and Exelixis, Inc.	10-K	000-30235	10.29	3/15/2005	
10.37*	Fourth Amendment dated July 10, 2008, to the Loan and Security Agreement, dated October 28, 2002, by and between SmithKlineBeecham Corporation d/b/a GlaxoSmithKline and Exelixis, Inc.	10-Q	000-30235	10.4	8/5/2008	

**Table of Contents**

Exhibit Number	Exhibit Description	Form	Incorporation by Reference		Filing Date	Filed Herewith
			File Number	Exhibit/Appendix		
10.38*	Letter Agreement, dated February 17, 2009, between Exelixis, Inc. and SmithKlineBeecham Corporation d/b/a GlaxoSmithKline.	10-Q,  as amended	000-30235	10.1	5/7/2009	
10.39*	Collaboration Agreement, dated December 15, 2006, between Exelixis, Inc. and Bristol-Myers Squibb Company.	10-K	000-30235	10.38	2/27/2007	
10.40*	Amendment No. 1, dated January 11, 2007, to the Collaboration Agreement, dated December 15, 2006, between Exelixis, Inc. and Bristol-Myers Squibb Company.	10-Q	000-30235	10.3	11/5/2007	
10.41*	Letter Agreement, dated June 26, 2008, between Exelixis, Inc. and Bristol-Myers Squibb Company.	10-Q	000-30235	10.5	8/5/2008	
10.42*	Amendment No. 2, dated October 1, 2009, to the Collaboration Agreement, dated December 15, 2006, by and between Exelixis, Inc. and Bristol-Myers Squibb Company.	10-Q	000-30235	10.3	10/29/2009	
10.43*	Amendment No. 3, dated October 8, 2010, to the Collaboration Agreement, dated December 15, 2006, by and between Exelixis, Inc. and Bristol-Myers Squibb Company.	10-K	000-30235	10.39	2/22/2011	
10.44*	Amended and Restated Collaboration Agreement, dated April 15, 2011, by and between Exelixis, Inc., Exelixis Patent Company, LLC., and Bristol-Myers Squibb Company.	10-Q	000-30235	10.5	8/4/2011	
10.45*	Collaboration Agreement, dated December 22, 2006, between Exelixis, Inc. and Genentech, Inc.	10-K	000-30235	10.39	2/27/2007	
10.46*	First Amendment, dated March 13, 2008, to the Collaboration Agreement, dated December 22, 2006, between Exelixis, Inc. and Genentech, Inc.	10-Q	000-30235	10.1	5/6/2008	

**Table of Contents**

Exhibit Number	Exhibit Description	Form	Incorporation by Reference		Filing Date	Filed Herewith
			File Number	Exhibit/Appendix Reference		
10.47	Second Amendment, dated April 30, 2010, to the Collaboration Agreement, dated December 22, 2006, between Exelixis, Inc. and Genentech, Inc.	10-Q	000-30235	10.5	8/5/2010	
10.48	Lease, dated May 12, 1999, between Britannia Pointe Grand Limited Partnership and Exelixis, Inc.	S-1, as amended	333-96335	10.11	2/7/2000	
10.49	First Amendment, dated March 29, 2000, to Lease, dated May 12, 1999, between Britannia Pointe Grand Limited Partnership and Exelixis, Inc.	10-Q	000-30235	10.1	5/15/2000	
10.50	Second Amendment, dated January 31, 2001, to Lease dated May 12, 1999, between Britannia Pointe Grand Limited Partnership and Exelixis, Inc.	S-1, as amended	333-152166	10.44	7/7/2008	
10.51	Third Amendment, dated May 24, 2001, to Lease dated May 12, 1999, between Britannia Pointe Grand Limited Partnership and Exelixis, Inc.	10-K	000-30235	10.46	2/22/2011	
10.52	Lease Agreement, dated May 24, 2001, between Britannia Pointe Grand Limited Partnership and Exelixis, Inc.	10-Q	000-30235	10.48	8/5/2004	
10.53	First Amendment, dated February 28, 2003, to Lease, dated May 24, 2001, between Britannia Pointe Grand Limited Partnership and Exelixis, Inc.	S-1, as amended	333-152166	10.46	7/7/2008	
10.54	Second Amendment, dated July 20, 2004, to Lease, dated May 24, 2001, between Britannia Pointe Grand Limited Partnership and Exelixis, Inc.	10-Q	000-30235	10.49	8/5/2004	
10.55	Lease Agreement, dated May 27, 2005, between Exelixis, Inc. and Britannia Pointe Grand Limited Partnership.	8-K	000-30235	10.1	5/27/2007	
10.56	Sublease, dated July 25, 2011, between Exelixis, Inc. and Nodality, Inc.	10-Q	000-30235	10.3	10/27/2011	

**Table of Contents**

Exhibit Number	Exhibit Description	Form	Incorporation by Reference			Filed Herewith
			File Number	Exhibit/Appendix Reference	Filing Date	
10.57	Consent to Sublease, dated August 16, 2011, by and among HCP Life Science REIT, Inc., Exelixis, Inc., and Nodality, Inc.	10-Q	000-30235	10.4	10/27/2011	
10.58	Sublease, dated July 25, 2011, between Exelixis, Inc. and Threshold Pharmaceuticals, Inc.	10-Q	000-30235	10.5	10/27/2011	
10.59	Consent to Sublease, dated August 19, 2011, by and among HCP Life Science REIT, Inc., Exelixis, Inc., and Threshold Pharmaceuticals, Inc.	10-Q	000-30235	10.6	10/27/2011	
10.60	Lease Agreement, dated September 14, 2007, between ARE-San Francisco No. 12, LLC and Exelixis, Inc.	10-Q	000-30235	10.5	11/5/2007	
10.61	First Amendment, dated May 31, 2008, to Lease Agreement, dated September 14, 2007, between ARE-San Francisco No. 12, LLC and Exelixis, Inc.	10-Q	000-30235	10.1	8/5/2008	
10.62	Second Amendment, dated October 23, 2008, to Lease Agreement, dated September 14, 2007, between ARE-San Francisco No. 12, LLC and Exelixis, Inc.	10-K	000-30235	10.62	3/10/2009	
10.63	Third Amendment, dated October 24, 2008, to Lease Agreement, dated September 14, 2007, between ARE-San Francisco No. 12, LLC and Exelixis, Inc.	10-K	000-30235	10.63	3/10/2009	
10.64	Fourth Amendment, dated July 9, 2010, to Lease Agreement, dated September 14, 2007, between ARE-San Francisco No. 12, LLC and Exelixis, Inc.	10-Q	000-30235	10.2	11/4/2010	
10.65	Sublease Agreement, dated July 9, 2010, by and between Exelixis, Inc. and Onyx Pharmaceuticals, Inc.	10-Q	000-30235	10.4	11/4/2010	
10.66	Consent to Sublease dated July 9, 2010 by and among ARE-San Francisco No. 12, LLC, Exelixis, Inc. and Onyx Pharmaceuticals, Inc.	10-Q	000-30235	10.3	11/4/2010	



**Table of Contents**

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Form</b>	<b>Incorporation by Reference</b>		<b>Filing Date</b>	<b>Filed Herewith</b>
			<b>File Number</b>	<b>Exhibit/ Appendix Reference</b>		
10.67	Loan and Security Agreement, dated May 22, 2002, by and between Silicon Valley Bank and Exelixis, Inc.	10-Q	000-30235	10.34	8/6/2002	
10.68	Loan Modification Agreement, dated December 21, 2004, between Silicon Valley Bank and Exelixis, Inc.	8-K	000-30235	10.1	12/23/2004	
10.69	Amendment No. 7, dated December 21, 2006, to the Loan and Security Agreement, dated May 22, 2002, between Silicon Valley Bank and Exelixis, Inc.	8-K	000-30235	10.1	12/27/2006	
10.70	Amendment No. 8, dated December 21, 2007, to the Loan and Security Agreement, dated May 22, 2002, between Silicon Valley Bank and Exelixis, Inc.	8-K	000-30235	10.1	12/26/2007	
10.71	Amendment No. 9, dated December 22, 2009, to the Loan and Security Agreement, dated May 22, 2002, between Silicon Valley Bank and Exelixis, Inc.	8-K	000-30235	10.1	12/23/2009	
10.72*	Amendment No. 10, dated June 2, 2010, to the Loan and Security Agreement, dated May 22, 2002, by and between Silicon Valley Bank and Exelixis, Inc.	10-Q	000-30235	10.3	8/5/2010	
10.73*	Amendment No. 11, dated August 18, 2011, to the Loan and Security Agreement, dated May 22, 2002, by and between Silicon Valley Bank and Exelixis, Inc.	10-Q	000-30235	10.7	10/27/2011	
10.74*	Collaboration Agreement, dated December 11, 2008, by and between Exelixis, Inc. and Bristol-Myers Squibb Company.	10-K	000-30235	10.65	3/10/2009	
10.75*	Amendment No. 1, dated December 17, 2008, to the Collaboration Agreement, dated December 11, 2008, by and between Exelixis, Inc. and Bristol-Myers Squibb Company.	10-K	000-30235	10.66	3/10/2009	

**Table of Contents**

Exhibit Number	Exhibit Description	Form	Incorporation by Reference			Filed Herewith
			File Number	Exhibit/Appendix	Filing Date	
10.76*	Amendment No. 2, dated September 1, 2009, to the Collaboration Agreement dated December 11, 2008, by and between Exelixis, Inc. and Bristol-Myers Squibb Company.	10-Q	000-30235	10.2	10/29/2009	
10.77*	Amendment No. 3, dated October 8, 2010, to the Collaboration Agreement dated December 11, 2008, by and between Exelixis, Inc. and Bristol-Myers Squibb Company.	10-K	000-30235	10.68	2/22/2011	
10.78	Termination Agreement dated June 18, 2010 between Exelixis, Inc. and Bristol-Myers Squibb Company	10-Q	000-30235	10.4	8/5/2010	
10.79*	Letter Agreement, dated December 11, 2008, between Exelixis, Inc. and Bristol-Myers Squibb Company.	10-K	000-30235	10.67	3/10/2009	
10.80*	Amended and Restated Collaboration Agreement, dated April 15, 2011, by and between Exelixis, Inc., Exelixis Patent Company, LLC., and Bristol-Myers Squibb Company.	10-Q	000-30235	10.6	8/4/2011	
10.81*	License Agreement, dated May 27, 2009, between Exelixis, Inc. and Sanofi.	10-Q,	000-30235	10.1	7/30/2009	
		as amended				
10.82*	Collaboration Agreement, dated May 27, 2009, between Exelixis, Inc. and Sanofi.	10-Q,	000-30235	10.2	7/30/2009	
		as amended				
10.83**	Termination Agreement, dated December 22, 2011, between Exelixis, Inc. and Sanofi.					X
10.84	Letter, dated May 27, 2009, relating to regulatory filings for the Collaboration Agreement, dated May 27, 2009, between Exelixis, Inc. and Sanofi.	10-Q,	000-30235	10.3	7/30/2009	
		as amended				
10.85	Note Purchase Agreement, dated June 2, 2010, by and between Deerfield Private Design Fund, L.P., Deerfield Private Design International, L.P. and Exelixis, Inc.	10-Q	000-30235	10.1	8/5/2010	

**Table of Contents**

Exhibit Number	Exhibit Description	Form	Incorporation by Reference			Filed Herewith
			File Number	Exhibit/Appendix	Filing Date	
10.86	Security Agreement, dated July 1, 2010, by and between Deerfield Private Design Fund, L.P., Deerfield Private Design International, L.P. and Exelixis, Inc.	10-Q	000-30235	10.2	8/5/2010	
10.87*	License Agreement, dated October 8, 2010, by and between Bristol-Myers Squibb Company and Exelixis, Inc.	10-K	000-30235	10.76	2/22/2011	
10.88*	Amended and Restated License Agreement, dated April 15, 2011, by and between Exelixis, Inc., Exelixis Patent Company, LLC, and Bristol-Myers Squibb Company.	10-Q	000-30235	10.7	8/4/2011	
10.89*	Collaboration Agreement, dated October 8, 2010, by and between Bristol-Myers Squibb Company and Exelixis, Inc.	10-K	000-30235	10.77	2/22/2011	
10.90*	Amended and Restated Collaboration Agreement, dated April 15, 2011, by and between Exelixis, Inc., Exelixis Patent Company, LLC, and Bristol-Myers Squibb Company.	10-Q	000-30235	10.8	8/4/2011	
10.91**	Exclusive License Agreement, dated December 20, 2011, between Exelixis, Inc. and Merck.					X
23.1	Consent of Independent Registered Public Accounting Firm.					X
24.1	Power of Attorney (contained on signature page).					X
31.1	Certification required by Rule 13a-14(a) or Rule 15d-14(a)					X
31.2	Certification required by Rule 13a-14(a) or Rule 15d-14(a).					X
32.1	Certification by the Chief Executive Officer and the Chief Financial Officer of Exelixis, Inc., as required by Rule 13a-14(b) or 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).					X

**Table of Contents**

Exhibit Number	Exhibit Description	Form	Incorporation by Reference			Filed Herewith
			File Number	Reference	Filing Date	
101.INS#	XBRL Instance Document					X
101.SCH#	XBRL Taxonomy Extension Schema Document					X
101.CAL#	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF#	XBRL Taxonomy Extension Definition Linkbase					X
101.LAB#	XBRL Taxonomy Extension Labels Linkbase Document					X
101.PRE#	XBRL Taxonomy Extension Presentation Linkbase Document					X

Management contract or compensatory plan.

\* Confidential treatment granted for certain portions of this exhibit.

\*\* Confidential treatment requested for certain portions of this exhibit.

This certification accompanies this Annual Report on Form 10-K, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of this Annual Report on Form 10-K), irrespective of any general incorporation language contained in such filing.

# XBRL information is furnished and not filed for purposes of Sections 11 and 12 of the Securities Act of 1933 and Section 18 of the Securities Exchange Act of 1934, and is not subject to liability under those sections, is not part of any registration statement or prospectus to which it relates and is not incorporated or deemed to be incorporated by reference into any registration statement, prospectus or other document.