

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
Total current assets	324,209	183,486
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
Total assets	\$ 495,736	\$ 360,790
<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
Total current liabilities	198,123	199,941
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
Total liabilities	564,485	589,115
Commitments		
Stockholders' deficit:		
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)
Total stockholders' deficit	(68,749)	(228,325)
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>
Revenues:		
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>
Operating expenses:		
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>
Other income (expense):		
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>
Cash flows from operating activities:		
Net loss	\$ (27,490)	\$ (43,249)
Adjustments to reconcile net loss to net cash used in operating activities:		
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
Changes in assets and liabilities:		
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)
Net cash used in operating activities	(43,276)	(53,739)
Cash flows from investing activities:		
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)
Net cash (used in) provided by investing activities	(31,502)	27,611
Cash flows from financing activities:		
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)
Net cash provided by (used in) financing activities	179,389	(2,376)
Net increase in cash and cash equivalents	104,611	(28,504)
Cash and cash equivalents, at beginning of period	97,440	86,796
Cash and cash equivalents, at end of period	\$ 202,051	\$ 58,292

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
Total	\$ 392,519	18	\$ (50)	\$ 392,487
	<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
Total	\$ 392,519	18	\$ (50)	\$ 392,487

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
-------	------------	-------	---------	------------

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

**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
Total antidilutive shares	25,170,820	39,569,841

**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):

	Three Months Ended March 31,
	2011
	2010

## 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):

	Three Months Ended March 31,	
	2011	2010
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>
	<b>(1)</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):

# Edgar Filing: EXELIXIS INC - Form 10-Q

	Three months Ended March 31,	
	2011	2010
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- $\alpha$  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, 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	\$ 11.1
Milestones	2.6	8.6
License revenue, amortization of upfront payments, including amortization of premiums for equity purchases	22.8	24.6
Collaboration reimbursements	0.7	(2.1)
Total revenues	\$ 35.9	\$ 42.2
Dollar decrease	\$ 6.3	
Percentage decrease	14.9%	

Total revenues by customer, 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>
sanofi-aventis	\$ 18.6	\$ 19.7
Bristol-Myers Squibb	16.8	14.1
Boehringer Ingelheim	0.5	1.4
Genentech		7.0
Total revenues	\$ 35.9	\$ 42.2
Dollar decrease	\$ 6.3	
Percentage decrease	14.9%	

The decrease in revenues for the three months ended March 31, 2011, as compared to the prior year period, was primarily due to a one-time milestone payment of \$7.0 million in 2010 related to our MEK collaboration with Genentech. In addition, there was a decrease in license revenue in 2011 related to our amended 2007 collaboration with Bristol-Myers Squibb Company, or Bristol-Myers Squibb, as a result of an extension to the duration of our performance obligations under the agreement resulting in a reduction, in the current period, in revenue recognition related to the upfront payment. These decreases were partially offset by an increase in collaboration reimbursement revenue in 2011 related to our 2008 cancer collaboration with Bristol-Myers Squibb for cabozantinib and XL281 and our new collaboration with Bristol-Myers Squibb for TGR5.

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

Total collaboration reimbursement revenue consisted of research and development expenses and reimbursements related to our 2008 cancer collaboration agreement with Bristol Myers-Squibb for cabozantinib and XL281. To the extent that net annual research and development funding payments are expected to be received from Bristol-Myers Squibb, these payments will be presented as collaboration reimbursement revenues. In years when net research and development funding payments were expected to be payable to Bristol-Myers Squibb, these payments would have been presented as collaboration cost-sharing expense. For the year ended December 31, 2010, we received net collaboration reimbursement revenues. However, for the three months ended March 31, 2011, we recorded a net payable to Bristol-Myers Squibb, resulting in negative revenues of \$2.1 million. For the year ending December 31, 2011 and for future years, due to the termination of the collaboration in June 2010 with respect to cabozantinib and the work we are conducting for XL281, we expect to record only collaboration reimbursement revenues and do not expect any further collaboration reimbursement revenues to be recognized with respect to cabozantinib.

**Table of Contents****Research and Development Expenses**

Total research and development expenses, 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>
Research and development expenses	\$ 45.7	\$ 64.8
Dollar decrease	\$ 19.1	
Percentage decrease	29.4%	

The decrease for the three months ended March 31, 2011, as compared to the comparable period in 2010, resulted primarily from the following:

**Personnel** Personnel expense, which includes salaries, bonuses, related fringe benefits, recruiting and relocation costs, decreased by \$7.8 million, or 45%, primarily due to the reduction in headcount resulting from our restructuring plans implemented in March and December 2010.

**Laboratory Supplies** Laboratory supplies decreased by \$3.1 million, or 81%, primarily due to the decrease in headcount and other cost cutting measures as a result of our March and December 2010 restructuring plans.

**General Corporate Costs** There was a decrease of \$2.5 million, or 24%, in the allocation of general corporate costs (such as facility costs, property taxes and insurance) to research and development, primarily as a result of a decrease in personnel and the exit of certain facilities in San Diego and South San Francisco, as a result of our March and December 2010 restructuring plans, and the resulting decrease in costs to be allocated.

**Stock-Based Compensation** Stock-based compensation expense decreased by \$1.9 million, or 51%, as a result of our reduction in headcount from our March and December 2010 restructuring plans.

**Clinical Trials** Clinical trial expenses, which include services performed by third-party contract research organizations and other vendors, decreased by \$1.1 million, or 5%, primarily due to the wind-down of activities associated with XL184-201 (GBM study), XL228 and XL388 trials, the transfer of XL413 and XL139 to Bristol Myers-Squibb, and the decrease in patient activity for XL281 trials. These decreases were partially offset by an increase in clinical trial and manufacturing activities for cabozantinib and XL765.

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

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

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

expenses to relate to the clinical development of cabozantinib.

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

	Three Months Ended March 31,		Inception to date (1)
	2011	2010	
Drug discovery	\$ 5.7	\$ 20.6	\$ 444.3
Development	38.0	39.4	619.0
Other	2.0	4.8	96.1
Total	\$ 45.7	\$ 64.8	\$ 1,159.4

**Table of Contents**

(1) Inception is as of January 1, 2006, the date on which we began tracking research and development expenses by category. While we do not track total research and development expenses separately for each program, beginning in fiscal 2006, we began tracking third party expenditures directly relating to each program as a way of monitoring external costs. Our third party research and development expenditures relate principally to our clinical trial and related development activities, such as preclinical and clinical studies and contract manufacturing, and represent only a portion of the costs related to each program. Third party expenditures for programs initiated prior to the beginning of fiscal 2006 have not been tracked from project inception, and therefore such expenditures from the actual inception for most of our programs are not available. We do not accumulate on a program-specific basis internal research and development expenses, such as salaries and personnel expenses, facilities overhead expenses and external costs not directly attributable to a specific project. Nevertheless, we believe that third party expenditures by program provide a reasonable estimate of the percentage of our total research and development expenses that are attributable to each such program. For the three months ended March 31, 2011, the programs representing the greatest portion of our external third party research and development expenditures were cabozantinib (75%), XL147 (15%), XL765 (7%) and XL281 (2%). The expenses for these programs were primarily included in the development category of our research and development expenses and exclude the impact of any amounts reimbursed by our partners.

We do not have reliable estimates regarding the timing of our clinical trials. We estimate that typical phase 1 clinical trials last approximately one year, phase 2 clinical trials last approximately one to two years and phase 3 clinical trials last approximately two to four years. However, the length of time may vary substantially according to factors relating to the particular clinical trial, such as the type and intended use of the drug candidate, the clinical trial design and the ability to enroll suitable patients. In general, we will incur increased research and development expenses for compounds that advance in clinical development, whereas expenses will end for compounds that do not warrant further clinical development.

We do not have reliable estimates of total costs for a particular drug candidate to reach the market. Our potential therapeutic products are subject to a lengthy and uncertain regulatory process that may involve unanticipated additional clinical trials and may not result in receipt of the necessary regulatory approvals. Failure to receive the necessary regulatory approvals would prevent us from commercializing the product candidates affected. In addition, clinical trials of our potential products may fail to demonstrate safety and efficacy, which could prevent or significantly delay regulatory approval.

**General and Administrative Expenses**

Total general and administrative expenses, 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>
General and administrative expenses	\$ 9.2	\$ 8.8
Dollar increase	\$ 0.3	
Percentage increase	3.7%	

The increase in general and administrative expenses for the three months ended March 31, 2011, as compared to the comparable period in 2010, was primarily due to a decrease in allocation of general corporate costs to research and development as a result of the reduction in headcount from our March and December 2010 restructuring plans, in addition to an increase in marketing and promotional expenses relating to cabozantinib. This increase was partially offset by a decrease in personnel and facility costs relating to our March and December 2010 restructurings.

**Restructuring Charge**

	<b>Three Months Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
Restructuring charge	\$ 4.8	\$ 16.1
Dollar change	\$ 11.3	
Percentage decrease	70.3%	

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

As part of our ongoing efforts to manage costs and our strategy to focus our resources and development efforts our most advanced compound, cabozantinib, we implemented two restructuring plans during 2010 resulting in an aggregate reduction of 410 employees, including 24 employees who were notified during March 2011. The restructuring charge taken in 2010 primarily related to termination benefits for the initial reduction in 243 positions, while the restructuring charge taken in 2011 related primarily to facility charges in

**Table of Contents**

association with the exit and potential sublease of one of our South San Francisco buildings. As a result of our December 2010 restructuring plan, we expect to incur additional restructuring charges, primarily related to facility costs, through the end of 2017.

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

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

	<b>Three Months Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
Total other income (expense), net	\$ (3.8)	\$ 4.2
Dollar change	\$ 8.0	
Percentage change	189.5%	

Total other income (expense), net consists primarily of interest income earned on our marketable securities and gains on sales of businesses, offset by interest expense incurred on our notes payable, bank obligations, capital lease obligations, convertible notes and loans and our credit facility. The change in total other income for the three months ended March 31, 2011, as compared to the comparable period in 2010, was primarily due to increased interest expense as a result of our entry into a note purchase agreement with Deerfield in June 2010 in addition to the recording of a \$4.5 million gain in 2010 relating to the sale of our plant trait business.

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

The following table summarizes our cash flow activities for the three months ended March 31, 2011 and 2010 (dollar amounts presented in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
Consolidated net loss	\$ (27,490)	\$ (43,249)
Adjustments to reconcile net loss to net cash provided by operating activities	9,456	8,510
Changes in operating assets and liabilities	(25,242)	(19,000)
Net cash used in operating activities	(43,276)	(53,739)
Net cash (used in) provided by investing activities	(31,502)	27,611
Net cash provided by (used in) financing activities	179,389	(2,376)
Net increase (decrease) in cash and cash equivalents	104,611	(28,504)
Cash and cash equivalents, at beginning of period	97,440	86,796
Cash and cash equivalents, at end of period	\$ 202,051	\$ 58,292

To date, we have financed our operations primarily through the sale of equity, payments and loans from collaborators and banks, debt-financing arrangements and equipment financing facilities. We have also financed certain of our research and development activities under our agreements with various collaborators. As of 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. In addition, as of March 31, 2011, approximately \$94.6 million of cash and cash equivalents and marketable securities served as collateral under our loan and security agreement with Silicon Valley Bank.

***Operating Activities***

Our operating activities used cash of \$43.3 million for the three months ended March 31, 2011, compared to cash used of \$53.7 million for the comparable period in 2010. Cash used by operating activities for the 2011 period related primarily to our net loss of \$27.5 million, in addition to a \$25.4 million reduction in deferred revenue, a decrease in our restructuring liability of \$1.5 million and an increase in our prepaid and other

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

current assets of \$1.3 million. These increases in cash used were partially offset by non-cash charges totaling \$8.9 million relating to stock-based compensation, depreciation and amortization, accretion of implied interest under our 2010 note purchase agreement with Deerfield and impairment of assets due to our March and December 2010 restructuring plans. In addition, we had an increase in our accounts payable and other accrued liabilities of \$2.9 million.

Cash used by operating activities for the 2010 period related primarily to our net loss of \$43.2 million, in addition to a \$26.4 million reduction in deferred revenue and an increase in current assets of \$3.4 million. These increases in cash used were partially offset by non-cash charges totaling \$12.1 million relating to stock-based compensation and depreciation and amortization and asset

## **Table of Contents**

impairment as a result of our restructuring. In addition, we had increases in our accrued liabilities relating to our March 2010 restructuring and decreases in our receivables balance relating to our collaboration partners.

### *Investing Activities*

Our investing activities used cash of \$31.5 million for the three months ended March 31, 2011, compared to cash provided of \$27.6 million for the comparable period in 2010. Cash used by investing activities for the 2011 period was primarily driven by the purchase of \$60.0 million of marketable securities. This use of cash was offset by proceeds from the maturity of marketable securities of \$26.7 million and a decrease in restricted cash of \$2.2 million.

Cash provided by investing activities for the 2010 period was primarily driven by proceeds from the maturity of marketable securities of \$34.0 million in addition to the sale of investments prior to maturity of \$12.8 million and an additional gain of \$4.5 million associated with our 2007 transaction with Agrigenetics. These cash proceeds were offset by the purchase of \$23.6 million of marketable securities and additional purchases of property and equipment of \$0.3 million. The proceeds provided by the sale and maturity of our investments were used to fund our operations.

### *Financing Activities*

Our financing activities provided cash of \$179.4 million for the three months ended March 31, 2011, compared to cash used of \$2.4 million for the comparable period in 2010. Cash provided by our financing activities for the 2011 period was due to proceeds from the issuance of 17.3 million shares of common stock for net proceeds of \$179.3 million and proceeds from the exercise of stock options of \$3.8 million partially offset by cash used for principal payments on notes payable and bank obligations of \$3.8 million. Cash used by our financing activities for the 2010 period was due to principal payments on notes payable and bank obligations of \$3.2 million offset by proceeds from employee option exercises of \$0.9 million.

We finance property and equipment purchases through equipment financing facilities, such as bank notes payable. Proceeds from collaboration loans and common stock issuances are used for general working capital purposes, such as research and development activities and other general corporate purposes. Over the next several years, we are required to make certain payments on notes and our loan from GlaxoSmithKline.

### *Cash Requirements*

We have incurred net losses since inception, including a net loss of \$27.5 million for three months ended March 31, 2011. While we expect our net loss in 2011 to decrease compared to 2010, we anticipate negative operating cash flow for the foreseeable future. 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 will depend on many factors that may require us to use available capital resources significantly earlier than we currently anticipate. These factors include:

the cabozantinib development program We are focusing our resources and development efforts on cabozantinib, our most advanced compound, which is being studied in a variety of tumor types, with the goal of rapidly commercializing the compound. 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 the RDT. Data from the RDT were released at the 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 and hepatoma. Updated interim data presented at 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 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. Objective tumor responses have been observed in patients with cabozantinib in

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

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. In addition, we are conducting ongoing exploratory clinical trials for cabozantinib in other tumor types, including renal cell carcinoma. Our development plan for cabozantinib is dependent on the extent of our available financial resources. There can be no assurance that we will have

**Table of Contents**

sufficient financial resources independently or through other arrangements to fund a broad development plan for cabozantinib. If adequate funds are not available, we may be required to delay, discontinue or elect not to pursue one or more trials for cabozantinib;

repayment of our loan from GlaxoSmithKline In October 2002, we entered into a collaboration agreement with GlaxoSmithKline. 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. 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 on 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 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. However, there can be no assurance that we will have sufficient funds to repay amounts 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;

repayment of the notes under our note purchase agreement with Deerfield On June 2, 2010, we entered into a note purchase agreement with Deerfield, pursuant to which, on July 1, 2010, we sold to Deerfield an aggregate of \$124.0 million initial principal amount of our secured convertible notes, due June 2015, for an aggregate purchase price of \$80.0 million, less closing fees and expenses. The outstanding principal amount of the notes bears interest in the annual amount of \$6.0 million, payable quarterly in arrears. We will be required to make mandatory prepayments on the notes on an annual basis in 2013, 2014 and 2015 equal to 15% of 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 optional or mandatory prepayment in cash, at any time after July 1, 2011, subject to certain limitations, we have the right to convert all or a portion of the principal amount of the notes into, or satisfy all or any portion of the optional prepayment amounts or mandatory prepayment amounts (other than the first \$10.0 million of mandatory prepayments required in 2013 and 2014) with shares of our common stock. Additionally, in lieu of making any payment of accrued and unpaid interest in respect of the notes in cash, 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. In the event the market price for our common stock is depressed, we may not be able to convert the principal amount of the notes or satisfy our payment obligations in full using shares of our common stock due to restrictions in the agreement on the number of shares we may issue. In addition, the issuance of shares of our common stock to convert the notes or satisfy our payment obligations may result in significant dilution to our stockholders. As a result, we may need to obtain additional funding to satisfy our repayment obligations. There can be no assurance that we will have sufficient funds to repay the notes or satisfy our payment obligations under the note purchase agreement when due or that we will comply with the conditions to our ability to convert the principal amount of the notes into or satisfy our payment obligations with shares of our common stock;

repayment of our loan from Silicon Valley Bank On June 2, 2010, we amended our loan and security agreement with Silicon Valley Bank to provide for a new seven-year term loan in an amount of \$80.0 million. The principal amount outstanding under the term loan accrues interest at 1.0% per annum, which interest is due and payable monthly. We are required to repay the term loan in one balloon principal payment, representing 100% of the principal balance and accrued and unpaid interest, on May 31, 2017. We have the option to prepay all, but not less than all, of the amounts advanced under the term loan, provided that we pay all unpaid accrued interest thereon that is due through the date of such prepayment and the interest on the entire principal balance of the term loan that would otherwise have been paid after such prepayment date until the maturity date of the term loan. In accordance with the terms of the loan and security agreement, we are also required to maintain on deposit an amount equal to at least 100% of the outstanding

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

principal balance of the term loan at all times as support for our obligations under the loan and security agreement. As a result, although the proceeds of the new term loan improve our ability to comply with minimum working capital and cash covenants imposed by our debt instruments with GlaxoSmithKline and Deerfield and thus provide us with more flexibility to use our other

## **Table of Contents**

cash resources, the proceeds of the term loan cannot directly be used to satisfied our other obligations without causing a default under our loan and security agreement with Silicon Valley Bank;

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

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

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

our ability to control costs;

our ability to remain in compliance with, or amend or cause to be waived, financial covenants contained in agreements with third parties;

the amount of our cash and cash equivalents and marketable securities that serve as collateral for bank lines of credit;

future clinical trial results;

our need to expand our product and clinical development efforts;

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

the cost and timing of regulatory approvals;

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

the effect of competing technological and market developments;

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

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

One or more of these factors or changes to our current operating plan may require us to use available capital resources significantly earlier than we anticipate. If our capital resources are insufficient to meet future capital requirements, we will have to raise additional funds. We may seek to raise funds through the sale of equity or debt securities or through external borrowings. In addition, we may enter into additional strategic partnerships or collaborative arrangements for the development and commercialization of our compounds. However, we may be unable to raise sufficient additional capital when we need it, on favorable terms or at all. The sale of equity or convertible debt securities in the future may be

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

dilutive to our stockholders, and debt-financing arrangements may require us to pledge certain assets and enter into covenants that would restrict certain business activities or our ability to incur further indebtedness, and may contain other terms that are not favorable to our stockholders or us. If we are unable to obtain adequate funds on reasonable terms, we may be required to curtail operations significantly or obtain funds by entering into financing, supply or collaboration agreements on unattractive terms or we may be required to relinquish rights to technology or product candidates or to grant licenses on terms that are unfavorable to us.

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

**GlaxoSmithKline** Our loan and security agreement with GlaxoSmithKline contains financial covenants pursuant to which our working capital (the amount by which our current assets exceed our current liabilities as defined by the agreement, which excludes restricted cash and deferred revenue) must not be less than \$25.0 million and our cash and investments (total cash, cash equivalents and investments as defined by the agreement, which excludes restricted cash) must not be less than \$50.0 million. As of March 31, 2011, our working capital was \$225.9 million and our cash and investments were \$387.5 million. If we default on the financial covenants under the loan and security agreement, GlaxoSmithKline may, among other remedies, declare immediately due and payable all obligations under the loan and security agreement. Outstanding borrowings and accrued interest under the loan and security agreement totaled \$36.2 million at March 31, 2011. The final installment of principal and accrued interest under the loan is due on October 27, 2011.

**Deerfield** Our note purchase agreement with Deerfield contains an event of default that would be triggered if our cash and cash equivalents fall below \$10.0 million as of December 30, 2011, subject to a cure period. Upon such an event of default, Deerfield may declare all or a portion of the Put Price to be immediately due and payable. Cash and cash equivalents for purposes of our note purchase agreement includes our total cash, cash equivalents and short-term and long-term marketable securities. As of March 31, 2011, our cash and cash equivalents were \$391.7 million.

**Silicon Valley Bank** Our loan and security agreement with Silicon Valley Bank requires that we maintain \$80.0 million at all times on deposit in a non-interest bearing demand deposit account(s) as support for our obligations under the loan and security agreement. If the balance on our deposit account(s) falls below \$80.0 million for more than 10 days, Silicon

## **Table of Contents**

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. Our loan and security agreement with Silicon Valley Bank also contains similar deposit covenants with respect to funds drawn under our equipment lines of credit.

If we cannot raise additional capital in order to remain in compliance with our financial covenants or if we are unable to renegotiate such covenants and the lender exercises its remedies under the agreement, we would not be able to operate under our current operating plan.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Our market risks at March 31, 2011 have not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2010, filed with the Securities and Exchange Commission on February 22, 2011. Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio and our long-term debt. We have estimated the effects on our interest rate sensitive assets and liabilities based on a one percentage point hypothetical adverse change in interest rates as of March 31, 2011 and December 31, 2010. As of March 31, 2011 and December 31, 2010, a decrease in the interest rates of one percentage point would have had a net adverse change in the fair value of interest rate sensitive assets and liabilities of \$9.0 million and \$9.7 million, respectively.

In addition, we have exposure to fluctuations in certain foreign currencies in countries in which we conduct clinical trials. Most of our foreign expenses incurred are associated with establishing and conducting clinical trials for cabozantinib and various other compounds in our pipeline at sites outside of the United States. Our agreements with the foreign sites that conduct such clinical trials generally provide that payments for the services provided will be calculated in the currency of that country, and converted into U.S. dollars using various exchange rates based upon when services are rendered or the timing of invoices. When the U.S. dollar weakens against foreign currencies, the U.S. dollar value of the foreign-currency denominated expense increases, and when the U.S. dollar strengthens against these currencies, the U.S. dollar value of the foreign-currency denominated expense decreases. As of March 31, 2011 and December 31, 2010, approximately \$3.7 million and \$3.1 million respectively of our clinical accrual balance related to foreign currencies. As of March 31, 2011 and December 31, 2010, an adverse change of one percentage point in the in foreign currency exchange rates would have resulted in a net loss of \$37 thousand and \$31 thousand, respectively.

### **ITEM 4. CONTROLS AND PROCEDURES**

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

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

## **PART II. OTHER INFORMATION**

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

*In addition to the factors discussed elsewhere in this report and our other reports filed with the Securities and Exchange Commission, the following are important factors that could cause actual results or events to differ materially from those contained in any forward-looking statements made by us or on our behalf. The risks and uncertainties described below are not the only ones facing the company. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. If any of the following risks or such other risks actually occurs, our business could be harmed.*

***We have marked with an asterisk (\*) those risk factors below that reflect substantive changes from the risk factors included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010 filed with the Securities and Exchange Commission on February 22, 2011.***

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

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

We will need to raise additional capital to:

fund our operations and clinical trials;

## **Table of Contents**

continue our research and development efforts; and

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

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 will depend on many factors that may require us to use available capital resources significantly earlier than we currently anticipate. These factors include:

the cabozantinib development program We are focusing our resources and development efforts on cabozantinib, our most advanced compound, which is being studied in a variety of tumor types, with the goal of rapidly commercializing the compound. 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 the RDT. Data from the RDT were released at the 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 and hepatoma. Updated interim data presented at 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 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. 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. In addition, we are conducting ongoing exploratory clinical trials for cabozantinib in other tumor types, including renal cell carcinoma. Our development plan for cabozantinib is dependent on the extent of our available financial resources. There can be no assurance that we will have sufficient financial resources independently or through other arrangements to fund a broad development plan for cabozantinib. If adequate funds are not available, we may be required to delay, discontinue or elect not to pursue one or more trials for cabozantinib;

repayment of our loan from GlaxoSmithKline In October 2002, we entered into a collaboration agreement with GlaxoSmithKline. 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. 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 on 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 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. However, there can be no assurance that we will have sufficient funds to repay amounts 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;

repayment of the notes under our note purchase agreement with Deerfield On June 2, 2010, we entered into a note purchase agreement with entities affiliated with Deerfield Management Company, L.P., or Deerfield, pursuant to which, on July 1, 2010, we sold to Deerfield an aggregate of \$124.0 million initial principal amount of our secured convertible notes, due June 2015, for an aggregate purchase price of \$80.0 million, less closing fees and expenses. The outstanding principal amount of the notes bears

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

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 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)

## **Table of Contents**

determined as of the date of prepayment, plus accrued and unpaid interest, plus in the case of a prepayment of the full principal amount of the notes (other than prepayments upon the occurrence of specified transactions relating to a change of control or a substantial sale of assets), all accrued interest that would have accrued between the date of such prepayment and the next anniversary of the note purchase agreement. In lieu of making any optional or mandatory prepayment in cash, at any time after July 1, 2011, subject to certain limitations, we have the right to convert all or a portion of the principal amount of the notes into, or satisfy all or any portion of the optional prepayment amounts or mandatory prepayment amounts (other than the first \$10.0 million of mandatory prepayments required in 2013 and 2014) with shares of our common stock. Additionally, in lieu of making any payment of accrued and unpaid interest in respect of the notes in cash, 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. In the event the market price for our common stock is depressed, we may not be able to convert the principal amount of the notes or satisfy our payment obligations in full using shares of our common stock due to restrictions in the agreement on the number of shares we may issue. In addition, the issuance of shares of our common stock to convert the notes or satisfy our payment obligations may result in significant dilution to our stockholders. As a result, we may need to obtain additional funding to satisfy our repayment obligations. There can be no assurance that we will have sufficient funds to repay the notes or satisfy our payment obligations under the note purchase agreement when due or that we will comply with the conditions to our ability to convert the principal amount of the notes into or satisfy our payment obligations with shares of our common stock;

repayment of our loan from Silicon Valley Bank On June 2, 2010, we amended our loan and security agreement with Silicon Valley Bank to provide for a new seven-year term loan in an amount of \$80.0 million. The principal amount outstanding under the term loan accrues interest at 1.0% per annum, which interest is due and payable monthly. We are required to repay the term loan in one balloon principal payment, representing 100% of the principal balance and accrued and unpaid interest, on May 31, 2017. We have the option to prepay all, but not less than all, of the amounts advanced under the term loan, provided that we pay all unpaid accrued interest thereon that is due through the date of such prepayment and the interest on the entire principal balance of the term loan that would otherwise have been paid after such prepayment date until the maturity date of the term loan. In accordance with the terms of the loan and security agreement, we are also required to maintain on deposit an amount equal to at least 100% of the outstanding principal balance of the term loan at all times as support for our obligations under the loan and security agreement. As a result, although the proceeds of the new term loan improve our ability to comply with minimum working capital and cash covenants imposed by our debt instruments with GlaxoSmithKline and Deerfield and thus provide us with more flexibility to use our other cash resources, the proceeds of the term loan cannot directly be used to satisfied our other obligations without causing a default under our loan and security agreement with Silicon Valley Bank;

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

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

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

our ability to control costs;

our ability to remain in compliance with, or amend or cause to be waived, financial covenants contained in agreements with third parties;

the amount of our cash and cash equivalents and marketable securities that serve as collateral for bank lines of credit;

future clinical trial results;

our need to expand our product and clinical development efforts;

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

the cost and timing of regulatory approvals;

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

the effect of competing technological and market developments;

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

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

One or more of these factors or changes to our current operating plan may require us to use available capital resources significantly earlier than we anticipate. If our capital resources are insufficient to meet future capital requirements, we will have to raise additional funds. We may seek to raise funds through the sale of equity or debt securities or through external borrowings. In

## **Table of Contents**

addition, we may enter into additional strategic partnerships or collaborative arrangements for the development and commercialization of our compounds. However, we may be unable to raise sufficient additional capital when we need it, on favorable terms or at all. The sale of equity or convertible debt securities in the future may be dilutive to our stockholders, and debt-financing arrangements may require us to pledge certain assets and enter into covenants that would restrict certain business activities or our ability to incur further indebtedness, and may contain other terms that are not favorable to our stockholders or us. If we are unable to obtain adequate funds on reasonable terms, we may be required to curtail operations significantly or obtain funds by entering into financing, supply or collaboration agreements on unattractive terms or we may be required to relinquish rights to technology or product candidates or to grant licenses on terms that are unfavorable to us.

We may need to obtain additional funding in order to stay in compliance with financial covenants contained in agreements with third parties. As described above under Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources Cash Requirements, the terms of our debt owed to GlaxoSmithKline, Deerfield and Silicon Valley Bank each contain covenants requiring us to maintain specified cash balances or working capital. The failure to comply with these covenants could result in an acceleration of the underlying debt obligations. If we cannot raise additional capital in order to remain in compliance with such covenants or if we are unable to renegotiate such covenants and the lender exercises its remedies under the agreement, we would not be able to operate under our current operating plan.

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

We have incurred net losses since inception, including a net loss of \$27.5 million for the three months ended March 31, 2011. As of that date, we had an accumulated deficit of \$1,210 million. We expect to continue to incur net losses and anticipate negative operating cash flow for the foreseeable future. We have not yet completed the development, including obtaining regulatory approval, of cabozantinib or any other product candidates and, consequently, have not generated revenues from the sale of pharmaceutical products. We have derived substantially all of our revenues to date from collaborative research and development agreements. Revenues from research and development collaborations depend upon continuation of the collaborations, research funding, the achievement of milestones and royalties we earn from any future products developed from the collaborative research. If research funding we receive from collaborators decreases, we are unable to successfully achieve milestones or our collaborators fail to develop successful products, we will not earn the revenues contemplated under such collaborative agreements. The amount of our net losses will depend, in part, on the rate of growth, if any, in our license and contract revenues and on the level of our expenses. These losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Our research and development expenditures and general and administrative expenses have exceeded our revenues to date, and we expect to spend significant additional amounts to fund the development of cabozantinib. As a result, we expect to continue to incur substantial operating expenses, and, consequently, we will need to generate significant additional revenues to achieve profitability. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

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

Managing costs is a key element of our business strategy. Consistent with this element of our strategy, on December 1, 2010 we implemented a restructuring that will result in a reduction of our workforce by approximately 65% over a two-year period. We anticipate that we will incur restructuring charges through the end of 2017 as we implement this restructuring.

We are still assessing our ability to sublease certain of our facilities in light of the workforce reduction as well as the potential for sublease income. Estimates for sublease income would require significant assumptions regarding the time required to contract with subtenants, the amount of idle space we would be able to sublease and potential future sublease rates. If we are able to vacate certain of our facilities, we would need to continue to update our estimate of the lease exist costs in our financial statements until we were able to negotiate an exit to the lease or negotiate a sublease for the remaining term of the lease.

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

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

Most of our foreign expenses incurred are associated with establishing and conducting clinical trials for cabozantinib. The amount of expenses incurred will be impacted by fluctuations in the currencies of those countries in which we conduct clinical trials. Our agreements with the foreign sites that conduct such clinical trials generally provide that payments for the services provided will be calculated in the currency of that country, and converted into U.S. dollars using various exchange rates based upon when services are rendered or the timing of invoices. When the

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

U.S. dollar weakens against foreign currencies, the U.S. dollar value of the foreign-currency denominated expense increases, and when the U.S. dollar strengthens against these currencies, the U.S. dollar value of the foreign-currency denominated expense decreases. Consequently, changes in exchange rates may affect our results of operations.

---

## **Table of Contents**

***Global credit and financial market conditions could negatively impact the value of our current portfolio of cash equivalents or short-term investments and our ability to meet our financing objectives.***

Our cash and cash equivalents are maintained in highly liquid investments with remaining maturities of 90 days or less at the time of purchase. Our short-term and long-term investments consist primarily of readily marketable debt securities with remaining maturities of more than 90 days at the time of purchase. While as of the date of this filing we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents, short-term investments or long-term investments since March 31, 2011, no assurance can be given that a deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or investments or our ability to meet our financing objectives.

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

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

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

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

Clinical trials are inherently risky and may reveal that our product candidates are ineffective or have unacceptable toxicity or other side effects that may significantly decrease the likelihood of regulatory approval. The results of preliminary studies do not necessarily predict clinical or commercial success, and later-stage clinical trials may fail to confirm the results observed in earlier-stage trials or preliminary studies. Although we have established timelines for manufacturing and clinical development of cabozantinib based on existing knowledge of our compounds in development and industry metrics, we may not be able to meet those timelines.

We may experience numerous unforeseen events during, or as a result of, clinical testing that could delay or prevent commercialization of cabozantinib, including:

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

negative or inconclusive clinical trial results may require us to conduct further testing or to abandon projects that we had expected to be promising;

our competitors may subsequently discover other compounds or therapies that we believe show significantly improved safety or efficacy compared to cabozantinib;

patient registration or enrollment in our clinical testing may be lower than we anticipate, resulting in the delay or cancellation of clinical testing; and

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

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

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

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

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

the number of patients that ultimately participate in the clinical trial;

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

## **Table of Contents**

the number of clinical sites included in the trials; and

the length of time required to enroll suitable patient subjects.

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

***If third parties upon which we rely do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize cabozantinib.***

We do not have the ability to independently conduct clinical trials for cabozantinib, and we rely on third parties we do not control such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize cabozantinib.

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

We do not have the manufacturing capabilities or experience necessary to enable us to produce materials for our clinical trials. We rely on collaborators and third-party contractors to produce cabozantinib for clinical testing. These suppliers must comply with applicable regulatory requirements, including the FDA's current GMP. Our current and anticipated future dependence upon these third-party manufacturers may adversely affect our future profit margins and our ability to develop and commercialize cabozantinib on a timely and competitive basis. These manufacturers may not be able to produce material on a timely basis or manufacture material at the quality or in the quantity required to meet our development timelines and applicable regulatory requirements. We may not be able to maintain or renew our existing third-party manufacturing arrangements, or enter into new arrangements, on acceptable terms, or at all. Our third-party manufacturers could terminate or decline to renew our manufacturing arrangements based on their own business priorities, at a time that is costly or inconvenient for us. If we are unable to contract for the production of materials in sufficient quantity and of sufficient quality on acceptable terms, our clinical trials may be delayed. Delays in preclinical or clinical testing could delay the initiation of clinical trials.

Our third-party manufacturers may not be able to comply with the GMP regulations, other applicable FDA regulatory requirements or similar regulations applicable outside of the United States. Additionally, if we are required to enter into new supply arrangements, we may not be able to obtain approval from the FDA of any alternate supplier in a timely manner, or at all, which could delay or prevent the clinical development and commercialization of cabozantinib. Failure of our third-party manufacturers or us to obtain approval from the FDA or to comply with applicable regulations could result in sanctions being imposed on us, including fines, civil penalties, delays in or failure to grant marketing approval of cabozantinib, injunctions, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products and compounds, operating restrictions and criminal prosecutions, any of which could have a significant adverse affect on our business.

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

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



## **Table of Contents**

### **Risks Related to Our Relationships with Third Parties**

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

We have established collaborations with leading pharmaceutical and biotechnology companies, including Bristol-Myers Squibb, sanofi-aventis, Genentech, Boehringer Ingelheim, GlaxoSmithKline and Daiichi Sankyo, for the development and ultimate commercialization of a significant number of compounds generated from our research and development efforts. We continue to pursue collaborations for selected unpartnered preclinical and clinical programs and compounds. Our dependence on our relationships with existing collaborators for the development and commercialization of our compounds subjects us to, and our dependence on future collaborators for development and commercialization of additional compounds will subject us to, a number of risks, including:

we are not able to control the amount and timing of resources that our collaborators will devote to the development or commercialization of drug candidates or to their marketing and distribution;

we may not be able to control the amount and timing of resources that our potential future collaborators may devote to the development or commercialization of drug candidates or to their marketing and distribution;

collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a drug candidate, repeat or conduct new clinical trials or require a new formulation of a drug candidate for clinical testing;

disputes may arise between us and our collaborators that result in the delay or termination of the research, development or commercialization of our drug candidates or that result in costly litigation or arbitration that diverts management's attention and resources;

collaborators may experience financial difficulties;

collaborators may not be successful in their efforts to obtain regulatory approvals in a timely manner, or at all;

collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;

business combinations or significant changes in a collaborator's business strategy may adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;

a collaborator could independently move forward with a competing drug candidate developed either independently or in collaboration with others, including our competitors;

we may be precluded from entering into additional collaboration arrangements with other parties in an area or field of exclusivity;

future collaborators may require us to relinquish some important rights, such as marketing and distribution rights; and

collaborations may be terminated (as occurred with respect to cabozantinib, that was previously subject to our 2008 collaboration with Bristol-Myers Squibb) or allowed to expire, which would delay the development and may increase the cost of developing our drug candidates.

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

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

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

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

**Table of Contents*****We may be unable to establish collaborations for selected preclinical and clinical compounds.***

Our strategy includes the pursuit of new collaborations with leading pharmaceutical and biotechnology companies for the development and ultimate commercialization of selected preclinical and clinical programs and compounds, particularly those drug candidates for which we believe that the capabilities and resources of a partner can accelerate development and help to fully realize their therapeutic and commercial potential. We face significant competition in seeking appropriate collaborators, and these collaborations are complex and time consuming to negotiate and document. We may not be able to negotiate additional collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional collaborations because of the numerous risks and uncertainties associated with establishing additional collaborations. If we are unable to negotiate additional collaborations, we may not be able to realize value from a particular drug candidate, particularly those drug candidates as to which we believe a broad development program is appropriate or for which we have determined not to continue to utilize our own resources to develop. As a result, our revenues, capital resources and product development efforts could be adversely affected.

**Risks Related to Regulatory Approval of Cabozantinib*****Cabozantinib is subject to a lengthy and uncertain regulatory process that may not result in the necessary regulatory approvals, which could adversely affect our ability to commercialize this product candidate.***

Cabozantinib, as well as the activities associated with the research, development and commercialization of the product candidate, are subject to extensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory approval for cabozantinib would prevent us from commercializing this product candidate. We have not received regulatory approval to market cabozantinib in any jurisdiction and have only limited experience in preparing and filing the applications necessary to gain regulatory approvals. The process of obtaining regulatory approvals is expensive, and often takes many years, if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidates involved. Before an NDA can be submitted to the FDA, the product candidate must undergo extensive clinical trials, which can take many years and requires substantial expenditures. Any clinical trial may fail to produce results satisfactory to the FDA. For example, the FDA could determine that the design of a clinical trial is inadequate to produce reliable results. The regulatory process also requires preclinical testing, and data obtained from preclinical and clinical activities are susceptible to varying interpretations. The FDA has substantial discretion in the approval process and may refuse to approve any NDA or decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. For example, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of cabozantinib.

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

Even if the FDA or a comparable authority in another country approves cabozantinib, the approval may impose significant restrictions on the indicated uses, conditions for use, labeling, distribution, advertising, promotion, marketing and/or production of cabozantinib and may impose ongoing requirements for post-approval studies, including additional research and development and clinical trials. These agencies also may impose various civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval.

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

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

the effectiveness, or perceived effectiveness, of cabozantinib in comparison to competing products;

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

the existence of any significant side effects of cabozantinib, as well as their severity in comparison to any competing products;

potential advantages over alternative treatments;

the ability to offer cabozantinib for sale at competitive prices;

---

**Table of Contents**

relative convenience and ease of administration;

the strength of marketing and distribution support; and

sufficient third-party coverage or reimbursement.

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

We have no experience as a company in the sales, marketing and distribution of pharmaceutical products and do not have a sales and marketing organization. Developing a sales and marketing force would be expensive and time-consuming, could delay any product launch, and we may never be able to develop this capacity. To the extent that we enter into arrangements with third parties to provide sales, marketing and distribution services, our product revenues are likely to be lower than if we market and sell cabozantinib ourselves. If we are unable to establish adequate sales, marketing and distribution capabilities, independently or with others, we may not be able to generate product revenues.

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

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

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

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

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

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

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

an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, beginning in 2011;

---

**Table of Contents**

an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;

a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D, beginning in 2011;

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

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

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

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

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

a licensure framework for follow-on biologic products; and

a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

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

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

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

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

The biotechnology industry is highly fragmented and is characterized by rapid technological change. In particular, the area of kinase-targeted therapies is a rapidly evolving and competitive field. We face, and will continue to face, intense competition from biotechnology and pharmaceutical companies, as well as academic research institutions, clinical reference laboratories and government agencies that are pursuing research activities similar to ours. Some of our competitors have entered into collaborations with leading companies within our target markets, including some of our existing collaborators. In addition, significant delays in the development of cabozantinib could allow our competitors to bring products to market before us, which would impair our ability to commercialize cabozantinib. Our future success will depend upon our ability to maintain a competitive position with respect to technological advances. Any products that are developed through our technologies will compete in highly competitive markets. Further, our competitors may be more effective at using their technologies to develop commercial products. Many of the organizations competing with us have greater capital resources, larger research and development staff and facilities, more experience in obtaining regulatory approvals and more extensive product manufacturing and marketing capabilities. As a result, our competitors may be able to more easily develop technologies and products that would render our technologies and products, and those of our collaborators, obsolete and noncompetitive. There may also be drug candidates of which we are not aware at an earlier stage of development that may compete with cabozantinib. In addition, if cabozantinib is successfully developed, it may compete with existing therapies that

**Table of Contents**

have long histories of use, such as chemotherapy and radiation treatments in cancer indications. Examples of potential competition for cabozantinib include AstraZeneca's development-stage RET, VEGFR and EGFR inhibitor, vandetanib, other VEGF pathway inhibitors, including Genentech's bevacizumab, and other MET inhibitors, including Pfizer's crizotinib, ArQule's ARQ197, GlaxoSmithKline's foretinib (XL880) and Genentech's Met MAb.

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

To date, cabozantinib has been manufactured in small quantities for preclinical and clinical trials. If cabozantinib is approved by the FDA or other regulatory agencies for commercial sale, we will need to manufacture it in larger quantities. We may not be able to successfully increase the manufacturing capacity, whether in collaboration with third-party manufacturers or on our own, for cabozantinib in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If we are unable to successfully increase the manufacturing capacity for cabozantinib, the regulatory approval or commercial launch of the product candidate may be delayed or there may be a shortage in supply. Cabozantinib requires precise, high-quality manufacturing. The failure to achieve and maintain these high manufacturing standards, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously hurt our business.

**Risks Related to Our Intellectual Property**

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

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

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties (for example, the patent owner has failed to work the invention in that country or the third party has patented improvements). In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. Compulsory licensing of life-saving drugs is also becoming increasingly popular in developing countries either through direct legislation or international initiatives. Such compulsory licenses could be extended to include some of our product candidates, which could limit our potential revenue opportunities. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patent and other intellectual property protection, which makes it difficult to stop infringement. We rely on trade secret protection for our confidential and proprietary information. We have taken security measures to protect our proprietary information and trade secrets, but these measures may not provide adequate protection. While we seek to protect our proprietary information by entering into confidentiality agreements with employees, collaborators and consultants, we cannot assure you that our proprietary information will not be disclosed, or that we can meaningfully protect our trade secrets. In addition, our competitors may independently develop substantially equivalent proprietary information or may otherwise gain access to our trade secrets.

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

Our commercial success depends in part upon our ability to avoid infringing patents and proprietary rights of third parties and not to breach any licenses that we have entered into with regard to our technologies. Other parties have filed, and in the future are likely to file, patent applications covering genes and gene fragments, techniques and methodologies relating to model systems and products and technologies that we have developed or intend to develop. If patents covering technologies required by our operations are issued to others, we may have to obtain licenses

from third parties, which may not be available on commercially reasonable terms, or

## **Table of Contents**

at all, and may require us to pay substantial royalties, grant a cross-license to some of our patents to another patent holder or redesign the formulation of a product candidate so that we do not infringe third-party patents, which may be impossible to obtain or could require substantial time and expense.

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

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

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

### **Risks Related to Employees and Location**

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

We are highly dependent upon the principal members of our management and scientific staff, the loss of whose services might adversely impact the achievement of our objectives and the continuation of existing collaborations. Also, we may not have sufficient personnel to execute our business plan. Retaining and, where necessary, recruiting qualified clinical and scientific personnel will be critical to support activities related to advancing our clinical and preclinical development programs, and supporting our collaborative arrangements and our internal proprietary research and development efforts. The restructuring plans that we implemented in 2010 and additional and planned personnel reductions through 2012 could have an adverse impact on our ability to retain and recruit qualified personnel. Competition is intense for experienced clinical personnel, and we may be unable to retain or recruit clinical personnel with the expertise or experience necessary to allow us to pursue collaborations, develop our products and core technologies or expand our operations to the extent otherwise possible. Further, all of our employees are employed at will and, therefore, may leave our employment at any time.

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

We work with scientific and clinical advisors and collaborators at academic and other institutions that assist us in our research and development efforts. These advisors and collaborators are not our employees and may have other commitments that limit their availability to us. Although these advisors and collaborators generally agree not to do competing work, if a conflict of interest between their work for us and their work for another entity arises, we may lose their services. In such a circumstance, we may lose work performed by them, and our development efforts with respect to the matters on which they were working may be significantly delayed or otherwise adversely affected. In addition, although our advisors and collaborators sign agreements not to disclose our confidential information, it is possible that valuable proprietary knowledge may become publicly known through them.

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

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



## **Table of Contents**

### ***Security breaches may disrupt our operations and harm our operating results.***

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

### **Risks Related to Environmental and Product Liability**

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

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

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

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

We may be held liable if any product we or our collaborators develop causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing or sale. Regardless of merit or eventual outcome, product liability claims could result in decreased demand for our product candidates, injury to our reputation, withdrawal of patients from our clinical trials, substantial monetary awards to trial participants and the inability to commercialize any products that we may develop. These claims might be made directly by consumers, health care providers, pharmaceutical companies or others selling or testing our products. We have obtained limited product liability insurance coverage for our clinical trials in the amount of \$10.0 million per occurrence and \$10.0 million in the aggregate. However, our insurance may not reimburse us or may not be sufficient to reimburse us for expenses or losses we may suffer. Moreover, if insurance coverage becomes more expensive, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for cabozantinib, we intend to expand our insurance coverage to include the sale of commercial products, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, juries have awarded large judgments in class action lawsuits for claims based on drugs that had unanticipated side effects. In addition, the pharmaceutical and biotechnology industries, in general, have been subject to significant medical malpractice litigation. A successful product liability claim or series of claims brought against us could harm our reputation and business and would decrease our cash reserves.

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

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

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

the scope of our research and development activities;

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

recognition of upfront licensing or other fees or revenues;

payments of non-refundable upfront or licensing fees, or payment for cost-sharing expenses, to third parties;

acceptance of our technologies and platforms;

the success rate of our efforts leading to milestone payments and royalties;

## **Table of Contents**

the introduction of new technologies or products by our competitors;

the timing and willingness of collaborators to further develop or, if approved, commercialize our product outlicensed to them;

our ability to enter into new collaborative relationships;

the termination or non-renewal of existing collaborations;

the timing and amount of expenses incurred for clinical development and manufacturing cabozantinib;

adjustments to expenses accrued in prior periods based on management's estimates after the actual level of activity relating to such expenses becomes more certain;

the impairment of acquired goodwill and other assets;

the impact of our restructuring plans; and

general and industry-specific economic conditions that may affect our collaborators' research and development expenditures.

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

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

### ***Our stock price may be extremely volatile.***

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

adverse results or delays in our or our collaborators' clinical trials;

announcement of FDA approval or non-approval, or delays in the FDA review process, of cabozantinib or our collaborators' product candidates or those of our competitors or actions taken by regulatory agencies with respect to our, our collaborators' or our competitors' clinical trials;

the timing of achievement of our clinical, regulatory, partnering and other milestones, such as the commencement of clinical development, the completion of a clinical trial, the filing for regulatory approval or the establishment of collaborative arrangements for one or more of our outlicensed programs and compounds;

actions taken by regulatory agencies with respect to cabozantinib or our clinical trials for cabozantinib;

the announcement of new products by our competitors;

quarterly variations in our or our competitors' results of operations;

developments in our relationships with our collaborators, including the termination or modification of our agreements;

conflicts or litigation with our collaborators;

litigation, including intellectual property infringement and product liability lawsuits, involving us;

failure to achieve operating results projected by securities analysts;

changes in earnings estimates or recommendations by securities analysts;

financing transactions;

developments in the biotechnology or pharmaceutical industry;

sales of large blocks of our common stock or sales of our common stock by our executive officers, directors and significant stockholders;

departures of key personnel or board members;

developments concerning current or future collaborations;

FDA or international regulatory actions;

## **Table of Contents**

third-party reimbursement policies;

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

general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

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

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

### ***Future sales of our common stock may depress our stock price.***

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

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

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

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

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

a classified Board of Directors;

a prohibition on actions by our stockholders by written consent;

the inability of our stockholders to call special meetings of stockholders;

the ability of our Board of Directors to issue preferred stock without stockholder approval, which could be used to institute a poison pill that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our Board of Directors;

limitations on the removal of directors; and

advance notice requirements for director nominations and stockholder proposals.

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

## **ITEM 6. EXHIBITS**

### **(a) Exhibits**

The exhibits listed on the accompanying exhibit index are filed or incorporated by reference (as stated therein) as part of this Quarterly Report on Form 10-Q.

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: May 3, 2011

EXELIXIS, INC.

/s/ Frank Karbe  
Frank Karbe

Executive Vice President and Chief Financial Officer

*(Principal Financial and Accounting Officer)*

**Table of Contents****EXHIBIT INDEX**

			Incorporation by Reference			Filed Herewith
			Exhibit/			
Exhibit				Appendix		
Number	Exhibit Description	Form	File Number	Reference	Filing Date	
2.2*	Share Sale and Transfer Agreement, dated November 20, 2007, by and between Taconic Farms, Inc. and Exelixis, Inc.	10-K	000-30235	2.3	2/25/2008	
3.1	Amended and Restated Certificate of Incorporation of Exelixis, Inc.	10-K	000-30235	3.1	3/10/2010	
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Exelixis, Inc.	10-K	000-30235	3.2	3/10/2010	
3.3	Amended and Restated Bylaws of Exelixis, Inc.	8-K	000-30235	3.1	10/4/2007	
4.1	Specimen Common Stock Certificate.	S-1,	333-96335	4.1	2/7/2000	
		as amended				
4.2	Form of Warrant, dated June 13, 2006, to purchase 750,000 shares of Exelixis, Inc. common stock in favor of Symphony Evolution Holdings LLC.	8-K	000-30235	4.1	6/15/2006	
4.3	Form of Warrant, dated June 10, 2009, to purchase 500,000 shares of Exelixis, Inc. common stock in favor of Symphony Evolution Holdings LLC.	10-Q,	000-30235	4.4	7/30/2009	
		as amended				
4.4*	Warrant Purchase Agreement, dated June 9, 2005, between Exelixis, Inc. and Symphony Evolution Holdings LLC.	10-Q	000-30235	10.8	8/9/2005	
4.5*	Form Warrant to Purchase Common Stock of Exelixis, Inc. issued or issuable to Deerfield Private Design Fund, L.P., Deerfield Private Design International, L.P., Deerfield Partners, L.P. and Deerfield International Limited	8-K	000-30235	4.9	6/9/2008	
4.6	Form of Common Stock Agreement and Warrant Certificate	S-3,	333-158792	4.17	4/24/2009	
		as amended				
4.7	Form of Preferred Stock Agreement and Warrant Certificate	S-3,	333-158792	4.18	4/24/2009	
		as amended				
4.8	Form of Debt Securities Warrant Agreement and Warrant Certificate	S-3,	333-158792	4.19	4/24/2009	
		as amended				
4.9	Form of Senior Debt Indenture	S-3,	333-158792	4.13	5/28/2009	
		as amended				
4.10	Form of Subordinated Debt Indenture	S-3,	333-158792	4.14	5/28/2009	
		as amended				

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

4.11	Form of Note, dated July 1, 2010, in favor of Deerfield Private Design International, L.P.	10-Q	000-30235	10.1	8/5/2010	
						(Exhibit A-1)
4.12	Form of Note, dated July 1, 2010, in favor of Deerfield Private Design Fund, L.P.	10-Q	000-30235	10.1	8/5/2010	
						(Exhibit A-2)
31.1	Certification required by Rule 13a-14(a) or Rule 15d-14(a).					X
31.2	Certification required by Rule 13a-14(a) or Rule 15d-14(a).					X
32.1**	Certification by the Chief Executive Officer and the Chief Financial Officer of Exelixis, Inc., as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).					X

**Table of Contents**

- \* Confidential treatment granted for certain portions of this exhibit.
- \*\* This certification accompanies this Quarterly Report on Form 10-Q, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of Exelixis, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of this Quarterly Report on Form 10-Q), irrespective of any general incorporation language contained in such filing.