

EXELIXIS INC  
Form 10-Q  
May 03, 2011  
Table of Contents

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

Washington, D.C. 20549

**FORM 10-Q**

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

For the quarterly period ended April 1, 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: 000-30235

**Exelixis, Inc.**

(Exact Name of Registrant as Specified in Its Charter)

Edgar Filing: EXELIXIS INC - Form 10-Q

**Delaware**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**04-3257395**  
(I.R.S. Employer  
Identification No.)

**210 East Grand Ave.**

**South San Francisco, CA 94080**

(Address of Principal Executive Offices) (Zip Code)

**(650) 837-7000**

(Registrant's Telephone Number, Including Area Code)

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 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.

Large accelerated filer  Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

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

As of April 28, 2011, there were 127,835,145 shares of the registrant's common stock outstanding.

---

**Table of Contents**

**EXELIXIS, INC.**

**QUARTERLY REPORT ON FORM 10-Q**

**FOR THE QUARTERLY PERIOD ENDED APRIL 1, 2011**

**INDEX**

<b><u>Part I. Financial Information</u></b>	<b>3</b>
Item 1. <u>Financial Statements</u>	3
<u>Condensed Consolidated Balance Sheets – March 31, 2011 and December 31, 2010</u>	3
<u>Condensed Consolidated Statements of Operations – Three Months Ended March 31, 2011 and 2010</u>	4
<u>Condensed Consolidated Statements of Cash Flows – Three Months Ended March 31, 2011 and 2010</u>	5
<u>Notes to Condensed Consolidated Financial Statements</u>	6
Item 2. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	16
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	31
Item 4. <u>Controls and Procedures</u>	31
<b><u>Part II. Other Information</u></b>	<b>31</b>
Item 1A. <u>Risk Factors</u>	31
Item 6. <u>Exhibits</u>	45
<b><u>SIGNATURES</u></b>	<b>46</b>
<b><u>EXHIBITS</u></b>	
<u>Exhibit 31.1</u>	
<u>Exhibit 31.2</u>	
<u>Exhibit 32.1</u>	

**Table of Contents****PART I. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****EXELIXIS, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS**

(in thousands)

	<b>March 31, 2011 (unaudited)</b>	<b>December 31, 2010 (1)</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 202,051	\$ 97,440
Marketable securities	99,621	65,224
Other receivables	5,771	5,896
Prepaid expenses and other current assets	16,766	14,926
<b>Total current assets</b>	<b>324,209</b>	<b>183,486</b>
Restricted cash and investments	4,199	6,399
Long-term investments	85,825	87,314
Property and equipment, net	13,605	15,811
Goodwill	63,684	63,684
Other assets	4,214	4,096
<b>Total assets</b>	<b>\$ 495,736</b>	<b>\$ 360,790</b>
<b>LIABILITIES AND STOCKHOLDERS DEFICIT</b>		
Current liabilities:		
Accounts payable	\$ 2,945	\$ 2,046
Accrued compensation and benefits	6,888	6,555
Accrued clinical trial liabilities	31,681	30,975
Other accrued liabilities	15,993	15,026
Current portion of notes payable and bank obligations	8,064	8,848
Current portion of convertible loans	28,900	28,900
Current portion of restructuring	3,850	7,294
Deferred revenue	99,802	100,297
<b>Total current liabilities</b>	<b>198,123</b>	<b>199,941</b>
Long-term portion of notes payable and bank obligations	85,825	87,314
Long-term portion of convertible loans	85,240	83,396
Long-term portion of restructuring	8,954	6,987
Other long-term liabilities	8,772	9,005
Deferred revenue	177,571	202,472
<b>Total liabilities</b>	<b>564,485</b>	<b>589,115</b>
<b>Commitments</b>		
<b>Stockholders deficit:</b>		
Common stock	127	109

Edgar Filing: EXELIXIS INC - Form 10-Q

Additional paid-in-capital	1,140,700	953,608
Accumulated other comprehensive income	(32)	12
Accumulated deficit	(1,209,544)	(1,182,054)
<b>Total stockholders' deficit</b>	<b>(68,749)</b>	<b>(228,325)</b>
Total liabilities and stockholders' deficit	\$ 495,736	\$ 360,790

- (1) The condensed consolidated balance sheet at December 31, 2010 has been derived from the audited consolidated financial statements at that date but does not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements.

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

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

	<b>Three Months Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
<b>Revenues:</b>		
Contract	\$ 12,410	\$ 19,740
License	22,789	24,565
Collaboration reimbursement	694	(2,106)
<b>Total revenues</b>	<b>35,893</b>	<b>42,199</b>
<b>Operating expenses:</b>		
Research and development	45,691	64,751
General and administrative	9,165	8,835
Restructuring charge	4,767	16,065
<b>Total operating expenses</b>	<b>59,623</b>	<b>89,651</b>
<b>Loss from operations</b>	<b>(23,730)</b>	<b>(47,452)</b>
<b>Other income (expense):</b>		
Interest income and other, net	183	315
Interest expense	(3,943)	(612)
Gain on sale of business		4,500
<b>Total other income (expense), net</b>	<b>(3,760)</b>	<b>4,203</b>
<b>Net loss</b>	<b>\$ (27,490)</b>	<b>\$ (43,249)</b>
<b>Net loss per share, basic and diluted</b>	<b>\$ (0.24)</b>	<b>\$ (0.40)</b>
<b>Shares used in computing basic and diluted loss per share amounts</b>	<b>113,215</b>	<b>107,976</b>

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

**Table of Contents****EXELIXIS, INC.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(in thousands)****(unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (27,490)	\$ (43,249)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation and amortization	1,929	3,072
Stock-based compensation expense	3,603	6,526
Impairment of assets due to restructuring	122	2,474
Gain on sale of business		(4,500)
Accretion of debt discount	3,324	
Other	478	938
<b>Changes in assets and liabilities:</b>		
Other receivables	125	4,774
Prepaid expenses and other current assets	(1,279)	(3,403)
Other assets	114	11
Accounts payable and other accrued expenses	2,905	(4,619)
Restructuring liability	(1,478)	10,769
Other long-term liabilities	(232)	(152)
Deferred revenue	(25,397)	(26,380)
<b>Net cash used in operating activities</b>	<b>(43,276)</b>	<b>(53,739)</b>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(405)	(252)
Proceeds from sales of property and equipment		175
Proceeds from sale of business		4,500
Decrease in restricted cash and investments	2,200	
Proceeds from maturities of marketable securities	26,718	33,971
Proceeds from sales of marketable securities		12,780
Purchases of marketable securities	(60,015)	(23,563)
<b>Net cash (used in) provided by investing activities</b>	<b>(31,502)</b>	<b>27,611</b>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common stock	179,347	
Proceeds from exercise of stock options and warrants	3,794	871
Principal payments on notes payable and bank obligations	(3,752)	(3,247)
<b>Net cash provided by (used in) financing activities</b>	<b>179,389</b>	<b>(2,376)</b>
<b>Net increase in cash and cash equivalents</b>	<b>104,611</b>	<b>(28,504)</b>
Cash and cash equivalents, at beginning of period	97,440	86,796
<b>Cash and cash equivalents, at end of period</b>	<b>\$ 202,051</b>	<b>\$ 58,292</b>

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





---

**Table of Contents**

**EXELIXIS, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 2011**

**(unaudited)**

**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 resources and development efforts exclusively on cabozantinib (XL184), our most advanced compound, 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. Cabozantinib inhibits MET, VEGFR2 and RET, proteins that are key drivers of tumor growth and/or vascularization. Cabozantinib is the most advanced inhibitor of MET in clinical development and is being evaluated in a broad development program encompassing multiple cancer indications. We have also developed a portfolio of other novel compounds that we believe have the potential to address serious unmet medical needs, most of which are being advanced by partners as part of collaborations.

**Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and pursuant to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission ( SEC ). Accordingly, they do not include all of the information and footnotes required by U.S. generally accepted accounting principles ( GAAP ) for complete financial statements. In our opinion, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the results of operations and cash flows for the period presented have been included. Certain reclassifications of prior period amounts have been made to our condensed consolidated financial statements to conform to the current period presentation.

Exelixis has adopted a 52- or 53-week fiscal year that ends on the Friday closest to December 31<sup>st</sup> of each year. Fiscal year 2010, a 52-week year, ended on December 31, 2010, and fiscal year 2011, a 52-week year, will end on December 30, 2011. For convenience, references in these Condensed Consolidated Financial Statements and Notes as of and for the fiscal quarters ended April 2, 2010 and April 1, 2011 are indicated as ended March 31, 2010 and 2011, respectively.

Operating results for the three-month period ended March 31, 2011 are not necessarily indicative of the results that may be expected for the fiscal year ending December 30, 2011 or for any future period. These financial statements and notes should be read in conjunction with the consolidated financial statements and notes thereto for the fiscal year ended December 31, 2010 included in our Annual Report on Form 10-K filed with the SEC on February 22, 2011.

**Use of Estimates**

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of certain assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ significantly from those estimates.

**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

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

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 accordance with the loan arrangement. Unrealized gains and losses on available-for-sale investments are reported as a separate component of stockholders' 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.

**Table of Contents****EXELIXIS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****March 31, 2011****(unaudited)**

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

	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>
Money market funds	\$ 173,852	\$	\$	\$ 173,852
Commercial paper	129,915	2		129,917
Corporate bonds	64,375	14	(45)	64,344
U.S. Government sponsored enterprises	11,259	2		11,261
Municipal bonds	13,118		(5)	13,113
<b>Total</b>	<b>\$ 392,519</b>	<b>18</b>	<b>\$ (50)</b>	<b>\$ 392,487</b>

  

	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>
As reported:				
Cash equivalents	\$ 288,671	\$	\$ (4)	\$ 288,667
Marketable securities	84,498	16	(21)	84,493
Restricted cash and investments	4,199			4,199
Long-term investments	15,151	2	(25)	15,128
<b>Total</b>	<b>\$ 392,519</b>	<b>18</b>	<b>\$ (50)</b>	<b>\$ 392,487</b>

As of March 31, 2011, all securities were in an unrealized loss position 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.

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):

	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>
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

Edgar Filing: EXELIXIS INC - Form 10-Q

Total	\$ 256,924	\$ 23	\$ (11)	\$ 256,936
	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>
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

**Table of Contents****EXELIXIS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****March 31, 2011****(unaudited)****Foreign Currency Forward Contract**

We have entered into foreign currency forward contracts to reduce our net exposure to Eurodollar currency fluctuations. In October 2010, we entered into a foreign contract for a notional amount of \$6.9 million that expired in March 2011. On March 30, 2011, we settled this contract for a net loss of \$0.4 million and a cash payment of \$0.2 million and entered into a new foreign contract for a notional amount of \$7.0 million that will expire in December 2011. The fair value of the foreign currency contract is estimated based on pricing models using readily observable inputs from actively quoted markets. The net unrealized gain/loss on our foreign currency forward contracts, neither of which are designated as a hedge, are recorded in our Consolidated Statements 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.

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 March 31, 2011 and December 31, 2010, respectively (in thousands):

As of March 31, 2011:

	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
Money market funds	\$ 173,852	\$	\$	\$ 173,852
Commercial paper		129,917		129,917
Corporate bonds		64,344		64,344
U.S. Government sponsored agencies		11,261		11,261
Municipal bonds		13,113		13,113
Total	\$ 173,852	\$ 218,635	\$	\$ 392,487

As of December 31, 2010:

	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
Money market funds	\$ 171,048	\$	\$	\$ 171,048
Commercial paper		19,283		19,283

Edgar Filing: EXELIXIS INC - Form 10-Q

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

**Table of Contents****EXELIXIS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****March 31, 2011****(unaudited)**

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 Management's Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources Cash Requirements 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):

	<b>March 31, 2011</b>	<b>December 31, 2010</b>
GlaxoSmithKline loan	\$ 27,337	\$ 26,693
Equipment lines of credit	13,820	16,064
Silicon Valley Bank loan	77,480	77,480
Total	\$ 118,637	\$ 120,237

At March 31, 2011 and December 31, 2010, the book value of our debt outstanding, including our 2010 financing with Deerfield, was \$208.0 million and \$208.5 million, respectively. 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.

**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 the quarters ending March 31, 2010 and March 31, 2011, we wrote down property and equipment in the amount of approximately \$2.5 million and \$0.1 million respectively in connection with our March and December 2010 restructuring plans. See Note 5 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.

**Net Loss Per Share**

Basic and diluted net loss per share are computed by dividing net loss for the period by the weighted average number of shares of common stock outstanding during the period. The calculation of diluted net loss per share excludes potential common stock because its effect is antidilutive.

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

Potential common stock consists of incremental common shares issuable upon the exercise of stock options and warrants and shares issuable pursuant to restricted stock units ( RSUs ) and upon conversion of our convertible loans.

As of March 31, 2011 and 2010, our potential common stock includes the following shares, all of which have been excluded from the computation of diluted net loss per share because their impact is antidilutive:

	<b>March 31, 2011</b>	<b>March 31, 2010</b>
Shares related to our GSK loan	3,153,729	9,784,549
Shares issuable upon the exercise of outstanding stock options	18,283,648	24,044,443
Shares issuable pursuant to the vesting of RSUs	1,483,443	2,740,849
Shares issuable upon the exercise of outstanding warrants	2,250,000	3,000,000
<b>Total antidilutive shares</b>	<b>25,170,820</b>	<b>39,569,841</b>



**Table of Contents****EXELIXIS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****March 31, 2011****(unaudited)****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. In December 2008, we entered into a worldwide collaboration with Bristol-Myers Squibb for the development of cabozantinib and XL281. However, 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, solely as to cabozantinib, on a worldwide basis. Prior to the termination of the collaboration with Bristol-Myers Squibb Company ( 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 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, are recorded as collaboration reimbursement revenues. Conversely, research and development expenses may include the net settlement of amounts we owe 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. Due to the termination of the collaboration in June 2010 with respect to cabozantinib and the work we are conducting for XL281, during the fiscal year ended December 31, 2010 and in future fiscal years, we were and will continue to be in a net receivable position, and will therefore present reimbursement payments as collaboration reimbursement revenues. 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.

**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.

**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, and expect that this adoption could have a material impact on our financial statements going forward.

**NOTE 2. Comprehensive Loss**

Comprehensive loss represents consolidated net loss plus any unrealized gains and losses on available-for-sale securities not reflected in our Consolidated Statements of Operations. Comprehensive loss was as follows (in thousands):

<b>Three Months Ended March 31,</b>	
<b>2011</b>	<b>2010</b>

Edgar Filing: EXELIXIS INC - Form 10-Q

Consolidated net loss	\$ (27,490)	\$ (43,249)
Unrealized losses on available-for-sale securities	(43)	(57)
Comprehensive loss	\$ (27,533)	\$ (43,306)

**NOTE 3. Stock-Based Compensation**

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

	<b>Three Months Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
Research and development expense	\$ 1,748	\$ 3,648
General and administrative expense	1,332	1,852
Restructuring expense	449	995
Total employee stock-based compensation expense	\$ 3,529	\$ 6,495

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:

**Table of Contents****EXELIXIS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****March 31, 2011****(unaudited)**

	<b>Stock Options</b>		<b>Employee Stock Purchase Plan</b>	
	<b>Three Months Ended March 31,</b>		<b>Three Months Ended March</b>	
	<b>2011</b>	<b>2010</b>	<b>2011</b>	<b>2010</b>
Weighted average fair value of awards	\$ N/A	\$ 3.80	\$ 1.47	\$ 1.92
Risk-free interest rate	N/A	2.50%	0.16%	0.16%
Dividend yield	N/A	0%	0%	0%
Volatility	N/A	60%	65%	60%
Expected life	N/A	5.2 years	0.5 years	0.5 years

(1) There were no options granted during the three months ended March 31, 2011.

A summary of all stock option activity for the three months ended March 31, 2011 is presented below:

	<b>Shares</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Term</b>	<b>Aggregate Intrinsic Value</b>
Options outstanding at December 31, 2010	19,630,030	\$ 7.52		
Granted	0	0		
Exercised	(650,017)	5.85		
Cancelled	(696,365)	11.15		
Options outstanding at March 31, 2011	18,283,648	\$ 7.44	5.18 years	\$ 77,031,922
Exercisable at March 31, 2011	14,702,142	\$ 7.68	4.60 years	\$ 58,971,457

As of March 31, 2011, \$10.3 million of total unrecognized compensation expense related to employee stock options was expected to be recognized over a weighted-average period of 2.02 years.

A summary of all RSU activity for the three months ended March 31, 2011 is presented below:

	<b>Shares</b>	<b>Weighted Average Grant Date Fair Value</b>	<b>Weighted Average Remaining Contractual Term</b>	<b>Aggregate Intrinsic Value</b>
RSUs outstanding at December 31, 2010	2,172,431	\$ 7.31		
Awarded	35,100	11.82		
Released	(442,622)	7.49		
Forfeited	(281,466)	7.44		
Awards outstanding at March 31, 2011	1,483,443	7.34	1.52 years	\$ 17,015,091

As of March 31, 2011, \$8.2 million of total unrecognized compensation expense related to employee RSUs was expected to be recognized over a weighted-average period of 2.93 years.

**NOTE 4. Collaborations**

**Bristol-Myers Squibb**

*2010 Collaboration Agreements*

*TGR5 License Agreement*

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 received a worldwide exclusive license to XL475 and has 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.

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 and commercial milestones of up to \$150.0 million, as well as royalties on commercial sales of any such products.

**Table of Contents**

**EXELIXIS, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**March 31, 2011**

**(unaudited)**

*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 and commercial milestones of up to \$150.0 million, as well as royalties on commercial sales of any such products.

*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.

Under the terms of the collaboration agreement, Bristol-Myers Squibb has an exclusive worldwide license to develop and commercialize XL281. We will carry out certain clinical trials of XL281 which may include a backup program on XL281. Bristol-Myers Squibb is responsible for funding all future development of XL281, including our activities. We are 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.

On June 18, 2010, we regained full rights to develop and commercialize cabozantinib under our collaboration agreement with Bristol-Myers Squibb following receipt of notice from Bristol-Myers Squibb of its decision to terminate the 2008 collaboration, 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 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. The collaboration remains in full force and effect with respect to XL281 and the upfront license fees continue to be recognized over the estimated performance obligation which was revised in the second quarter of 2010 and is now expected to be completed during 2013.

The upfront payment of \$195.0 million and the license payments of \$45.0 million are being recognized ratably from the effective date of the agreement over the estimated development term and recorded as license revenues. Any milestone payments that we may receive under the collaboration agreement will be recognized ratably over the remaining development term but recorded as contract revenues. We record as operating expense 100% of the cost incurred for work performed by us under the collaboration agreement. Prior to the termination of the collaboration as to cabozantinib, there were periods during which Bristol-Myers Squibb partially reimbursed us for certain research and development expenses, and other periods during which we owed Bristol-Myers Squibb for research and development expenses that Bristol-Myers Squibb incurred on the development of cabozantinib, less amounts reimbursable to us by Bristol-Myers Squibb for both cabozantinib and XL281. Due to the termination of the collaboration in June 2010 with respect to cabozantinib and the work we are conducting for XL281, during the fiscal year ended December 31, 2010 and in future fiscal years, we were and will continue to be in a net receivable position, and will therefore present these reimbursement payments as collaboration reimbursement revenues.

Amounts attributable to programs under the 2008 Bristol-Myers Squibb collaboration agreement consisted of the following (in thousands):

	<b>Three months Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
Exelixis research and development expenses (1)	\$ 611	\$ 19,896
Net amount due from (owed to) collaboration partner	\$ 694	\$ (2,106)

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

---

**Table of Contents****EXELIXIS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****March 31, 2011****(unaudited)***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.

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. As of the effective date in November 2010, we are recognizing the \$20.0 million payment plus the remaining deferred revenue balance of \$15.5 million from the original 2007 cancer agreement, over the obligation period of 3.5 years as determined by the new ROR collaboration. 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 and we completed a technology transfer during 2010 to enable Bristol-Myers Squibb to continue the LXR program.

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

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

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 under the collaboration.

### **sanofi-aventis**

In May 2009, we entered into a global license agreement with sanofi-aventis for XL147 and XL765 and a broad collaboration for the discovery of inhibitors of phosphoinositide-3 kinase ( 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),



**Table of Contents**

**EXELIXIS, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**March 31, 2011**

**(unaudited)**

less applicable withholding taxes of \$7.0 million, for a net receipt of \$133.0 million. We expect to receive a refund payment from the French government at the end of 2011 with respect to the withholding taxes previously withheld.

Under the license agreement, sanofi-aventis 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-aventis is responsible for funding all development activities with respect to XL147 and XL765, including our activities. Following the effectiveness of the license agreement, we have been conducting the majority of the clinical trials for XL147 and XL765 at the expense of sanofi-aventis. As provided for under the license agreement, however, the parties have agreed to transition all future development activities for these compounds to sanofi-aventis. The parties anticipate that the transition will be completed by the end of the second quarter of 2011. As a result of the transition of development activities to sanofi-aventis, we expect to no longer receive reimbursements from sanofi-aventis with respect to XL147 and XL765 and we plan to reduce our development capacity such that no further operating expenses will be incurred in connection with these programs once the transition is complete.

Under the collaboration agreement, the parties 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-a and -β. sanofi-aventis will continue to provide us with guaranteed annual research and development funding during the research term and is 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 are entitled to receive guaranteed research funding of \$21.0 million over three years to cover certain of our costs under the collaboration agreement. sanofi-aventis will have sole responsibility for all subsequent clinical, regulatory, commercial and manufacturing activities of any products arising from the collaboration; however, we may be requested to conduct certain clinical trials at sanofi-aventis expense. The research term under the collaboration is three years, although sanofi-aventis has the right to extend the term for an additional one-year period upon prior written notice.

For both the license and the collaboration combined, we will be eligible to receive development, regulatory and commercial milestones of over \$1.0 billion in the aggregate, as well as royalties on sales of any products commercialized under the license or collaboration. The aggregate upfront payments of \$140.0 million will be recognized over the estimated research and development term of four years, and recorded as license revenues, from the effective date of the agreements.

sanofi-aventis 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-aventis' 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-aventis to research, develop and commercialize such products.

The collaboration will automatically terminate under certain circumstances upon the expiration of the research term, in which case all licenses granted by the parties to each other would terminate and revert to the respective party, subject to sanofi-aventis' right to receive, under certain circumstances, the first opportunity to obtain a license from us to any isoform-selective PI3K inhibitor. In addition, sanofi-aventis may, upon certain prior written notice to us, terminate the collaboration in whole or as to certain products following expiration of the research term, in which case we would receive, subject to certain terms, conditions and potential payment obligations by us, licenses from sanofi-aventis to research, develop and commercialize such products.

**NOTE 5: Restructurings**

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 the termination of 24 employees, for an aggregate reduction in headcount from both the March 2011 and 2010 restructuring plans of 410 employees. Of these reductions in headcount, 43 employees are continuing to provide service through various dates in 2011. The restructuring plans are a consequence of our decision to focus our resources and development efforts on the late-stage development and commercialization of our most advanced compound cabozantinib. Further personnel reductions are expected

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

to be made through the end of 2012 as we complete our obligations under collaboration agreements and withdraw resources from completed projects.

In connection with the 2010 and 2011 restructuring plans, we have recorded aggregate restructuring charges of \$37.5 million of which \$19.2 million related to termination benefits and \$18.3 million related to facility-related charges and the impairment of various assets. In connection with these restructuring plans, \$4.8 million was recorded during the first quarter of 2011, of which \$3.5 million was associated with lease-exit costs in connection with the exit and potential sublease of a single floor of one of our facilities in South San Francisco, California. The balance of the restructuring charges taken during the first quarter of 2011 primarily related to termination benefits for employees who will cease providing services during 2011.

With respect to our restructuring plans, we expect to incur an additional restructuring charge of \$1.6 million relating to the sublease and exit of one of our facilities in South San Francisco, California plus additional restructuring charges in the range of \$23 million to \$28 million, in connection with the anticipated sublease and complete exit of two other facilities in South San Francisco,

**Table of Contents****EXELIXIS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****March 31, 2011****(unaudited)**

California. We expect to record \$0.3 million of additional termination benefits and the majority of the facility-related charges discussed above as they are determined during the fiscal year ending December 31, 2011.

As of March 31, 2011, the 2010 restructuring plans have resulted in aggregate cash expenditures of \$20.3 million. We expect to pay an additional \$9.8 million, net of cash received from our subtenant, for the South San Francisco facility that we exited in June 2010. In addition, we expect to make cash expenditures in the range of \$30 million to \$35 million, including facility-related charges in connection with the anticipated sublease and complete exit of two of our buildings in South San Francisco, California and \$2.2 million relating to termination benefits. We expect the termination benefits to be paid during the second and third quarters of 2011 and the facility costs to be paid through 2017, or the end of our lease term.

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 March 2011 in connection with the 2010 and 2011 plans. As of March 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>
Balance as of December 31, 2010	\$ 5,523	\$ 8,688	\$	\$ 70	\$ 14,281
Restructuring charge recorded in 2011	1,543	3,519	(320)	25	4,767
Cash payments	(5,147)	(795)	(28)	(10)	(5,980)
Adjustments or non-cash credits including stock compensation expense	(550)	(62)	348		(264)
Ending accrual balance as of March 31, 2011	\$ 1,369	\$ 11,350	\$	\$ 85	\$ 12,804

**NOTE 6. 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 \$179.3 million in net proceeds from the offering after deducting the underwriting discount and related offering expenses.

---

**Table of Contents****ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*The following discussion and analysis contains 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 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, goal, objective, will, may, could, would, 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 Part II, Item 1A of this Form 10-Q, as well as those discussed elsewhere in this report.*

*This discussion and analysis should be read in conjunction with our financial statements and accompanying notes included in this report and the financial statements and accompanying notes thereto included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010, filed with the Securities and Exchange Commission, or SEC, on February 22, 2011. Operating results are not necessarily indicative of results that may occur in future periods. 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 resources and development efforts exclusively on cabozantinib (XL184), our most advanced compound, 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, most of which are being advanced by partners as part of collaborations.

Cabozantinib inhibits MET, VEGFR2 and RET, proteins that are key drivers of tumor growth and/or vascularization. Cabozantinib is the most advanced inhibitor of MET in clinical development and 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 ovarian cancer, based on encouraging interim data that has emerged from a randomized discontinuation trial investigating cabozantinib in nine distinct tumor types. Cabozantinib is also being studied in an ongoing global phase 3 registration trial in medullary thyroid cancer. We expect to release top-line results from the phase 3 trial during the middle of 2011 and to potentially submit a new drug application, or NDA, for cabozantinib as a treatment for medullary thyroid cancer in the United States by the end of 2011.

Based on the strength of our expertise in biology, drug discovery and development, we have established collaborations with leading pharmaceutical and biotechnology companies, including Bristol-Myers Squibb Company, sanofi-aventis, Genentech, Inc. (a wholly owned member of the Roche Group), Boehringer Ingelheim GmbH, GlaxoSmithKline and Daiichi Sankyo Company Limited for the majority of the remaining 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. With respect to our partnered compounds, we are eligible to receive potential milestone payments under our collaborations totaling approximately \$3.7 billion in the aggregate on a non-risk adjusted basis, of which 13% are related to clinical development milestones, 47% are related to regulatory milestones and 40% are related to commercial milestones.

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 near-term 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.

As part of our ongoing efforts to manage costs and our strategy to focus our resources and development efforts on our most advanced compound, cabozantinib, we implemented two restructuring plans during 2010 and an additional restructuring plan in March 2011 that resulted in an overall reduction in our workforce by 410 employees. Personnel reductions were made across our entire organization, including discovery, development and general & administrative departments. We expect to make additional reductions through the end of 2012 as we complete our obligations under collaboration agreements and withdraw resources from completed projects. 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 actively pursuing collaborations or other external opportunities for the continued development of these compounds and programs. Discovery and clinical activities under various collaborations will continue to be funded by partners until we complete our contractual

obligations.

---

## **Table of Contents**

Such funded programs include XL147, XL765 and isoform-selective phosphoinositide-3 kinase, or PI3K, inhibitors in collaboration with sanofi-aventis, our sphingosine-1-phosphate type 1 receptor, or S1P1 receptor, collaboration with Boehringer Ingelheim and XL281 and our ROR collaboration with Bristol-Myers Squibb.

### **Cabozantinib**

Cabozantinib is a first-in-class inhibitor of tumor growth, metastasis and angiogenesis that simultaneously targets MET, VEGFR2 and RET, which are key kinases involved in the development and progression of many cancers. It has recently been shown in preclinical models that treatment with selective inhibitors of VEGF signaling can result in tumors that are more invasive and aggressive compared to control treatment. In preclinical studies, upregulation of MET has been shown to occur in concert with development of invasiveness after selective anti-VEGF therapy, and may constitute a mechanism of acquired or evasive resistance to agents that target VEGF signaling without inhibiting MET. Accordingly, treatment with cabozantinib in similar preclinical studies resulted in tumors that were less invasive and aggressive compared to control or selective anti-VEGF treatment. Therefore, we believe that cabozantinib has the potential for improving outcomes in a range of indications, including those where selective anti-VEGF therapy has shown minimal or no activity.

The current clinical program for cabozantinib is focused on the treatment of metastatic castration-resistant prostate cancer and ovarian cancer, based on encouraging interim data that has emerged from a randomized discontinuation trial, or RDT, investigating cabozantinib in nine distinct tumor types. Data from the RDT were released at the American Society of Clinical Oncology, or ASCO, Annual Meeting in June 2010 and demonstrated broad activity for cabozantinib across multiple tumor types, in particular, metastatic castration-resistant prostate, ovarian, non-small cell lung and hepatocellular cancers. Updated interim data presented at the 22<sup>nd</sup> EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics in November 2010, or the 2010 EORTC Symposium, and at the ASCO 2011 Genitourinary Cancers Symposium in February 2011 suggest that cabozantinib has a novel and differentiated clinical profile in metastatic castration-resistant prostate cancer and ovarian cancer. The data presented indicate that cabozantinib has shown novel activity against bone and soft tissue lesions in patients with metastatic castration-resistant prostate cancer. In addition, we have observed resolution of metastatic bone lesions on bone scan in patients with metastatic breast cancer, renal cell carcinoma, thyroid cancer and melanoma. Another priority for us will be to generate additional data in the various other cohorts of the RDT, including melanoma, breast cancer, non-small cell lung cancer and hepatocellular cancer, to support further prioritization of our clinical and commercial options. In addition, we are conducting ongoing exploratory clinical trials for cabozantinib in other tumor types, including renal cell carcinoma. Objective tumor responses have been observed in patients with cabozantinib in 12 of 13 unique tumor types investigated to date, reflecting the broad potential clinical activity and commercial opportunity with this new agent.

We also are focusing our efforts on our ongoing phase 3 clinical trial of cabozantinib as a potential treatment for medullary thyroid cancer. This registration trial was initiated in July 3, 2008 following agreement between the United States Food and Drug Administration, or FDA, and us on the trial design through the FDA's Special Protocol Assessment process. We expect to release top-line results from the phase 3 trial during the middle of 2011 and to potentially submit an NDA for cabozantinib as a treatment for medullary thyroid cancer in the United States by the end of 2011.

In January 2011, we announced that 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 U.S. 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.

In April 2011, the FDA designated cabozantinib as a Fast Track development program for patients with unresectable, locally advanced or metastatic medullary thyroid carcinoma. The Fast Track process is designed to facilitate the development, and expedite the review of drugs to treat serious diseases and fill an unmet medical need. A drug that receives Fast Track designation is eligible for rolling review, which means that a drug company can submit completed sections of its NDA for review by the FDA. In addition, most drugs that receive Fast Track designation are likely to be considered appropriate to receive a priority review.

---

## **Table of Contents**

### **Recent Developments**

#### ***2011 Public Offering***

On March 15, 2011, we completed an underwritten public offering of 17,250,000 shares of our common stock, including 2,250,000 shares sold pursuant to the full exercise of an option granted to the underwriters to purchase additional shares. Our aggregate net proceeds from the offering were \$179.3 million after deducting the underwriting discount and related offering expenses.

#### ***Acceptance of Cabozantinib Abstracts for Presentation at American Society of Clinical Oncology (ASCO)***

Three abstracts for cabozantinib have been accepted for oral presentation at the 2011 ASCO Annual Meeting, which will be held June 3-7 in Chicago, Illinois. Data from the castration-resistant prostate cancer and ovarian cancer cohorts of the RDT as well as the overall RDT will be the subject of three distinct oral presentations at ASCO.

### **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.

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

In December 2008, we entered into a worldwide collaboration with Bristol-Myers Squibb for cabozantinib and XL281. 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 June 18, 2010, we regained full rights to develop and commercialize cabozantinib under our collaboration agreement with Bristol-Myers Squibb following receipt of notice from Bristol-Myers Squibb of its decision to terminate the 2008 collaboration, 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 relating to cabozantinib terminated and its rights to cabozantinib reverted to us, and we received, subject to certain terms and conditions, licenses from Bristol-Myers Squibb to research, develop and commercialize cabozantinib.

We are focusing our 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 actively pursuing collaborations or other external opportunities for the continued development of these compounds and programs. Discovery and clinical activities under various collaborations are expected to continue at funded levels 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 March 31, 2011, we had \$391.7 million in cash and cash equivalents, marketable securities and long-term investments, which included restricted cash and investments of \$4.2 million and approximately \$94.6 million of cash and cash equivalents and marketable securities that we are required to maintain on deposit with Silicon Valley Bank pursuant to covenants in our loan and security agreement with Silicon Valley Bank. We anticipate that our current cash and cash equivalents, marketable securities, long-term investments and funding that we expect to receive from existing collaborators 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 repay amounts outstanding under our loan and security agreement with GlaxoSmithKline in cash or shares of our common stock;

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 GlaxoSmithKline, 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 making any

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

optional or mandatory prepayment in cash, at any time after July 1, 2011, 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, at any time after July 1, 2011, 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.

---

**Table of Contents**

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. We are required to maintain at all times on deposit in a non-interest bearing demand deposit account(s) with Silicon Valley Bank or one of its affiliates a compensating balance, which constitutes 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. 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 6.00%. 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.

We are also required to maintain at all times on deposit in a non-interest bearing demand deposit account(s) with Silicon Valley Bank or one of its affiliates, funds equal to the amount of proceeds we have drawn with respect to equipment lines of credit under our loan and security agreement with Silicon Valley Bank.

***sanofi-aventis***

In May 2009, we entered into a global license agreement with sanofi-aventis for XL147 and XL765 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 expect to receive a refund payment from the French government in 2011 with respect to the withholding taxes previously withheld.

Under the license agreement, sanofi-aventis 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-aventis is responsible for funding all development activities with respect to XL147 and XL765, including our activities. Following the effectiveness of the license agreement, we have been conducting the majority of the clinical trials for XL147 and XL765 at the expense of sanofi-aventis. As provided for under the license agreement, however, the parties have agreed to transition all future development activities for these compounds to sanofi-aventis. The parties anticipate that the transition will be completed by the end of the second quarter of 2011. As a result of the transition of development activities to sanofi-aventis, we expect to no longer receive reimbursements from sanofi-aventis with respect to XL147 and XL765 and we plan to reduce our development capacity such that no further operating expenses will be incurred in connection with these programs once the transition is complete.

Under the collaboration agreement, the parties 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-aventis will continue to provide us with guaranteed annual research and development funding during the research term and is responsible for funding all development activities for each product following approval of the investigational new drug application filed with the applicable regulatory authorities for such product. We are entitled to receive guaranteed research funding of \$21.0 million over three years to cover certain of our costs under the collaboration agreement. sanofi-aventis will have sole responsibility for all subsequent clinical, regulatory, commercial and manufacturing activities of any products arising from the collaboration; however, we may be requested to conduct certain clinical trials at sanofi-aventis expense. The research term under the collaboration is three years, although sanofi-aventis has the right to extend the term for an additional one-year period upon prior written notice.

For both the license and the collaboration combined, we will be eligible to receive development, regulatory and commercial milestones of over \$1.0 billion in the aggregate, as well as royalties on sales of any products commercialized under the license or collaboration.

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

sanofi-aventis 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-aventis license relating to such product would terminate and revert to us, and we would

---

**Table of Contents**

receive, subject to certain terms, conditions and potential payment obligations, licenses from sanofi-aventis to research, develop and commercialize such products.

The collaboration will automatically terminate under certain circumstances upon the expiration of the research term, in which case all licenses granted by the parties to each other would terminate and revert to the respective party, subject to sanofi-aventis' right to receive, under certain circumstances, the first opportunity to obtain a license from us to any isoform-selective PI3K inhibitor. In addition, sanofi-aventis may, upon certain prior written notice to us, terminate the collaboration in whole or as to certain products following expiration of the research term, in which case we would receive, subject to certain terms, conditions and potential payment obligations by us, licenses from sanofi-aventis to research, develop and commercialize such products.

***Restructuring Plans***

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 the termination of 24 employees, for an aggregate reduction in headcount from both the March 2011 and 2010 restructuring plans of 410 employees. Of these reductions in headcount, 43 employees are continuing to provide service through various dates in 2011. The restructuring plans are a consequence of our decision to focus our resources and development efforts on the late-stage development and commercialization of our most advanced compound cabozantinib. Further personnel reductions are expected to be made through the end of 2012 as we complete our obligations under collaboration agreements and withdraw resources from completed projects.

In connection with the 2010 and 2011 restructuring plans, we have recorded aggregate restructuring charges of \$37.5 million of which \$19.2 million related to termination benefits and \$18.3 million related to facility-related charges and the impairment of various assets. In connection with these restructuring plans, \$4.8 million was recorded during the first quarter of 2011, of which \$3.5 million was associated with lease-exit costs in connection with the exit and potential sublease of a single floor of one of our facilities in South San Francisco, California. The balance of the restructuring charges taken during the first quarter of 2011 primarily related to termination benefits for employees who will cease providing services during 2011.

With respect to our restructuring plans, we expect to incur an additional restructuring charge of \$1.6 million relating to the sublease and exit of one of our facilities in South San Francisco, California plus additional restructuring charges in the range of \$23 million to \$28 million, in connection with the anticipated sublease and complete exit of two other facilities in South San Francisco, California. We expect to record \$0.3 million of additional termination benefits and the majority of the facility-related charges discussed above as they are determined during the fiscal year ending December 31, 2011.

As of March 31, 2011, the 2010 restructuring plans have resulted in aggregate cash expenditures of \$20.3 million. We expect to pay an additional \$9.8 million, net of cash received from our subtenant, for the South San Francisco facility that we exited in June 2010. In addition, we expect to make cash expenditures in the range of \$30 million to \$35 million, including facility-related charges in connection with the anticipated sublease and complete exit of two of our buildings in South San Francisco, California and \$2.2 million relating to termination benefits. We expect the termination benefits to be paid during the second and third quarters of 2011 and the facility costs to be paid through 2017, or the end of our lease term.

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 plan.

***GlaxoSmithKline Loan Repayment Obligations***

In October 2002, we entered into a collaboration with GlaxoSmithKline to discover and develop novel therapeutics in the areas of vascular biology, inflammatory disease and oncology. As part of the collaboration, we entered into a loan and security agreement with GlaxoSmithKline, pursuant to which we borrowed \$85.0 million for use in our efforts under the collaboration. The loan bears interest at a rate of 4.0% per annum and is secured by certain intellectual property, technology and equipment created or utilized pursuant to the collaboration. On October 27, 2010, we paid approximately \$37.0 million in cash to GlaxoSmithKline as the second of three installments of principal and accrued interest due under the loan agreement. After giving effect to all repayments made, as of March 31, 2011, the aggregate principal and interest outstanding under the loan was \$36.2 million. The final installment of principal and accrued interest under the loan is due October 27, 2011. Repayment of all or any of the amounts advanced to us under the loan agreement may, at our election, be made in the form of our common stock at fair market value, subject to certain conditions, or cash. In the event the market price for our common stock is depressed, we may not be able to repay the loan 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

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

shares of our common stock to repay the loan 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 that we will have sufficient funds to repay amounts

**Table of Contents**

outstanding under the loan when due or that we will satisfy the conditions to our ability to repay the loan in shares of our common stock.

**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. For example, in the fourth quarter of 2010, in association with the new ROR agreement with Bristol-Myers Squibb, the estimated research term under our 2007 cancer collaboration with Bristol-Myers Squibb was extended from December 2011 until April 2014, resulting in an extension in the period over which we recognized milestone revenues and a decrease in the milestone revenues recognized each quarter. 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 cancer collaboration with Bristol-Myers Squibb, we estimated our term to be through August 2013, which is the estimated term of our performance obligations for XL281. We estimate that this is the period over which we are 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. 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 cancer collaboration with Bristol-Myers Squibb and prior to its termination by Bristol-Myers Squibb as to cabozantinib, 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, are recorded as collaboration reimbursement revenues. Conversely, research and development expenses may include the net settlement of amounts we owe 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 on 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 are 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

---

**Table of Contents**

statement of operations. Notwithstanding termination by Bristol-Myers Squibb, revenues from the 2008 cancer collaboration will continue to be determined and reflected on an annual basis.

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 2008, under our collaboration with GlaxoSmithKline, we accelerated \$18.5 million in previously deferred revenue as a result of the development term concluding on the earliest scheduled end date of October 27, 2008, instead of the previously estimated end date of October 27, 2010.

***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 study. 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 study. 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.

***Stock Option Valuation***

Our estimate of compensation expense requires us to determine the appropriate fair value model and a number of complex and subjective assumptions including our stock price volatility, employee exercise patterns, future forfeitures and related tax effects. The most significant assumptions are our estimates of the expected volatility and the expected term of the award. 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 March 31, 2011, \$10.3 million of total unrecognized compensation expense related to stock options was expected to be recognized over a weighted-average period of 2.02 years in addition to \$8.2 million of total unrecognized compensation expense relating to restricted stock units, which was expected to be recognized over 2.93 years. See Note 3 of the Notes to Consolidated Financial Statements for a further discussion on stock-based compensation.

***Restructuring Charges***

We record costs and liabilities associated with exit and disposal activities at fair value in the period in which the cost or liability is incurred. Restructuring charges consist of charges related to employee severance and benefits, lease termination costs, equipment write-downs and other restructuring related charges. Charges related to employee severance and benefits are determined based on the estimated severance and fringe benefit charge for identified employees. Our facility charges are based upon our ability to vacate certain of our facilities and the timing and nature of potential future sublease rates. Based on our future equipment needs, we have disposed of certain assets no longer in use and recorded



a charge to impair the book value to an amount relative to our expected future use of the remaining assets.

**Table of Contents**

If the actual amounts differ from our estimates, the amount of restructuring charges could be materially impacted. See Note 5 of the Notes to Consolidated Financial Statements for a further discussion on our restructuring plan.

**Fiscal Year Convention**

We have adopted a 52- or 53-week fiscal year that ends on the Friday closest to December 31<sup>st</sup> of each year. Fiscal year 2010, a 52-week year, ended on December 31, 2010, and fiscal year 2011, a 52-week year, will end on December 30, 2011. For convenience, references in this report as of and for the fiscal quarters ended April 2, 2010 and April 1, 2011 and as of the fiscal year ending December 30, 2011 are indicated as ended March 31, 2010 and 2011 and as ending December 31, 2011, respectively.

**Results of Operations*****Revenues***

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

	<b>Three Months Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
Contract revenue:		
Research and development funding	\$ 9.8	\$