

EXELIXIS INC
Form 10-Q
November 04, 2010
[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 October 1, 2010

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.)

170 Harbor Way

P.O. Box 511

South San Francisco, California 94083

(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 October 29, 2010, there were 108,984,958 shares of the registrant's common stock outstanding.

Table of Contents

EXELIXIS, INC.

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTERLY PERIOD ENDED OCTOBER 1, 2010

INDEX

<u>Part I. Financial Information</u>	3
Item 1. <u>Financial Statements.</u>	3
<u>Condensed Consolidated Balance Sheets – September 30, 2010 and December 31, 2009</u>	3
<u>Condensed Consolidated Statements of Operations – Three Months and Nine Months Ended September 30, 2010 and 2009</u>	4
<u>Condensed Consolidated Statements of Cash Flows – Nine Months Ended September 30, 2010 and 2009</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>	17
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk.</u>	35
Item 4. <u>Controls and Procedures.</u>	35
<u>Part II. Other Information</u>	35
Item 1A. <u>Risk Factors.</u>	35
Item 6. <u>Exhibits.</u>	49
<u>SIGNATURES</u>	50
EXHIBITS	
<u>Exhibit 10.1</u>	
<u>Exhibit 10.2</u>	
<u>Exhibit 10.3</u>	
<u>Exhibit 10.4</u>	
<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)**

	September 30, 2010 (unaudited)	December 31, 2009 ⁽¹⁾
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 95,342	\$ 86,796
Marketable securities	71,929	116,290
Other receivables	7,306	11,864
Prepaid expenses and other current assets	17,635	15,050
Total current assets	192,212	230,000
Restricted cash and investments	6,399	6,444
Long-term investments	87,295	11,463
Property and equipment, net	18,776	29,392
Goodwill	63,684	63,684
Other assets	4,540	2,427
Total assets	\$ 372,906	\$ 343,410
LIABILITIES, NONCONTROLLING INTEREST AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 2,906	\$ 7,403
Accrued clinical trial liabilities	30,060	24,000
Other accrued liabilities	19,625	16,399
Accrued compensation and benefits	12,069	16,677
Current portion of notes payable and bank obligations	9,005	11,204
Current portion of convertible loans	28,050	28,050
Deferred revenue	102,254	103,385
Total current liabilities	203,969	207,118
Long term portion of notes payable and bank obligations	87,295	11,463
Long term portion of convertible loans	110,561	28,900
Other long-term liabilities	23,415	17,325
Deferred revenue	165,259	242,329
Total liabilities	590,499	507,135
Commitments		
Stockholders' deficit:		

Edgar Filing: EXELIXIS INC - Form 10-Q

Exelixis, Inc. stockholders' deficit:		
Common stock	109	108
Additional paid-in-capital	946,469	925,736
Accumulated other comprehensive income	18	155
Accumulated deficit	(1,164,189)	(1,089,724)
Total Exelixis, Inc. stockholders' deficit	(217,593)	(163,725)
Noncontrolling interest		
Total stockholders' deficit	(217,593)	(163,725)
Total liabilities, noncontrolling interest, and stockholders' deficit	\$ 372,906	\$ 343,410

- (1) The condensed consolidated balance sheet at December 31, 2009 has been derived from the audited consolidated financial statements at that date but does not include all of the information and footnotes required by 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)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Revenues:				
Contract	\$ 11,865	\$ 24,608	\$ 43,915	\$ 37,615
License	24,542	30,368	73,648	70,066
Collaboration reimbursements	18,067		26,706	
Total revenues	54,474	54,976	144,269	107,681
Operating expenses:				
Research and development	49,388	60,186	168,375	170,567
General and administrative	8,952	8,643	27,358	25,910
Collaboration cost sharing		2,965		2,807
Restructuring charge	339		25,823	
Total operating expenses	58,679	71,794	221,556	199,284
Loss from operations	(4,205)	(16,818)	(77,287)	(91,603)
Other income (expense):				
Interest income and other, net	(376)	355	331	1,276
Interest expense	(4,094)	(2,122)	(5,378)	(6,356)
Gain on sale of business			7,797	1,800
Loss on deconsolidation of Symphony Evolution, Inc.				(9,826)
Total other income (expense), net	(4,470)	(1,767)	2,750	(13,106)
Consolidated loss before taxes	(8,675)	(18,585)	(74,537)	(104,709)
Income tax benefit (provision)	72	(6,860)	72	(6,014)
Consolidated net loss	(8,603)	(25,445)	(74,465)	(110,723)
Loss attributable to noncontrolling interest.				4,337
Net loss attributable to Exelixis, Inc.	\$ (8,603)	\$ (25,445)	\$ (74,465)	\$ (106,386)
Net loss per share, basic and diluted, attributable to Exelixis, Inc.	\$ (0.08)	\$ (0.24)	\$ (0.69)	\$ (1.00)
Shares used in computing basic and diluted loss per share amounts	108,667	107,336	108,373	106,853

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

	Nine Months Ended September 30,	
	2010	2009
Cash flows from operating activities:		
Consolidated net loss	\$ (74,465)	\$ (110,723)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	8,276	9,558
Stock-based compensation expense	16,744	17,512
Impairment of assets	2,481	
Gain on sale of business	(7,797)	
Loss on deconsolidation of Symphony Evolution, Inc.		9,826
Accretion of Deerfield implied interest	1,661	
Other	2,415	621
Changes in assets and liabilities:		
Other receivables	4,558	(8,035)
Prepaid expenses and other current assets	(2,957)	(2,909)
Other assets	(1,720)	1,111
Accounts payable and other accrued expenses	(1,210)	1,305
Accrued restructuring liability	9,169	
Other long-term liabilities	(1,256)	1,287
Deferred revenue	(78,201)	116,606
Net cash used in operating activities	(122,302)	36,159
Cash flows from investing activities:		
Purchases of investments held by Symphony Evolution, Inc.		(49)
Proceeds on sale of investments held by Symphony Evolution, Inc.		4,497
Purchases of property and equipment	(1,481)	(1,592)
Proceeds from sale of property and equipment	179	
Proceeds on sale of business	8,600	1,800
Increase (decrease) in restricted cash and investments	45	(729)
Proceeds from maturities of marketable securities	95,100	5,998
Proceeds from sale of marketable securities	12,780	7,793
Purchases of marketable securities	(141,186)	(121,889)
Net cash used in investing activities	(25,963)	(104,171)
Cash flows from financing activities:		
Proceeds from exercise of stock options and warrants	1,054	4
Proceeds from employee stock purchase plan	2,122	2,150
Proceeds from note payable and bank obligations	162,508	
Principal payments on notes payable and bank obligations	(8,873)	(11,245)
Repayments, net from deconsolidation of Symphony Evolution, Inc.		(25)
Net cash provided by (used in) financing activities	156,811	(9,116)

Edgar Filing: EXELIXIS INC - Form 10-Q

Net increase (decrease) in cash and cash equivalents	8,546	(77,128)
Cash and cash equivalents, at beginning of period	86,796	247,698
Cash and cash equivalents, at end of period	\$ 95,342	\$ 170,570

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

Table of Contents

EXELIXIS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2010

(unaudited)

NOTE 1. Organization and Summary of Significant Accounting Policies

Organization

Exelixis, Inc. (Exelixis, we, our or us) is committed to developing innovative therapies for cancer. Through our drug discovery and development activities, we are building a portfolio of novel compounds that we believe have the potential to be high-quality, differentiated pharmaceutical products. Our most advanced pharmaceutical programs focus on drug discovery and development of small molecule drugs for cancer. XL184, an inhibitor of MET, VEGFR2 and RET, is our most advanced drug candidate and is currently being evaluated in a broad development program.

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.

Exelixis has adopted a 52- or 53-week fiscal year that ends on the Friday closest to December 31st of each year. Fiscal year 2009, a 52-week year, ended on January 1, 2010, and fiscal year 2010, a 52-week year, will end on December 31, 2010. For convenience, references in these Condensed Consolidated Financial Statements and Notes as of and for the fiscal year ended January 1, 2010 are indicated on a calendar year basis as ended December 31, 2009 and as of and for the fiscal quarters ended October 2, 2009 and October 1, 2010 are indicated as ended September 30, 2009 and 2010, respectively.

Operating results for the three and nine months ended September 30, 2010 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2010 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, 2009 included in our Annual Report on Form 10-K filed with the SEC on March 10, 2010.

Basis of Consolidation

The consolidated financial statements include the accounts of Exelixis and our wholly owned subsidiaries as well as one former variable interest entity, Symphony Evolution, Inc. (SEI), for which we were the primary beneficiary. As of June 9, 2009, our purchase option for SEI expired and as a result, we are no longer considered to be the primary beneficiary (refer to Note 6 of the financial statements included in our Annual Report on Form 10-K filed with the SEC on March 10, 2010). All significant intercompany balances and transactions have been eliminated.

Cash and Investments

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

All marketable securities are classified as available-for-sale and are carried at fair value. We view our available-for-sale portfolio as available for use in current operations. Accordingly, we have classified certain investments as short-term marketable securities, even though the stated maturity date may be one year or more beyond the current balance sheet date. Available-for-sale securities are stated at fair value based upon quoted market prices of the securities. We have classified certain investments as cash and cash equivalents or marketable securities that collateralize loan balances. However, they are not restricted to withdrawal. Unrealized gains and losses on available-for-sale investments are

Edgar Filing: EXELIXIS INC - Form 10-Q

reported as a separate component of stockholders' equity. Realized gains and losses, net, on available-for-sale securities are included in interest income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

Table of Contents**EXELIXIS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****September 30, 2010****(unaudited)**

The following summarizes available-for-sale securities included in cash and cash equivalents, restricted cash, and marketable securities as of September 30, 2010 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	\$ 150,606	\$	\$	\$ 150,606
Commercial paper	28,995	1		28,996
Corporate bonds	32,435	28	(12)	32,451
U.S. government agency securities	2,002	1		2,003
Government sponsored enterprises	35,547	2	(2)	35,547
Municipal bonds	12,040			12,040
Total	\$ 261,625	\$ 32	\$ (14)	\$ 261,643

As of September 30, 2010, all of our investments in debt securities had remaining maturities of less than one year.

The following summarizes available-for-sale securities included in cash and cash equivalents, restricted cash, and marketable securities as of December 31, 2009 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	\$ 74,465			\$ 74,465
Commercial paper	24,277			24,277
Corporate bonds	55,808	152	(17)	55,943
U.S. government agency securities	11,077	8		11,085
Government sponsored enterprises	37,990	17	(1)	38,006
Municipal bonds	17,769		(3)	17,766
Total	\$ 221,386	177	(21)	\$ 221,542

Foreign Currency Forward Contract

We have entered into foreign currency forward contracts to reduce our net exposure to Eurodollar currency fluctuations. We entered into a contract in February 2010 which had a notional amount of approximately \$7.0 million that expired in June 2010. In June 2010, we settled this contract for a net gain and cash receipt of \$0.7 million and entered into another foreign contract for a notional amount of \$6.1 million that expired in October 2010. The fair value of the foreign currency contracts is estimated based on pricing models using readily observable inputs from actively quoted markets. As of September 30, 2010, the fair value of the current foreign currency forward contract was a loss of

Edgar Filing: EXELIXIS INC - Form 10-Q

approximately \$0.8 million, and was classified in other accrued liabilities on our consolidated balance sheet. The net unrealized gain/loss on our foreign currency forward contracts, neither of which was designated as a hedge, was recorded in our consolidated statement of operations as Interest income and other (net).

Fair Value Measurements

The fair value of our financial instruments reflects the amounts that would be received upon sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price). The fair value hierarchy has the following three levels:

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

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

Level 3 unobservable inputs.

Our financial instruments are valued using quoted prices in active markets or based upon other observable inputs. The following tables set forth the fair value of our financial assets for the periods ended September 30, 2010 and December 31, 2009, respectively (in thousands):

Table of Contents**EXELIXIS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****September 30, 2010****(unaudited)**

As of September 30, 2010:

	Level 1	Level 2	Level 3	Total
Money market funds	\$ 150,606	\$	\$	\$ 150,606
Commercial paper		28,996		28,996
Corporate bonds		32,451		32,451
U.S. government agency securities		2,003		2,003
Government sponsored enterprises		35,547		35,547
Municipal bonds		12,040		12,040
Foreign currency forward contract ⁽¹⁾		(757)		(757)
Total	\$ 150,606	\$ 110,280	\$	\$ 260,886

⁽¹⁾ As of September 30, 2010, the fair value of our Level 2 current assets included approximately \$0.8 million in unrealized losses related to a foreign exchange forward contract established during the quarter ended September 30, 2010.

As of December 31, 2009:

	Level 1	Level 2	Level 3	Total
Money market funds	\$ 74,465	\$	\$	\$ 74,465
Commercial paper		24,277		24,277
Corporate bonds		55,943		55,943
U.S. government agency securities		11,085		11,085
Government sponsored enterprises		38,006		38,006
Municipal bonds		17,766		17,766
Total	\$ 74,465	\$ 147,077	\$	\$ 221,542

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 Deerfield Private Design Fund, L.P. and Deerfield Private Design International, L.P. (collectively, the Deerfield Entities) and the current non-liquid market in structured notes, there is no practicable method to determine the fair value of this instrument. See Note 6 for details on the structure and terms of our 2010 financing with the Deerfield Entities. The estimated fair value of our outstanding debt, excluding our 2010 financing with the Deerfield Entities, was as follows (in thousands):

Edgar Filing: EXELIXIS INC - Form 10-Q

	September 30, 2010	December 31, 2009
GlaxoSmithKline loan	\$ 53,893	\$ 50,191
Equipment lines of credit	16,183	22,530
Silicon Valley Bank Loan	77,384	
 Total	 \$ 147,460	 \$ 72,721

At September 30, 2010 and December 31, 2009, the book value of our debt outstanding, including our 2010 financing with the Deerfield Entities, was \$233.0 million and \$79.6 million, respectively. Our payment commitments associated with these debt instruments are generally 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.

Net Loss Per Share

Basic and diluted net loss per share are computed by dividing the net loss attributable to Exelixis, Inc. 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. Potential common stock consists of incremental common shares issuable upon the exercise of stock options and warrants and shares issuable under restricted stock units (RSUs) and upon conversion of our convertible loans.

As of September 30, 2010, our potential common stock includes 23,036,592 shares related to convertible notes payable, 20,185,410 shares issuable upon the exercise of outstanding stock options, 2,196,756 shares issuable under RSUs and 2,250,000 shares issuable upon the exercise of outstanding warrants, all of which have been excluded from the computation of diluted net loss per share because their impact is antidilutive.

Table of Contents**EXELIXIS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****September 30, 2010****(unaudited)****Collaboration Arrangements**

Collaborative agreement reimbursement revenue or collaboration cost sharing expenses are recorded as earned or owed based on the performance requirements by both parties under the respective contracts. Under our 2008 cancer collaboration with Bristol-Myers Squibb Company (Bristol-Myers Squibb), both parties have been 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 on those projects, are recorded as collaboration reimbursement revenue. 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 on joint development projects, less amounts reimbursable to us by Bristol-Myers Squibb on these projects. In 2009, when net research and development funding payments were payable to Bristol-Myers Squibb, these payments were presented as collaboration cost-sharing expense. However, during the fiscal year ending December 31, 2010 and in future fiscal years, we expect to be in a net receivable position, and will therefore present reimbursement payments as collaboration reimbursement revenue. Revenue and expenses from collaborations that are not co-development agreements are recorded as contract revenue or research and development expenses in the period incurred.

Recent Accounting Pronouncements

In March 2010, Accounting Standards Codification Topic 605, *Revenue Recognition* (ASC 605) was amended to define a milestone and clarify that the milestone method of revenue recognition is a valid application of the proportional performance model when applied to research or development arrangements. Accordingly, a company can make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. We adopted ASC 605 in the third quarter of 2010 on a prospective basis. However, we are not changing our method by which we recognize milestones and therefore do not expect our adoption of ASC 605 to have a material effect on our financial statements going forward.

Accounting Standards Update No. 2009-13, *Revenue Recognition Topic 605: Multiple Deliverable Revenue Arrangements* A Consensus of the FASB Emerging Issues Task Force (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. We expect to adopt this guidance prospectively beginning on January 1, 2011. We believe that the adoption of ASU 2009-13 could have a material impact on our financial statements going forward.

NOTE 2. Comprehensive Loss

Comprehensive loss represents consolidated net loss plus the results of certain stockholders' equity changes, which are comprised of unrealized gains and losses on available-for-sale securities, not reflected in the consolidated statements of operations. Comprehensive loss was as follows (in thousands):

Three Months Ended		Nine Months Ended	
September 30,		September 30,	
2010	2009	2010	2009

Edgar Filing: EXELIXIS INC - Form 10-Q

Consolidated net loss	\$ (8,603)	\$ (25,445)	\$ (74,465)	\$ (110,723)
Increase in unrealized gains (losses) on available-for-sale securities		76	(138)	96
Comprehensive loss	(8,603)	(25,369)	(74,603)	(110,627)
Comprehensive loss attributable to the noncontrolling interest				4,337
Comprehensive loss attributable to Exelixis, Inc.	\$ (8,603)	\$ (25,369)	\$ (74,603)	\$ (106,290)

NOTE 3. Stock-Based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Research and development expense	\$ 2,477	\$ 3,979	\$ 9,148	\$ 11,789
General and administrative expense	2,956	1,951	6,546	5,689
Restructuring-related stock compensation expense			961	
Total employee stock-based compensation expense	\$ 5,433	\$ 5,930	\$ 16,655	\$ 17,478

Table of Contents**EXELIXIS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****September 30, 2010****(unaudited)**

During July 2010, our former Chief Executive Officer, George A. Scangos, Ph.D., resigned as an employee of Exelixis and in connection with such resignation agreed to cancel unvested stock options exercisable for 981,302 and unvested RSUs with respect to 101,050 share of our common stock. Due to Dr. Scangos' continued services as a director of Exelixis he would have been entitled to retain his stock options and RSUs. Therefore, we treated the cancellation as a modification of his stock option and RSU agreements and recorded a non-cash compensation charge of approximately \$1.5 million to our consolidated statement of operations during the third quarter of 2010. To calculate the charge, we assumed Dr. Scangos would continue to serve as a director until our 2011 annual stockholder meeting.

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:

	Stock Options		ESPP	
	Three Months Ended September 30,		Three Months Ended September 30,	
	2010 (1)	2009 (2)	2010	2009
Weighted average fair value of awards	\$ N/A	\$ 3.54	\$ 2.08	\$ 1.37
Risk-free interest rate	N/A	2.5%	0.25%	0.30%
Dividend yield	N/A	0%	0%	0%
Volatility	N/A	67%	75%	61%
Expected life	N/A	5.6 years	0.5 years	0.44 years

(1) There were no options granted during the three months ended September 30, 2010.

	Stock Options		ESPP	
	Nine Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009(2)	2010	2009
Weighted average fair value of awards	\$ 3.60	\$ 2.93	\$ 1.99	\$ 1.67
Risk-free interest rate	2.25%	2.3%	0.20%	0.18%
Dividend yield	0%	0%	0%	0%
Volatility	70%	67%	66%	65%
Expected life	5.2 years	5.6 years	0.5 years	0.17 years

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

On July 7, 2009, we commenced a stock option exchange program approved by our stockholders on May 14, 2009. The exchange program was open to all eligible employees who, at the start of the exchange program, were employed by us or one of our subsidiaries and remained employed through August 5, 2009, the date that the replacement stock options were granted. As a result of the exchange, 9.9 million options

Edgar Filing: EXELIXIS INC - Form 10-Q

were cancelled, of which 7.3 million and 2.6 million were vested and unvested, respectively. Of the 7.2 million replacement options that were granted, 5.1 million were issued in exchange for vested options and will vest over a one year term, while 2.1 million options were issued in exchange for unvested options and will vest over three years, with a one year cliff. In association with these grants, we expect to recognize incremental compensation cost of approximately \$0.8 million ratably over the vesting period, of which we have recognized approximately \$0.1 million as of September 30, 2009.

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

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

Table of Contents**EXELIXIS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****September 30, 2010****(unaudited)**

A summary of all stock option activity for the nine months ended September 30, 2010 is presented below:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Options outstanding at December 31, 2009	24,393,598	\$ 7.46		
Granted	243,500	6.28		
Exercised	(206,851)	5.10		
Cancelled	(4,244,837)	7.33		
Options outstanding at September 30, 2010	20,185,410	\$ 7.49	5.8 years	\$ 11,517
Exercisable at September 30, 2010	14,507,195	\$ 7.89	5.0 years	\$ 5,288

As of September 30, 2010, \$15.5 million of total unrecognized compensation expense related to employee stock options was expected to be recognized over a weighted-average period of 2.44 years.

A summary of all RSU activity for the nine months ended September 30, 2010 is presented below:

	Shares	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
RSUs outstanding at December 31, 2009	2,679,224	\$ 7.46		
Awarded	145,575	6.20		
Forfeited	(628,043)	7.45		
Awards outstanding at September 30, 2010	2,196,756	\$ 7.39	1.6 years	\$ 8,721,121

As of September 30, 2010, \$11.1 million of total unrecognized compensation expense related to employee RSUs was expected to be recognized over a weighted-average period of 3.39 years.

NOTE 4. Collaborations***Bristol-Myers Squibb***

Edgar Filing: EXELIXIS INC - Form 10-Q

2008 Cancer Collaboration. In December 2008, we entered into a worldwide collaboration with Bristol-Myers Squibb for XL184 and XL281. Upon effectiveness of the collaboration agreement, Bristol-Myers Squibb made an upfront cash payment of \$195.0 million and additional license payments of \$45.0 million, which were received in 2009. On June 18, 2010, we regained full rights to develop and commercialize XL184 following receipt of notice from Bristol-Myers Squibb of its decision to terminate the 2008 collaboration, solely as to XL184, on a worldwide basis.

Bristol-Myers Squibb received 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 on 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.

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 revenue. Any milestone payments that we may receive under the collaboration agreement will be recognized ratably over the remaining development term but recorded as contract revenue. 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 XL184, 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 joint development projects, less amounts reimbursable to us by Bristol-Myers Squibb on these projects. For the year ended December 31, 2009, we incurred a net payable to Bristol-Myers Squibb and presented these payments as collaboration cost sharing expense. However, during the fiscal year ending December 31, 2010 and in future fiscal years, we expect to be in a net receivable position, and will therefore present these reimbursement payments as collaboration reimbursement revenue.

Table of Contents**EXELIXIS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****September 30, 2010****(unaudited)**

As a result of the termination of the 2008 collaboration with respect to XL184, we regained full rights to develop and commercialize XL184 and on June 28, 2010, in connection with the termination, we received a \$17.0 million transition payment from Bristol-Myers Squibb which was recognized in full as collaboration reimbursement revenue in the third quarter of 2010. This transition payment was made in satisfaction of Bristol-Myers Squibb's obligations under the collaboration agreement to continue to fund its share of development costs for XL184 for a period of three months following the notice of termination. As a result of the termination, Bristol-Myers Squibb's license relating to XL184 was terminated, the rights to XL184 reverted to us, and we will receive, subject to certain terms and conditions, licenses from Bristol-Myers Squibb to research, develop and commercialize XL184. 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 expected to be completed during 2013.

Amounts attributable to both programs under the collaboration agreement consisted of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009 (2)	2010	2009 (2)
Exelixis research and development expenses (1)	\$ 845	\$ 15,218	\$ 41,320	\$ 34,987
Net amount due from (owed to) collaboration partner	18,067	(2,965)	26,706	(2,807)

- (1) Total research and development expenses attributable to us include direct third party expenditures plus estimated internal personnel costs.
 (2) The net amount owed to the collaborative partner is classified as an increase in operating expenses for the three and nine months ended September 30, 2009.

On October 8, 2010, we entered into new agreements with Bristol-Myers Squibb relating to two of our programs and amended certain of our existing collaborations agreements. See Note 7 for details regarding these transactions.

sanofi-aventis

On May 27, 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. The effectiveness of the license and collaboration on July 20, 2009 triggered upfront payments of \$140.0 million (\$120.0 million for the license and \$20.0 million for the collaboration), which we received during the third quarter of fiscal 2009.

Under the license agreement, sanofi-aventis received a worldwide exclusive license to XL147 and XL765, which are currently in phase 1, phase 1b/2 and phase 2 clinical trials, and has sole responsibility for all subsequent clinical, regulatory, commercial and manufacturing activities. It is expected that we will continue to participate in the conduct of ongoing and potential future clinical trials and manufacturing activities. Sanofi-aventis is responsible for funding all future development activities with respect to XL147 and XL765, including our activities. Under the collaboration agreement, the parties are combining efforts in establishing several preclinical PI3K programs and jointly share responsibility for research and preclinical activities related to isoform-selective inhibitors of PI3K- α and - β . Sanofi-aventis will 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. Sanofi-aventis will have sole responsibility for all subsequent clinical, regulatory, commercial and manufacturing activities of any products arising from the

Edgar Filing: EXELIXIS INC - Form 10-Q

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.

In addition to the aggregate upfront cash payments for the license and collaboration agreements, 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. 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 revenue, from the effective date of the agreements. For the nine months ended September 30, 2010, we recognized \$26.3 million in license revenue related to such upfront payments. Any milestone payments that we may receive under the agreements will be amortized over the remaining research and development term and recorded as contract revenue. We will record as operating expenses all costs incurred for work performed by us under the agreements. Reimbursements we receive from sanofi-aventis under the agreements will be recorded as contract revenue as earned, commencing as of the effective date, including reimbursements for costs incurred under the license from the date of signing. In addition, the guaranteed research funding that we expect to receive over the three year research term under the collaboration will be recorded as contract revenue commencing as of the effective date of the

Table of Contents

EXELIXIS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

September 30, 2010

(unaudited)

collaboration. For the nine months ended September 30, 2010, we recognized \$32.3 million in contract revenue related to cost reimbursement and guaranteed research funding.

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.

Boehringer Ingelheim

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

Under the terms of the agreement, Boehringer Ingelheim paid us an upfront cash payment of \$15.0 million for the development and commercialization rights to our S1P1R agonist program. We share responsibility for discovery activities under the collaboration. The agreement provides that the parties will each conduct research under a mutually agreed upon research plan until such time that we submit a compound that has met agreed-upon criteria, or such later time as agreed upon by the parties. The parties are responsible for their respective costs and expenses incurred in connection with performing research under the collaboration. Under the collaboration, Boehringer Ingelheim also has the right, at its own expense, to conduct additional research on S1P1R agonists outside of the scope of the research plan agreed to by the parties. The agreement further provides that Boehringer Ingelheim will receive an exclusive worldwide license to further develop, commercialize and manufacture compounds developed under the collaboration and will have sole responsibility for, and shall bear all costs and expenses associated with, all subsequent preclinical, clinical, regulatory, commercial and manufacturing activities. In return, we will potentially receive up to \$339.0 million in further development, regulatory and commercial milestones and are eligible to receive royalties on worldwide sales of products commercialized under the collaboration. The upfront payment is being recognized ratably over the estimated research term and recorded as license revenue from the effective date of the agreement. During the first half of 2010, the expected research term was extended from eleven months to twenty three months through March 2011, resulting in an extension of the term for revenue recognition purposes and a corresponding decrease in license revenue recognized each quarter. From commencement of the collaboration through September 30, 2010, we have recognized a total of \$13.6 million in license revenue under this agreement.

Boehringer Ingelheim may, upon certain prior notice to us, terminate the agreement as to any product developed under the collaboration. In the event of such termination election, Boehringer Ingelheim's license relating to such product would terminate and revert to us, and we would receive, subject to certain terms and conditions, licenses from Boehringer Ingelheim to research, develop and commercialize such product.

NOTE 5: 2010 Restructuring Charge

On March 8, 2010, we implemented a restructuring plan that resulted in a reduction of our workforce by approximately 40%, or 270 employees. A small number of the terminated employees were subsequently recalled and the termination of a small group of employees has been delayed, all of whom continue to provide services to us. The remaining impacted employees were terminated immediately upon implementation of the plan or by March 31, 2010. The decision to restructure our operations was based on our corporate strategy to focus our efforts on our lead

Edgar Filing: EXELIXIS INC - Form 10-Q

clinical compounds, XL184, XL147 and XL765, by dedicating the majority of our resources to aggressively drive these drug candidates through development towards commercialization.

In connection with the 2010 restructuring plan, we recorded a charge of approximately \$16.1 million in the first quarter of 2010 primarily related to one-time termination benefits, which includes the modification of certain stock option awards previously granted to the terminated employees. The modification accelerates the vesting of any stock options that would have vested over the period beginning from cessation of employment through August 5, 2010. Employees who were terminated in March also received an additional two months to exercise their options, for which a small charge was taken. The remainder of the charge was for the impairment of various assets and for non-cash charges relating to the closure of our facility in San Diego, California. The total impairment charge of \$2.5 million was due to the disposal and write-down to estimated fair-market value of fixed assets that were deemed redundant or will have a reduced useful life as a result of us vacating our San Diego facility and our exit of one of our South

Table of Contents**EXELIXIS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****September 30, 2010****(unaudited)**

San Francisco facilities. The fair-value of the fixed assets impaired assumed that we would exit the South San Francisco building by June 30, 2010, which subsequently occurred.

On July 9, 2010, we entered into a sublease with Onyx Pharmaceuticals, Inc. (Onyx) with respect to approximately 68,738 square feet of the property located at 249 East Grand Avenue, South San Francisco, California. The term of the sublease commenced on September 1, 2010, and will expire on November 30, 2015, the end of our lease term. Under the sublease, Onyx agreed to pay us monthly base rent for the subleased premises in addition to certain operating expenses. In connection with the execution and delivery of the sublease, we also entered into an amendment to our lease with the landlord, pursuant to which, among other things, our right to extend the term of the lease was terminated. We recorded further restructuring expenses of approximately \$9.4 million during the second quarter of 2010 and \$0.3 million during the third quarter of 2010 associated primarily with lease-exit costs associated with the sublease and exit of our South San Francisco building, partially offset by a reduction in one-time termination benefits following the recall of certain employees that were originally terminated under the restructuring plan and the continued delay in the termination of the small group of employees referred to above.

We expect that the restructuring plan will result in total cash expenditures of approximately \$24.8 million, of which approximately \$14.3 million is expected to be paid in 2010. The balance will be paid over an additional five years and primarily relates to net payments due under the lease for our South San Francisco building that we exited during the second quarter of 2010, partially offset by payments due to us under the sublease agreement that we signed in July 2010.

The outstanding restructuring liability is included in Accrued Compensation and Benefits , Other Accrued Expenses , and Other Long-Term Liabilities on our Condensed Consolidated Balance Sheet as of September 30, 2010 and the components are summarized in the following table (in thousands):

	Employee Severance And Other Benefits	Facility Charges	Asset Impairment	Legal and Other Fees	Total
Restructuring charge as of December 31, 2009	\$	\$	\$	\$	\$
Restructuring charge recorded in the nine months ended September 30 2010	11,702	11,609	2,482	30	25,823
Cash payments	(10,456)	(3,238)		(10)	(13,704)
Adjustments or non-cash credits including stock compensation expense	(1,082)	613	(2,482)		(2,951)
Ending accrual balance as of September 30, 2010	\$ 164	\$ 8,984	\$	\$ 20	\$ 9,168

NOTE 6: Debt***Silicon Valley Bank Loan and Security Agreement***

In May 2002, we entered into a loan and security agreement with Silicon Valley bank for an equipment line of credit of up to \$16.0 million with a draw down period of one year. Each draw on the line of credit has a payment term of 48 months and bears interest at the bank's published prime rate. We extended the draw down period on the line-of-credit for an additional year in June 2003 and increased the principal amount of the line of credit from \$16.0 million to \$19.0 million in September 2003. This equipment line of credit was fully drawn as of December 31, 2004 and was fully paid off as of December 31, 2007.

Edgar Filing: EXELIXIS INC - Form 10-Q

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

In December 2006, we entered into a second loan modification agreement to the loan and security agreement originally entered into in May 2002. The terms associated with the original line of credit under the May 2002 agreement and December 2004 loan modification agreement were not modified. The December 2006 loan modification agreement provided for an additional equipment line of credit in the amount of up to \$25.0 million with a draw down period of approximately one year. Each advance must be repaid in 48 equal, monthly installments of principal, plus accrued interest, at an annual rate of 0.85% fixed and is subject to a prepayment penalty of 1.0%. The loan facility is secured by a non-interest bearing certificate of deposit account with the bank, in an amount equal to at least 100% of the outstanding obligations under the line of credit. This equipment line of credit was fully drawn as of December 31, 2008. The collateral balance of \$4.8 million is recorded in the accompanying consolidated balance sheet as cash and cash equivalents and marketable securities as the deposit account is not restricted as to withdrawal. The outstanding obligation under the line of credit as of September 30, 2010 and 2009 was \$4.3 million and \$10.5 million, respectively.

Table of Contents**EXELIXIS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****September 30, 2010****(unaudited)**

In December 2007, we entered into a third loan modification agreement to the loan and security agreement originally entered into in May 2002. The terms associated with the original line of credit under the May 2002 agreement and the subsequent loan modifications were not modified. The December 2007 loan modification agreement provides for an additional equipment line of credit in the amount of up to \$30.0 million with a draw down period of approximately 2 years. Each advance must be repaid in 48 equal, monthly installments of principal, plus accrued interest, at an annual rate of 0.75% fixed. In December 2009, we amended the agreement and extended the draw down period on the line-of-credit for an additional 18 months through June 2011 and increased the principal amount of the line of credit from \$30.0 million to \$33.6 million. Pursuant to the terms of the amendment, we are required to make minimum draws of \$2.5 million every 6 months through June 2011, for total additional draws of \$7.5 million. The loan facility requires security in the form of a non-interest bearing certificate of deposit account with the bank, in an amount equal to at least 100% of the outstanding obligations under the line of credit. In June 2008, we drew down \$13.6 million under this agreement, in December 2009, we drew down \$5.0 million, and in June 2010, in accordance with the terms of the modified agreement, we drew down an additional \$2.5 million. The collateral balance of \$12.5 million is recorded in the accompanying consolidated balance sheet as cash and cash equivalents and marketable securities as the deposit account is not restricted as to withdrawal. The outstanding obligation under the line of credit as of September 30, 2010 and 2009 was \$12.0 million and \$9.1 million, respectively.

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 1.00% 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.

Deerfield Financing

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

Edgar Filing: EXELIXIS INC - Form 10-Q

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, the Deerfield Entities may require us to prepay the notes at the optional prepayment price, plus accrued and unpaid interest and any other accrued and reimbursable expenses (the "Put Price"). Upon an event of default, the Deerfield Entities may declare all or a portion of the Put Price to be immediately due and payable.

We also entered into a security agreement in favor of the Deerfield Entities 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

Table of Contents

EXELIXIS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

September 30, 2010

(unaudited)

include customary representations and warranties and covenants made by us, including restrictions on the incurrence of additional indebtedness.

NOTE 7: Subsequent Event

On October 8, 2010, we entered into new agreements with Bristol-Myers Squibb relating to two of our programs. Under the first agreement, we will grant to Bristol-Myers Squibb a license to our small-molecule TGR5 agonist program, including rights to the program's lead compound, XL475, as well as potential backups. Under the second agreement, we will collaborate to discover, optimize, and characterize ROR antagonists. We simultaneously amended three of our existing collaboration agreements with Bristol-Myers Squibb for the treatment of cancer, cardiovascular and metabolic disorders, each as more fully described below.

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 will have a worldwide exclusive license to XL475 and will have sole control and responsibility for all subsequent research, development, commercial and manufacturing activities. The TGR5 License Agreement is subject to and will become effective upon clearance under the Hart-Scott-Rodino Antitrust Improvement Act of 1976, as amended ("HSR"). Upon effectiveness of the TGR5 License Agreement, Bristol-Myers Squibb is required to pay us an upfront cash payment of \$35.0 million. Additionally, for each product developed by Bristol-Myers Squibb under the license, we will be eligible to receive development and regulatory milestones of up to \$250.0 million in the aggregate and commercial milestones of up to \$150.0 million in the aggregate, as well as royalties on commercial sales of any such products.

ROR Collaboration Agreement

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 (the "ROR Collaboration Agreement"). The ROR Collaboration Agreement became effective on October 8, 2010. In consideration for entry into the ROR Collaboration Agreement, we will receive an upfront cash payment of \$5.0 million. We will also be eligible to receive additional development and regulatory milestones of up to \$255.0 million in the aggregate and commercial milestones of up to \$150.0 million in the aggregate, as well as royalties on commercial sales of any such products.

Amendments

We entered into amendments to our cancer collaboration agreement with Bristol-Myers Squibb dated December 11, 2008, as amended and our collaboration agreement with Bristol-Myers Squibb dated December 5, 2005, as amended, pursuant to which the parties made certain minor amendments to the rights and obligations of the parties under each agreement.

We also entered into an amendment to our cancer collaboration agreement with Bristol-Myers Squibb dated December 15, 2006, which became effective on January 11, 2007, as amended, pursuant to which we exercised our right to opt-out of further co-development of XL139 in consideration for a payment of \$20.0 million. The amendment is subject to and will become effective upon clearance under HSR. Upon the effectiveness of the amendment, we will 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 amendment, the research term will end, and we will have no further obligation to deliver to Bristol-Myers Squibb a third Investigational New Drug candidate under the collaboration agreement.

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, will, determine, may, eligible, could, would, estimate, goal, predict, potential, continue 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, 2009, filed with the Securities and Exchange Commission, or SEC, on March 10, 2010. 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 committed to discovering, developing and commercializing innovative therapies for the treatment of cancer. Through our integrated drug discovery and development activities, we are building a portfolio of novel compounds that we believe have the potential to be high-quality, differentiated pharmaceutical products that can make a meaningful difference in the lives of patients. The majority of our programs focus on discovery and development of small molecule drugs for cancer.

XL184, our most advanced drug candidate, inhibits MET, VEGFR2 and RET, proteins that are key drivers of tumor growth and/or vascularization. XL184 is the most advanced inhibitor of MET in clinical development and is being evaluated in a broad development program encompassing multiple solid tumor indications. A global phase 3 registration trial of XL184 as a potential treatment for medullary thyroid cancer is currently enrolling. Assuming positive results from this registration trial, we currently expect to submit a new drug application, or NDA, for XL184 as a treatment for medullary thyroid cancer in the United States in the second half of 2011. An immediate priority for us is to generate additional data in the five leading cohorts of hepatocellular carcinoma, melanoma, non-small cell lung cancer, ovarian cancer and prostate cancer in our ongoing randomized discontinuation trial to support the prioritization of our clinical and commercial options for XL184. Additional phase 2 clinical trials of XL184 in glioblastoma and non-small cell lung cancer are also ongoing. We are also preparing to initiate a phase 3 registration trial of XL184 as a potential treatment for recurrent glioblastoma by the end of 2010.

We are also actively pursuing the development of XL147 and XL765, leading inhibitors of phosphoinositide-3 kinase, or PI3K, that we out-licensed to sanofi-aventis in 2009. XL147 is a selective inhibitor of PI3K while XL765 is a dual inhibitor of PI3K and mTOR. Sanofi-aventis is responsible for funding all development activities with respect to XL147 and XL765, including our activities. We currently are conducting the majority of the clinical trials for these compounds. XL147 and XL765 are currently being evaluated in a series of phase 1b/2 clinical trials for a variety of solid tumor indications and a broad phase 2 clinical trial program that commenced in early 2010.

We also have several earlier novel drug candidates in clinical development for the treatment of cancer, and preclinical programs for cancer, metabolic disease and inflammation. 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, sanofi-aventis, Genentech (a wholly owned member of the Roche Group), Boehringer Ingelheim GmbH, GlaxoSmithKline and Daiichi-Sankyo that allow us to retain economic participation in compounds and support additional development of our pipeline. Our collaborations have historically fallen into one of two categories: collaborations in which we co-develop compounds with a partner, share development costs and profits from commercialization and may have the right to co-promote products in the United States, and collaborations in which we out-license compounds to a partner for further development and commercialization, have no further unreimbursed cost obligations and are entitled to receive milestones and royalties or a share of profits from commercialization. Under either form of collaboration, we may also be entitled to license fees, research funding and milestone payments from research results and subsequent product development activities. Reimbursement revenues and expenses under co-development collaborations are recorded as collaboration reimbursement revenue and collaboration cost-sharing expenses, respectively, while reimbursement revenues and expenses under other collaborations are recorded as contract revenue and research and development expenses in the period incurred.

Table of Contents

Our Strategy

Our business strategy is to leverage our biological expertise and integrated research and development capabilities to generate a pipeline of development compounds with significant therapeutic and commercial potential for the treatment of cancer and potentially other serious diseases.

Our strategy consists of three principal elements:

Focus on lead clinical compound We are focusing our development efforts on XL184. This drug candidate is the most advanced in our pipeline, and we believe that it has the greatest near-term therapeutic and commercial potential. As a result, we are dedicating our resources to aggressively advance this drug candidate through development toward commercialization.

Partner compounds We continue to pursue new collaborations with leading pharmaceutical and biotechnology companies for the development and ultimate commercialization of some of our preclinical and clinical 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. Collaborations provide us with a means of shifting all or a portion of the development costs related to partnered drug candidates and provide financial resources that we can apply to fund our share of the development of our lead clinical compounds and other areas of our pipeline. Our goal is to increase the portion of our development expenses that are reimbursed by partners while maintaining financial upside from potential downstream milestones and royalties if these drug candidates are marketed in the future.

Control costs We are committed to managing our costs, and we continually analyze our expenses to align expenses with our cash resources. We are selective with respect to funding our clinical development programs and have established definitive go/no-go criteria to ensure that we commit our resources only to those programs that we believe have the greatest therapeutic and commercial potential.

We are conducting a comprehensive corporate strategic review, with a focus on the evaluation of various options for advancing XL184 in light of emerging clinical data. The evaluation includes a review of XL184 clinical data and priorities, ongoing and planned clinical trials, potential partnering scenarios, regulatory strategies, the competitive landscape, our resources and financial considerations. Our goal remains to appropriately deploy our resources in a manner that is designed to maximize the therapeutic and commercial potential of XL184.

Our Pipeline

Overview

We have an extensive pipeline of compounds in various stages of development that will potentially treat cancer and various metabolic, cardiovascular and inflammatory disorders. All of our development compounds were generated through our internal drug discovery efforts, although we are developing certain of these compounds in collaboration with partners and have out-licensed others. We are focusing our development efforts on our lead clinical compound, XL184. This drug candidate is the most advanced in our pipeline, and we believe it has the greatest near-term therapeutic and commercial potential. As a result, we are dedicating our resources to aggressively advance this drug candidate through development towards commercialization.

XL184

XL184 inhibits MET, VEGFR2 and RET, proteins that are key drivers of tumor growth and/or vascularization. XL184 is the most advanced inhibitor of MET in clinical development and is being evaluated in a broad development program encompassing multiple solid tumor indications. A global phase 3 registration trial of XL184 as a potential treatment for medullary thyroid cancer is currently enrolling. Assuming positive results from this registration trial, we currently expect to submit a new drug application, or NDA, for XL184 as a treatment for medullary thyroid cancer in the United States in the second half of 2011. An immediate priority for us is to generate additional data in the five leading cohorts of hepatocellular carcinoma, melanoma, non-small cell lung cancer, ovarian cancer and prostate cancer in our ongoing randomized discontinuation trial to support the prioritization of our clinical and commercial options for XL184. Additional phase 2 clinical trials

Edgar Filing: EXELIXIS INC - Form 10-Q

of XL184 in glioblastoma and non-small cell lung cancer are also ongoing. We are also preparing to initiate a phase 3 registration trial of XL184 as a potential treatment for recurrent glioblastoma by the end of 2010.

Table of Contents**Other Compounds**

The following table sets forth those compounds that we have out-licensed to third parties:

Compound	Partner	Principal Targets	Indication	Stage of Development
XL880	GlaxoSmithKline	MET, VEGFR2	Cancer	Phase 2
XL147	sanofi-aventis	PI3K	Cancer	Phase 2
XL765	sanofi-aventis	PI3K, mTOR	Cancer	Phase 1b/2
XL139*	Bristol-Myers Squibb	Hedgehog	Cancer	Phase 1b
XL518	Genentech	MEK	Cancer	Phase 1b
XL281	Bristol-Myers Squibb	RAF	Cancer	Phase 1
XL652	Bristol-Myers Squibb	LXR	Metabolic and cardiovascular diseases	Phase 1
XL041	Bristol-Myers Squibb	LXR	Metabolic and cardiovascular diseases	Phase 1
XL475*	Bristol-Myers Squibb	TGR5 (agonist)	Metabolic disease	Preclinical
XL550	Daiichi-Sankyo	MR	Metabolic and cardiovascular diseases	Preclinical
S1P1R	Boehringer Ingelheim	S1P1R (agonist)	Inflammation	Preclinical
Isoform Selective PI3Ka and PI3Kb	sanofi-aventis	PI3Ka and PI3Kb	Cancer	Preclinical
ROR Antagonists	Bristol-Myers Squibb	ROR antagonist	Inflammation	Preclinical

* Upon clearance under the Hart-Scott-Rodino Antitrust Improvement Act of 1976, as amended, or HSR.

The following table sets forth those compounds for which we are pursuing collaborations or other external opportunities:

Compound	Principal Targets	Indication	Stage of Development
XL228	IGF1R , ABL, SRC	Cancer	Phase 1
XL388	TORC1 & 2	Cancer	IND
XL499	PI3K-d	Cancer and inflammation	Preclinical
XL541	S1P1R (antagonist)	Cancer	Preclinical
XL888	HSP90	Cancer	Phase 1

Recent Developments**Transactions with Bristol-Myers Squibb Company**

On October 8, 2010, we entered into new agreements with Bristol-Myers Squibb relating to two of our programs. Under the first agreement, we will grant to Bristol-Myers Squibb a license to our small-molecule TGR5 agonist program, including rights to the program's lead compound, XL475, as well as potential backups. Under the second agreement, we will collaborate to discover, optimize, and characterize ROR antagonists. We simultaneously amended three of our existing collaboration agreements with Bristol-Myers Squibb for the treatment of cancer, cardiovascular and metabolic disorders, each as more fully described below.

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, or, the TGR5 License Agreement. Pursuant to the terms of the TGR5 License Agreement, Bristol-Myers Squibb will have a worldwide exclusive license to XL475 and will have sole control and responsibility for all subsequent research, development, commercial and manufacturing activities. The TGR5 License Agreement is subject to and will become effective upon

Edgar Filing: EXELIXIS INC - Form 10-Q

clearance under HSR. Upon effectiveness of the TGR5 License Agreement, Bristol-Myers Squibb is required to pay us an upfront cash payment of \$35.0 million. Additionally, for each product developed by Bristol-Myers Squibb under the license, we will be eligible to receive development and regulatory milestones of up to \$250.0 million in the aggregate and commercial milestones of up to \$150.0 million in the aggregate, as well as royalties on commercial sales of any such products.

Bristol-Myers Squibb may at any time, upon specified prior notice to us, terminate the license on a product-by-product and country-by-country basis. In addition, either party may terminate the agreement for the other party's uncured material breach. In the event of termination by Bristol-Myers Squibb at will or by us for Bristol-Myers Squibb's uncured material breach, the license granted to Bristol-Myers Squibb would terminate, the right to such product would revert to us, and we would receive a royalty-free license, if

Table of Contents

terminated at will, or a royalty-bearing license, if terminated for an uncured material breach, from Bristol-Myers Squibb to develop and commercialize such product in the related country. In the event of termination by Bristol-Myers Squibb for our uncured material breach, Bristol-Myers Squibb would retain the right to such product and we would receive reduced royalties from Bristol-Myers Squibb on commercial sales of such product.

ROR Collaboration Agreement

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, or, the ROR Collaboration Agreement. In consideration for entry into the ROR Collaboration Agreement, we will receive an upfront cash payment of \$5.0 million. We will also be eligible to receive additional development and regulatory milestones of up to \$255.0 million in the aggregate and commercial milestones of up to \$150.0 million in the aggregate, as well as royalties on commercial sales of any such products.

Under the terms of the ROR Collaboration Agreement, we will be primarily responsible for activities related to the discovery, optimization and characterization of the ROR antagonists during the collaborative research period. The collaborative research period began on October 8, 2010 and will end on the earliest to occur of (i) October 8, 2013 if a compound has not satisfied certain specified criteria by such time, (ii) such time that a compound satisfies certain specified criteria, or (iii) October 8, 2015. Following the collaborative research period, Bristol-Myers Squibb will have sole responsibility for any further research, development, manufacture and commercialization of products developed under the collaboration and will bear all costs and expenses associated with those activities.

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

The ROR Collaboration Agreement became effective on October 8, 2010.

Amendment to 2008 Cancer Collaboration

We entered into Amendment No. 3 to our cancer collaboration agreement with Bristol-Myers Squibb dated December 11, 2008, as amended, or, the 2008 Cancer Collaboration Agreement, pursuant to which the parties made certain minor amendments to the rights and obligations of the parties with respect to XL281.

Amendment No. 3 to the 2008 Cancer Collaboration Agreement became effective on October 8, 2010.

Amendment to 2007 Cancer Collaboration

We entered into Amendment No. 3 to our cancer collaboration agreement with Bristol-Myers Squibb dated December 15, 2006, which became effective on January 11, 2007, as amended, or, the 2007 Cancer Collaboration Agreement, pursuant to which we exercised our right to opt-out of further co-development of XL139 in consideration for a payment of \$20.0 million. The amendment is subject to and will become effective upon clearance under HSR. Upon the effectiveness of the amendment, we will 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 amendment, the research term will end, and we will have no further obligation to deliver to Bristol-Myers Squibb a third Investigational New Drug, or IND, candidate under the collaboration agreement.

Amendment to LXR Collaboration

We entered into Amendment No. 1 to our collaboration agreement with Bristol-Myers Squibb dated December 5, 2005, as amended, or, the LXR Collaboration Agreement, pursuant to which we made certain minor amendments to the rights and obligations of the parties under the collaboration agreement.

Edgar Filing: EXELIXIS INC - Form 10-Q

Amendment No. 1 to the LXR Collaboration Agreement became effective on October 8, 2010.

Accounting Treatment

The TGR5 License Agreement, ROR Collaboration Agreement and Amendment No. 3 to the 2007 Cancer Collaboration Agreement will be accounted for as one unit of accounting with the revenue from all agreements being recognized over the longest

Table of Contents

commitment period. The ROR Collaboration Agreement has the longest commitment period of the three agreements with a research term of approximately 42 months. Therefore, we expect to recognize the upfront payments received under the TGR5 License Agreement and the ROR Collaboration Agreement ratably over approximately 42 months and to record them as license revenue.

The payment to be received under the Amendment No. 3 to the 2007 Cancer Collaboration Agreement will be added to the deferred revenue balance remaining as of the effective date of the amendment and we expect to recognize the combined total ratably over approximately 42 months and to record it as contract revenue.

For illustrative purposes, if the agreements become effective during the fourth quarter of 2010, we estimate the total incremental revenue related to the new and amended agreements in 2010 and 2011 will be approximately \$0.9 million and \$8.5 million, respectively. Any milestone payments that we may receive under any of the agreements will be recognized in accordance with our existing policy as contract revenue ratably over the remaining commitment period under the agreements.

Any costs incurred in connection with the ROR Collaboration Agreement or TGR5 License Agreement will be recorded as operating expense.

Loan Payment to GlaxoSmithKline

In October 2002, we entered into a loan and security agreement in connection with our collaboration with GlaxoSmithKline to discover and develop novel therapeutics in the areas of vascular biology, inflammatory disease and oncology. We borrowed an aggregate of \$85.0 million pursuant to the loan agreement. 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 October 27, 2010, the aggregate principal and interest outstanding under the loan was \$35.7 million.

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 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.

Limited Sources of Revenues

We currently 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.

Clinical Trials

We currently have multiple compounds in clinical development and expect to expand the development programs for our compounds, particularly XL184. Our compounds 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 each of our compounds depends upon the results of each stage of clinical development. In general, we will incur increased operating expenses for compounds that advance in clinical development, whereas expenses will end for compounds that do not warrant further clinical development.

We are responsible for all development costs for compounds in our pipeline that are not partnered. We typically share development costs with partners in our co-development collaborations, when we enter into such arrangements, and have no unreimbursed cost obligations with respect to compounds that we have out-licensed.

Liquidity

As of September 30, 2010, we had \$261.0 million in cash and cash equivalents and short-term and long-term marketable securities, which included restricted cash and investments of \$6.4 million. We anticipate that our current cash and cash equivalents, short-term and long-term

Edgar Filing: EXELIXIS INC - Form 10-Q

marketable securities, funding from our October 2010 transactions with Bristol-Myers Squibb and funding that we expect to receive from collaborators, which includes anticipated cash from additional business development activity, 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 XL184, our most advanced compound;

Table of Contents

the progress and scope of other research and development activities conducted by us;

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 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 the Deerfield Entities under the note purchase agreement;

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 XL184) that provide additional capital.

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

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.

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 the first half 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 currently in phase 1, phase 1b/2 and phase 2 clinical trials, and has sole responsibility for all subsequent clinical, regulatory, commercial and manufacturing activities. It is expected that we will continue to participate in the conduct of ongoing and potential future clinical trials and manufacturing activities. Sanofi-aventis is responsible for funding all future development activities with respect to XL147 and XL765, including our activities. Under the collaboration agreement, the parties are combining efforts in establishing several pre-clinical PI3K programs and jointly share responsibility for research and preclinical activities related to isoform-selective inhibitors of PI3K- and -β. Sanofi-aventis will 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 IND application filed with the applicable regulatory authorities for such product. 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.

In addition to the aggregate upfront cash payments for the license and collaboration agreements, 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. 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 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

Table of Contents

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.

2008 Cancer Collaboration with Bristol-Myers Squibb

In December 2008, we entered into a worldwide collaboration with Bristol-Myers Squibb for XL184 and XL281. Upon effectiveness of the collaboration agreement in December 2008, Bristol-Myers Squibb made an 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 XL184 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 XL184, on a worldwide basis. Bristol-Myers Squibb informed us that the termination was based upon its review of XL184 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 XL184 for a period of three months following the notice of termination. As a result of the termination, Bristol-Myers Squibb's license relating to XL184 has terminated and its rights to XL184 have reverted to us, and we received, subject to certain terms and conditions, licenses from Bristol-Myers Squibb to research, develop and commercialize XL184.

The upfront payment of \$195.0 million we received upon effectiveness of the collaboration agreement and the license payments of \$20.0 million and \$25.0 million that we received in the first quarter and second quarter of 2009, respectively, will be recognized ratably over the estimated development term, and recorded as license revenue, from the effective date of the agreement in December 2008. During the second quarter of 2010, we revised the development term from five years to four years and 8.5 months, which is our current estimate of the term of our performance obligation under the collaboration. Any milestone payments that we may receive under the agreement will be recognized ratably over the same revised period but will be recorded as contract revenue. We will record as operating expense 100% of the cost incurred for work performed by us on XL281. The transition payment we received in connection with the termination of the collaboration agreement as to XL184 was recognized as collaboration reimbursement revenue in the third quarter of 2010.

Prior to the termination of the collaboration by Bristol-Myers Squibb as to XL184, 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 joint development projects, less amounts reimbursable to us by Bristol-Myers Squibb on these projects. To the extent that net research and development funding payments were received from Bristol-Myers Squibb, these payments were presented as collaboration reimbursement revenue. In periods when net research and development funding payments were payable to Bristol-Myers Squibb, these payments were presented as collaboration cost sharing expense. Notwithstanding termination by Bristol-Myers Squibb, revenues from the collaboration will continue to be determined and reflected on an annual basis. As we fulfilled our responsibility for funding the initial \$100.0 million of combined costs in the second quarter of 2010 and received reimbursements from Bristol-Myers Squibb prior to the termination of the collaboration as to XL184, we expect to be in a net receivable position for the fiscal year ending December 31, 2010 and in future fiscal years, and will therefore present reimbursement payments as collaboration reimbursement revenue.

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 October 27, 2010, the aggregate principal and interest outstanding under the loan was \$35.7 million. The third 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. Following the conclusion on October 27, 2008 of the development term under our collaboration with GlaxoSmithKline, we are no longer eligible to receive selection milestone payments from GlaxoSmithKline to credit against outstanding loan

amounts, and in the

Table of Contents

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. 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.

Critical Accounting Estimates

Our consolidated financial statements and related notes are prepared in accordance with U.S. generally accepted accounting principles, or GAAP, which require us to make judgments, estimates and assumptions that affect the reported amounts of assets, liabilities, revenue 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 revenue 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 second quarter of 2010, the estimated research term under the Boehringer Ingelheim agreement was extended through March 2011, resulting in an extension in the period over which we will recognize license revenue and decreasing our license revenue recognized in the period to \$0.7 million. 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 estimate 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. This estimate was reduced from five years following notice from Bristol-Myers Squibb of its decision to terminate the 2008 collaboration as to XL184. License fees are classified as license revenue 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. There is diversity in practice on the recognition of milestone revenue. Other companies have adopted an alternative milestone revenue recognition policy, whereby the full milestone fee is recognized upon completion of the milestone. If we had adopted such a policy, our revenues recorded to date would have increased and our deferred revenues would have decreased by a material amount compared to total revenue recognized. 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 revenue when the milestone is achieved. Milestones are classified as contract revenue in our consolidated statement of operations.

Collaborative agreement reimbursement revenue consists of research and development support received from collaborators. Collaborative agreement reimbursement revenue is 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 XL184, certain research and development expenses were partially reimbursable to us. On an annual basis, the amounts that Bristol-Myers Squibb owed us, net of amounts reimbursable to Bristol-Myers Squibb by us on those projects, were recorded as revenue. Conversely, research and development expenses included the net settlement of amounts we owed Bristol-Myers Squibb for research and development expenses that Bristol-Myers Squibb incurred on joint development projects, less amounts reimbursable to us by Bristol-Myers Squibb on such projects. In annual periods when net research and development funding payments were payable to Bristol-Myers Squibb, these payments were presented as collaboration cost-sharing expense. Reimbursements under co-development agreements were classified as collaboration reimbursement revenue, while reimbursements under other arrangements were classified

Table of Contents

as contract revenue in our consolidated 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. 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

Substantial portions of our preclinical studies and all of our clinical trials have been performed by third-party contract research organizations, or CROs, and other vendors. We accrue expenses for preclinical studies performed by our vendors based on certain estimates over the term of the service period and adjust our estimates as required. We accrue 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. During the quarter ended September 30, 2010, we recorded a reduction of \$1.9 million, or \$0.02 per share, to our accrued clinical trial liabilities and research and development expense related to patient procedures in our phase 2 and 3 clinical trials for XL184.

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 September 30, 2010, \$15.5 million of total unrecognized compensation expense related to stock options was expected to be recognized over a weighted-average period of 2.44 years in addition to \$11.1 million of total unrecognized compensation expense relating to restricted stock units, or RSUs, which was expected to be recognized over 3.39 years. See Note 3 to our Consolidated Financial Statements for a further discussion on stock-based compensation.

Fiscal Year Convention

We have adopted a 52- or 53-week fiscal year that ends on the Friday closest to December 31st of each year. Fiscal year 2009, a 52-week year, ended on January 1, 2010, and fiscal year 2010, a 52-week year, will end on December 31, 2010. For convenience,

Table of Contents

references in this report as of and for the fiscal year ended January 1, 2010 are indicated on a calendar year basis, ended December 31, 2009, and as of and for the fiscal quarters ended October 2, 2009 and October 1, 2010 are indicated as ended September 30, 2009 and 2010, 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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Contract revenue:				
Research and development funding	\$ 10.5	\$ 18.2	\$ 32.6	\$ 21.8
Milestones	1.4	6.4	11.4	15.8
License revenue, amortization of upfront payments, including amortization of premiums for equity purchases	24.5	30.4	73.6	70.1
Collaboration reimbursements	18.1		26.7	
Total revenues	\$ 54.5	\$ 55.0	\$ 144.3	\$ 107.7

Dollar (decrease)/increase	\$ (0.5)	\$ 36.6
Percentage (decrease)/increase	(0.9%)	34.0%

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Sanofi-aventis	\$ 19.2	\$ 24.9	\$ 58.6	\$ 24.9
Bristol-Myers Squibb	34.6	22.4	75.9	63.5
Genentech		3.5	7.0	11.9
GlaxoSmithKline				0.5
Boehringer Ingelheim	0.7	4.2	2.8	6.7
SEI				0.2
Total revenues	\$ 54.5	\$ 55.0	\$ 144.3	\$ 107.7

Dollar (decrease)/increase	\$ (0.5)	\$ 36.6
Percentage (decrease)/increase	(0.9%)	34.0%

The small decrease in revenues for the three months ended September 30, 2010, as compared to the comparable period for the prior year, was primarily due to a one-time recognition of revenue in connection with drug supplies at the initiation of our May 2009 collaboration agreement with sanofi-aventis for XL147 and XL765 and the conclusion of the research funding portion of the Bristol Myers-Squibb LXR agreement and Genentech MEK program, offset by increased reimbursement revenue relating to our 2008 cancer collaboration agreement with Bristol Myers-Squibb for XL184 and XL281. In addition, we had a reduction in license revenue under our agreement with Boehringer Ingelheim as a result of extending the expected research term in early 2010 from eleven months to twenty three months through March 2011.

The increase in revenues for the nine months ended September 30, 2010, as compared to the comparable period for the prior year, was primarily due to our collaboration agreements with sanofi-aventis for XL147, XL765 and the discovery of inhibitors of P13K. In addition to the increase resulting from the agreements with sanofi-aventis, we also recognized an increase of \$26.7 million due to increased reimbursement revenue relating to our 2008 cancer collaboration agreement with Bristol Myers-Squibb for XL184 and XL281. These increases in revenue were partially offset by a reduction in milestone revenues related to our 2007 cancer collaboration with Bristol-Myers Squibb and the completion of revenue recognition under our LXR collaboration with Bristol-Myers Squibb.

Edgar Filing: EXELIXIS INC - Form 10-Q

Collaboration reimbursement revenue consisted of research and development expenses and reimbursements related to our 2008 cancer collaboration agreement with Bristol Myers-Squibb for XL184 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

Table of Contents

collaboration reimbursement revenue. In 2009, when net research and development funding payments were expected to be payable to Bristol-Myers Squibb, these payments were presented as collaboration cost sharing expense. However, for the year ending December 31, 2010, we expect to receive net collaboration reimbursements and have recorded collaboration reimbursement revenue of \$18.1 million and \$26.7 million for the three and nine months ended September 30, 2010, respectively. Collaboration reimbursement revenue for the three and nine months ended September 30, 2010 included the \$17.0 million transition payment received from Bristol-Myers Squibb upon termination of the 2008 collaboration with respect to XL184 during the second quarter of 2010.

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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Research and development expenses	\$ 49.4	\$ 60.2	\$ 168.4	\$ 170.6
Dollar decrease	\$ (10.8)		\$ (2.2)	
Percentage decrease	(17.9%)		(1.3%)	

Research and development expenses consist primarily of personnel expenses, clinical trials, consulting, laboratory supplies and facilities costs.

The decrease for the three months ended September 30, 2010, as compared to the comparable period in 2009, resulted primarily from the following:

Personnel Personnel expense, which includes salaries, bonuses, related fringe benefits, recruiting and relocation costs, decreased by \$6.1 million, or 34%, primarily due to a reduction in headcount resulting from our restructuring implemented in March 2010.

General Corporate Costs There was a decrease of \$2.7 million, or 24%, in the allocation of general corporate costs (such as facilities 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 restructuring plan, and the resulting decrease in costs to be allocated.

Laboratory Supplies Laboratory supplies decreased by \$2.4 million, or 60%, primarily due to the decrease in headcount and other cost cutting measures.

Stock-Based Compensation Stock-based compensation expense decreased by \$1.5 million or 37% as a result of our reduction in headcount from our restructuring implemented in March 2010.

These decreases were partially offset by an increase in clinical trial expenses. Clinical trial expenses, which include services performed by third-party contract research organizations and other vendors, increased by \$1.9 million, or 10%, primarily due to increased phase 2 and phase 3 clinical trial activity for XL184 and increased phase 2 clinical trial activity for XL147. These increases were partially offset by reduced activities and trial wind-down costs associated with various other compounds.

The decrease for the nine months ended September 30, 2010, as compared to the comparable period in 2009, resulted primarily from the following:

Personnel Personnel expense, which includes salaries, bonuses, related fringe benefits, recruiting and relocation costs, decreased by \$12.2 million, or 22%, primarily due to a reduction in headcount resulting from our restructuring implemented in March 2010.

General Corporate Costs There was a decrease of \$4.8 million, or 15%, in the allocation of general corporate costs (such as facilities 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 restructuring plan, and the resulting decrease in costs to be allocated.

Laboratory Supplies Laboratory supplies decreased by \$4.5 million, or 38%, primarily due to the decrease in headcount and other cost cutting measures.

Stock-Based Compensation Stock-based compensation expense decreased by \$2.6 million or 22% as a result of our reduction in headcount from our restructuring implemented in March 2010.

Table of Contents

These decreases were partially offset by an increase in clinical trial expenses and a decline in cost reimbursements. Clinical trial expenses, which include services performed by third-party contract research organizations and other vendors, increased by \$20.6 million, or 46%, primarily due to increased phase 2 and phase 3 clinical trial activity for XL184 and increased phase 2 clinical trial activity for XL147. These increases were partially offset by reduced activities associated with SEI-related compounds, for which the arrangement ended in 2009, as well as a decline in activities associated with various other compounds. In addition, under our 2007 contract research agreement with Agrigenetics, Inc., we received an increase in research and development funding of \$5.4 million that was recognized as a reduction to research and development expense in 2009. The Agrigenetics agreement ended in 2009. The 2010 research and development funding, which stems from our agreement with a third party relating to the sale of our cell factory business, ended in the second quarter of 2010.

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 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 and the clinical 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 includes the pursuit of commercial collaborations with major pharmaceutical and biotechnology companies for the development of our drug candidates.

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 September 30, 2010		Nine Months Ended September 30, 2010		Inception to date (1)
Drug discovery	\$ 11.7	\$ 21.5	\$ 45.5	\$ 66.2	\$ 430.0
Development	34.9	33.9	111.7	88.7	549.8
Other	2.8	4.8	11.2	15.7	91.6
Total	\$ 49.4	\$ 60.2	\$ 168.4	\$ 170.6	\$ 1,071.4

(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 nine months ended September 30, 2010, the programs representing the greatest portion of our external third party research and development expenditures were XL184 (65%), XL147 (14%), XL765 (7%), XL281 (4%) and XL228 (4%), respectively. 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.

Edgar Filing: EXELIXIS INC - Form 10-Q

We currently do not have reliable estimates regarding the timing of our clinical trials. We currently 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.

Table of Contents

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 currently 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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
General and administrative expenses	\$ 9.0	\$ 8.6	\$ 27.4	\$ 25.9
Dollar increase	\$ 0.4		\$ 1.5	
Percentage increase	3.6%		5.6%	

General and administrative expenses consist primarily of personnel expenses, employee stock-based compensation expense, facility costs and consulting and professional expenses, such as legal and accounting fees. The increase in expenses for the three and nine months ended September 30, 2010, as compared to the comparable periods in 2009, was primarily due to a change in the allocation of overhead expenses as a result of our March restructuring as well as increased stock compensation and patent costs, partially offset by decreased personnel and facility costs also related to our March restructuring. As a result of the cancellation of unvested stock options and RSUs in connection with the resignation of our former Chief Executive Officer, we recorded a non-cash compensation charge of approximately \$1.5 million to our consolidated statement of operations during the third quarter of 2010. Excluding the impact of this one-time charge, general and administrative expense would have declined period over period. See Note 3 to our Consolidated Financial Statements for a further discussion of this non-cash compensation charge.

Collaboration Reimbursement Revenue (Cost-Sharing Expenses)

Total collaboration reimbursement revenue (cost-sharing expenses), as compared to the prior year period, were as follows (dollar amounts are presented in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Collaboration reimbursement revenue (cost-sharing expenses)	\$ 18.1	\$ (3.0)	\$ 26.7	\$ (2.8)
Dollar change	\$ 21.1		\$ 29.5	
Percentage change	Not meaningful		Not meaningful	

Collaboration reimbursement revenue (cost-sharing expenses) consists of research and development expenses and reimbursements related to our 2008 cancer collaboration agreement with Bristol Myers-Squibb for XL184 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 revenue. In 2009, when net research and development funding payments were expected to be payable to Bristol-Myers Squibb, these payments were presented as collaboration cost-sharing expenses. However, for the year ending December 31, 2010, we expect to receive net collaboration reimbursements and have recorded collaboration reimbursement revenue of \$18.1 million and \$26.7 million for the three and nine months ended September 30, 2010, respectively. The collaboration reimbursement revenue for the three and nine months ended September 30, 2010 included the \$17.0 million transition payment received from Bristol-Myers Squibb upon termination of our 2008 cancer collaboration with respect to XL184, and we do not expect any further cost reimbursements to be recognized as revenue with respect to XL184.

Restructuring Charge

Edgar Filing: EXELIXIS INC - Form 10-Q

On March 8, 2010, we implemented a restructuring plan that resulted in a reduction of our workforce by approximately 40%, or 270 employees. A small number of the terminated employees were subsequently recalled and the termination of a small group of employees has been delayed, all of whom continue to provide services for us. The remaining impacted employees were terminated immediately upon implementation of the plan or by March 31, 2010. The decision to restructure our operations was based on our

Table of Contents

recently announced corporate strategy to focus our efforts on our lead clinical compounds, XL184, XL147 and XL765, by dedicating the majority of our resources to aggressively drive these drug candidates through development towards commercialization.

In connection with the 2010 restructuring plan, we recorded a charge of approximately \$16.1 million in the first quarter of 2010 primarily related to one-time termination benefits, which includes the modification of certain stock option awards previously granted to the terminated employees. The modification accelerates the vesting of any stock options that would have vested over the period beginning from cessation of employment through August 5, 2010. Employees also received an additional two months to exercise their options, for which a small charge was taken. The remainder of the charge was for the impairment of various assets and for non-cash charges relating to the closure of our facility in San Diego, California. We recorded additional restructuring expenses of approximately \$9.4 million during the second quarter of 2010 and \$0.3 million during the third quarter of 2010, primarily due to facility-related charges in connection with the sublease and exit of one of our buildings in South San Francisco, California. This charge was partially offset by a decrease in legal fees and one-time termination benefits relating to the recall of certain employees that were originally terminated under the restructuring plan and continued delay in the termination of the small group of employees described above. Our restructuring liability is recorded on discounted basis, using a credit-adjusted risk-free borrowing rate. We expect further restructuring expenses totaling approximately \$2.0 million, which will be incurred on a quarterly basis through the fourth quarter of 2015 due to interest expenses related to the exit of the South San Francisco building during the second quarter of 2010.

We expect that the restructuring plan will result in total cash expenditures of approximately \$24.8 million, of which approximately \$14.3 million is expected to be paid in 2010. The balance will be paid over an additional five years and primarily relates to net payments due under the lease for the building we exited in South San Francisco.

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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Total other income (expense), net	\$ (4.5)	\$ (1.8)	\$ 2.8	\$ (13.1)
Dollar change	\$ (2.7)		\$ 15.9	
Percentage change	152.9%		121.0%	

Total other income (expense), net consists primarily of interest income earned on our marketable securities and gains on asset sales, offset by interest expense incurred on our notes payable, bank obligations, capital lease obligations, convertible notes and loans and our credit facility. The change in total other income (expense) for the three months ended September 30, 2010, as compared to the comparable period in 2009, resulted primarily from the increase in interest expense associated with the 2010 Deerfield financing entered into during the second quarter of 2010. The change in total other income (expense) for the nine months ended September 30, 2010, as compared to the comparable period in 2009, resulted primarily from the recording of a \$9.8 million loss upon deconsolidation of Symphony Evolution, Inc., or SEI, as a result of the expiration of our purchase option for SEI in June 2009. In addition, we recorded an additional \$7.8 million gain in 2010 relating to the sale of our plant trait business and our cell factory business as compared to only a \$1.8 million gain for the same period in 2009.

Income Tax Benefit (Provision):

Total income tax benefits and provision for the three and nine month periods, as compared to the prior year periods, were as follows (dollar amounts are presented in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Tax benefit (provision)	\$ 0.1	\$ (6.9)	\$ 0.1	\$ (6.0)
Dollar change	\$ 7.0	1	\$ 6.1	
Percentage change	Not meaningful		Not meaningful	

During the third quarter of 2009, we recorded an income tax provision as a result of \$7.0 million of withholding tax associated with the \$140.0 million of upfront payments received from sanofi-aventis during the same period. This was offset by a \$0.8 million tax credit recorded during

Edgar Filing: EXELIXIS INC - Form 10-Q

the second quarter of 2009 as a result of the Housing and Economic Recovery Act of 2008 that was extended through 2009. In the third quarter of 2010, after filing our 2009 tax return, we adjusted the credit associated with the 2009 refundable credit and recorded an increase to our tax benefit of \$0.1 million.

Table of Contents***Noncontrolling Interest in Symphony Evolution, Inc.***

In 2005, we licensed three of our compounds, XL647, XL784 and XL999, to SEI in return for an \$80.0 million investment for the clinical development of these compounds. As part of the agreement, we received an exclusive purchase option to acquire all of the equity of SEI, thereby allowing us to reacquire XL647, XL784 and XL999 at our sole discretion. The purchase option expired on June 9, 2009. The expiration of the purchase option triggered a reconsideration event regarding our need to consolidate SEI, a variable interest entity. Upon the expiration of the purchase option, we no longer held a variable interest in the variable interest entity. Accordingly, we deconsolidated SEI and derecognized the SEI assets, liabilities and noncontrolling interest from our financial statements. For the nine months ended September 30, 2010 and 2009, the losses attributed to the noncontrolling interest holders were \$0 and \$4.3 million, respectively. The decrease in the losses attributable to noncontrolling interest holders was due to the deconsolidation of SEI in June 2009.

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

The following table summarizes our cash flow activities for the nine months ended September 30, 2010 and 2009, respectively (dollar amounts are presented in thousands):

	Nine Months Ended September 30,	
	2010	2009
Consolidated net loss	\$ (74,465)	\$ (110,723)
Adjustments to reconcile net loss to net cash provided by operating activities	23,780	37,517
Changes in operating assets and liabilities	(71,617)	109,365
Net cash (used in) provided by operating activities	(122,302)	36,159
Net cash used in investing activities	(25,963)	(104,171)
Net cash provided by (used in) financing activities	156,811	(9,116)
Net increase (decrease) in cash and cash equivalents	8,546	(77,128)
Cash and cash equivalents, at beginning of period	86,796	247,698
Cash and cash equivalents, at end of period	\$ 95,342	\$ 170,570

To date, we have financed our operations primarily through the sale of equity, payments and loans from collaborators and banks, and equipment financing facilities. We have also financed certain of our research and development activities under our agreements with SEI. As of September 30, 2010, we had \$261.0 million in cash and cash equivalents and short-term and long-term marketable securities, which included restricted cash and investments of \$6.4 million. In addition, as of September 30, 2010, approximately \$97.3 million of cash and cash equivalents and marketable securities served as collateral for bank loans.

Operating Activities

Our operating activities used cash of \$122.3 million for the nine months ended September 30, 2010, compared to cash provided of \$36.2 million for the comparable period in 2009. Cash used by operating activities for the 2010 period related primarily to our net loss attributable to Exelixis, Inc. of \$74.5 million, in addition to a \$78.2 million reduction in deferred revenue and a gain on sale of our plant trait and cell factory businesses of \$7.8 million. These increases in cash used were partially offset by non-cash charges totaling \$27.5 million relating to stock-based compensation, depreciation and amortization, and asset impairment as a result of our restructuring in addition to a restructuring liability of \$9.2 million primarily relating to our South San Francisco building. Cash provided by operating activities for the 2009 period related primarily to increases in deferred revenue of \$116.6 million and non-cash charges totaling \$36.9 million relating to stock-based compensation, the loss on our deconsolidation of SEI and depreciation and amortization. These increases in cash provided were partially offset by our net loss attributable to Exelixis, Inc. of \$110.7 million, and increases in receivables and prepaid expenses totaling \$10.9 million.

Investing Activities

Our investing activities used cash of \$26.0 million for the nine months ended September 30, 2010, compared to cash used of \$104.2 million for the comparable period in 2009. Cash used by investing activities for the 2010 period was primarily driven by the purchase of \$141.2 million of marketable securities and certificates of deposit. These uses of cash were offset by proceeds from the maturity of marketable securities of \$95.1 million in addition to the sale of investments prior to maturity of \$12.8 million and proceeds of \$8.6 million associated with our 2007 transaction with Agrigenetics and the sale of our cell factory business in 2010. The proceeds provided by the sale and maturity of our investments were used to fund our operations. Cash used by investing activities for the 2009 period was primarily driven by purchases of marketable securities of \$121.9 million, purchases of property and equipment of \$1.6 million, and a decrease in restricted cash and investments of \$0.7 million. This cash outflow was partially offset by proceeds of \$13.8

Table of Contents

million from the sale and maturities of marketable securities, proceeds of \$4.5 million on the sale of investments held by SEI and \$1.8 million in proceeds related to the adjustment to the gain on the 2007 sale of our plant trait business.

Financing Activities

Our financing activities provided cash of \$156.8 million for the nine months ended September 30, 2010, compared to cash used of \$9.1 million for the comparable period in 2009. Cash provided by our financing activities for the 2010 period was primarily due to our loan agreements with Silicon Valley Bank and the Deerfield entities for proceeds of \$162.5 million as well as proceeds from employee option exercises of \$2.1 million, offset by principal payments on notes payable and bank obligations of \$8.9 million. Cash used by our financing activities for the 2009 period was due to principal payments on notes payable and bank obligations of \$11.2 million, partially offset by the issuance of stock under the employee stock purchase plan of \$2.2 million.

We finance property and equipment purchases through equipment financing facilities, such as notes and bank obligations. 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, bank obligations and our loan from GlaxoSmithKline.

Cash Requirements

We have incurred net losses since inception, including a net loss attributable to Exelixis, Inc. of \$8.6 million and \$74.5 million for the three and nine months ended September 30, 2010, respectively. We expect our net loss in 2010 to decrease compared to 2009 and anticipate negative operating cash flow for the foreseeable future. As September 30, 2010, we had \$261.0 million in cash and cash equivalents and short-term and long-term marketable securities, which included restricted cash and investments of \$6.4 million and approximately \$97.3 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, short-term and long-term marketable securities, funding from our October 2010 transactions with Bristol-Myers Squibb and funding that we expect to receive from collaborators, which includes anticipated cash from additional business development activity, 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 XL184 development program We are focusing our development efforts on XL184, our most advanced compound, which is being studied in a variety of tumor types, with the goal of rapidly commercializing the compound. An immediate priority for us is to generate additional data in the five leading cohorts of hepatocellular carcinoma, melanoma, non-small cell lung cancer, ovarian cancer and prostate cancer in our ongoing randomized discontinuation trial to support the prioritization of our clinical and commercial options for XL184. Additional phase 2 clinical trials of XL184 in glioblastoma and non-small cell lung cancer are also ongoing. We are also preparing to initiate a phase 3 registration trial of XL184 as a potential treatment for recurrent glioblastoma by the end of 2010. We regained all rights to XL184 from Bristol-Myers Squibb in July 2010 and, as a result, we will bear all development costs going forward. Our development plan for XL184 is dependent on the extent of our available financial resources. There can be no assurance that we will have sufficient financial resources independent or through other arrangements to fund a broad development plan for XL184. If adequate funds are not available, we may be required to discontinue or elect not to pursue one or more trials for XL184;

repayment of our loan from GlaxoSmithKline 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 October 27, 2010, the aggregate principal and interest outstanding under the loan was \$35.7 million. The third 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. Following the conclusion on October 27, 2008 of the development term under our collaboration with GlaxoSmithKline, we are no longer eligible to receive selection milestone payments

Edgar Filing: EXELIXIS INC - Form 10-Q

from GlaxoSmithKline to credit against outstanding loan amounts, and 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 as

Table of Contents

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 the Deerfield Entities On June 2, 2010, we entered into a note purchase agreement with the Deerfield Entities, pursuant to which, on July 1, 2010, we sold to the Deerfield Entities, 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 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. 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 1.00% 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 the Deerfield Entities 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 progress and scope of other research and development activities conducted by us;

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 XL184) 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;

Table of Contents

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 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, the Deerfield Entities 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 September 30, 2010, our working capital was \$90.5 million and our cash and investments were \$254.6 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 \$72.5 million at September 30, 2010. The third installment of principal and accrued interest under the loan is due on October 27, 2011.

Deerfield Entities Our note purchase agreement with the Deerfield Entities 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 or below \$20.0 million as of December 28, 2010, subject to a cure period. Upon such an event of default, the Deerfield Entities 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 September 30, 2010, our cash and cash equivalents were \$261.0 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 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. Following the termination of our 2008 cancer collaboration with Bristol-Myers Squibb as to XL184, we regained full rights to develop and commercialize XL184, which rights are no longer subject to termination if our cash reserves and cash equivalents fall below \$80.0 million. Cash

Edgar Filing: EXELIXIS INC - Form 10-Q

reserves and cash equivalents for purposes of our 2008 collaboration with Bristol-Myers Squibb included our total cash, cash equivalents and investments (excluding any restricted cash), plus the amount then available for borrowing by us under certain financing arrangements.

We have contractual obligations in the form of operating leases, notes payable and licensing agreements. The following chart details our contractual obligations as of September 30, 2010 (in thousands):

Table of Contents

Contractual Obligations	Total	Payments Due by Period			
		Less than 1 year	1-3 years	4-5 years	More than 5 years
Convertible loans (1)	225,018	42,800	57,730	30,488	94,000
Notes payable and bank obligations	101,888	9,928	8,294	2,313	81,353
Operating leases (2)	103,201	14,948	29,935	30,537	27,781
Total contractual cash obligations	\$ 430,107	\$ 67,676	\$ 95,959	\$ 63,338	\$ 203,134

- (1) Includes interest payable on the convertible loans with GlaxoSmithKline of \$15.6 million. The debt and interest payable can be repaid in cash or common stock, subject to certain conditions, at our election.
- (2) Reflects payments of \$12.1 million received in connection with our sublease to Onyx Pharmaceuticals, Inc. for our South San Francisco building.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio and our long-term debt. As of September 30, 2010 and December 31, 2009, we had cash and cash equivalents, marketable securities, long-term investments and restricted cash and investments of \$261.0 million and \$221.0 million respectively. Our marketable securities and our investments are subject to interest rate risk, and our interest income may fluctuate due to changes in U.S. interest rates. We manage market risk through diversification requirements mandated by our investment policy, which limits the amount of our portfolio that can be invested in a single issuer. We limit our credit risk by limiting purchases to high-quality issuers. As of September 30, 2010 and December 31, 2009, we had debt outstanding of \$233.0 million and \$79.6 million, respectively. Our payment commitments associated with these debt instruments are primarily fixed and are comprised of interest payments, principal payments, or a combination of both. The fair value of our debt will fluctuate with movements of interest rates. We have estimated the effects on our interest rate sensitive assets and liabilities based on a one percentage point hypothetical adverse change in interest rates as of September 30, 2010 and December 31, 2009, respectively. As of September 30, 2010 and December 31, 2009, 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 \$9.7 million and \$0.3 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 XL184 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 September 30, 2010, 8.8% our clinical accrual balance related to foreign currencies. We incurred a net loss relating to foreign exchange fluctuations of \$0.1 million for the nine-month period ended September 30, 2010.

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.

Table of Contents

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, 2009 filed with the Securities and Exchange Commission on March 10, 2010.*

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

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

We will need to raise additional capital to:

fund our operations and clinical trials;

continue our research and development efforts; and

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

As of September 30, 2010, we had \$261.0 million in cash and cash equivalents and short-term and long-term marketable securities, which included restricted cash and investments of \$6.4 million and approximately \$97.3 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, short-term and long-term marketable securities, funding from our October 2010 transactions with Bristol-Myers Squibb and funding that we expect to receive from collaborators, which includes anticipated cash from additional business development activity, 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 XL184 development program We are focusing our development efforts on XL184, our most advanced compound, which is being studied in a variety of tumor types, with the goal of rapidly commercializing the compound. An immediate priority for us is to generate additional data in the five leading cohorts of hepatocellular carcinoma, melanoma, non-small cell lung cancer, ovarian cancer and prostate cancer in our ongoing randomized discontinuation trial to support the prioritization of our clinical and commercial options for XL184. Additional phase 2 clinical trials of XL184 in glioblastoma and non-small cell lung cancer are also ongoing. We are also preparing to initiate a phase 3 registration trial of XL184 as a potential treatment for recurrent glioblastoma by the end of 2010. We regained all rights to XL184 from Bristol-Myers Squibb in July 2010 and, as a result, we will bear all development costs going forward. Our development plan for XL184 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 XL184. If adequate funds are not available, we may be required to discontinue or elect not to pursue one or more trials for XL184;

repayment of our loan from GlaxoSmithKline 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 October 27, 2010, the aggregate principal and interest outstanding under the loan was \$35.7 million. The third 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. Following the conclusion on October 27, 2008 of the

Edgar Filing: EXELIXIS INC - Form 10-Q

development term under our collaboration with GlaxoSmithKline, we are no longer eligible to receive selection milestone payments from GlaxoSmithKline to credit against outstanding loan amounts, and 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 the Deerfield Entities On June 2, 2010, we entered into a note purchase agreement with the Deerfield Entities, pursuant to which, on July 1, 2010, we sold to the Deerfield Entities, 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

Table of Contents

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 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. 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 1.00% 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 the Deerfield Entities 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 progress and scope of other research and development activities conducted by us;

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 XL184) 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.

Table of Contents

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 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, the Deerfield Entities 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 attributable to Exelixis, Inc. of \$8.6 million for the three months ended September 30, 2010 and \$74.5 million for the nine months ended September 30, 2010. As of that date, we had an accumulated deficit of \$1,164.2 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 any of our pharmaceutical 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 research and development in order to enhance our technologies and undertake product development. We currently have numerous drug candidates in various stages of clinical development and we may submit an IND application for an additional drug candidate within the next 12 months. 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 March 8, 2010 we implemented a restructuring that resulted in a reduction of our workforce by approximately 40%, or 270 employees. We anticipate that we will incur restructuring charges through the end of 2015 as we implement this restructuring. We determined to recall a small number of the employees terminated in the March 2010 restructuring and to delay the termination of a small group of employees, all of whom continue to provide services for us.

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.*

Edgar Filing: EXELIXIS INC - Form 10-Q

Most of our foreign expenses incurred are associated with establishing and conducting clinical trials for XL184 and various other compounds in our pipeline at sites outside of the United States. 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

Table of Contents

such clinical trials generally provide that payments for the services provided will be calculated in the currency of that country, and converted into U.S. dollars using various exchange rates based upon when services are rendered or the timing of invoices. When the U.S. dollar weakens against foreign currencies, the U.S. dollar value of the foreign-currency denominated expense increases, and when the U.S. dollar strengthens against these currencies, the U.S. dollar value of the foreign-currency denominated expense decreases. Consequently, changes in exchange rates may affect our results of operations.

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 September 30, 2010, no assurance can be given that further 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 Product Candidates

Clinical testing of our 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 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 our product candidates, including:

our product candidates 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;

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

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

regulators or institutional review boards may not authorize, delay, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or their determination that participating patients are being exposed to unacceptable health risks.

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

Edgar Filing: EXELIXIS INC - Form 10-Q

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

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 a product candidate. The duration and the cost of clinical trials may vary significantly over the life of a project as a result of factors relating to the clinical trial, including, among others:

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

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

the number of clinical sites included in the trials; and

the length of time required to enroll suitable patient subjects.

Table of Contents

Any delay or termination described above 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.

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 and GlaxoSmithKline, 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 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 also 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 recently occurred with respect to XL184, our most advanced product candidate 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 receive research funding or 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, research funding, the achievement of milestones and royalties we earn from any future products developed from the collaborative research. If we are unable to receive research funding or 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 not renewed or is terminated early (as recently occurred with respect to XL184, our most advanced product candidate that 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,

Table of Contents

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 revenue from the termination or expiration of any of our existing or recently terminated arrangements.

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

Our strategy includes the pursuit of new collaborations with leading pharmaceutical and biotechnology companies for the development and ultimate commercialization of selected preclinical and clinical 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.

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 our product candidates.

We do not have the ability to independently conduct clinical trials for our product candidates, and we must 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 our product candidates.

We lack the capability to manufacture compounds for clinical trials and rely on third parties to manufacture our product candidates, 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 currently 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 our compounds for preclinical and clinical testing. These suppliers must comply with applicable regulatory requirements, including the FDA's current Good Manufacturing Practices, or GMP. Our current and anticipated future dependence upon these third-party manufacturers may adversely affect our future profit margins and our ability to develop and commercialize product candidates 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 level 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 filing of our INDs and 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 any related product candidates. 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 our product candidates, 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 some of our compounds currently under development may not be available on commercially reasonable terms, or at all, which may delay our development and commercialization of these compounds.

Edgar Filing: EXELIXIS INC - Form 10-Q

Some of the materials necessary for the manufacture of our compounds under development 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

Table of Contents

materials for our clinical trials and, potentially, for commercial distribution when and if we obtain marketing approval for these compounds. 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 the product candidates. Similarly, if we are unable to obtain critical manufacturing materials after regulatory approval has been obtained for a product candidate, the commercial launch of that product candidate could be delayed or there could be a shortage in supply, which could materially affect our ability to generate revenues from that product candidate. If suppliers increase the price of manufacturing materials, the price for one or more of our products may increase, which may make our products 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 our products.

Risks Related to Regulatory Approval of Our Product Candidates

Our product candidates are 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 products.

Our product candidates, as well as the activities associated with their research, development and commercialization, are subject to extensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory approval for a product candidate would prevent us from commercializing that product candidate. We have not received regulatory approval to market any of our product candidates 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 or our collaborative partners' 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 any of our drug candidates. The FDA could also require additional studies or trials to satisfy particular safety concerns noted in our or our collaborative partners' preclinical or clinical testing.

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 our product candidates may cause delays in the approval or rejection of an application.

Even if the FDA or a comparable authority in another country approves a product candidate, the approval may impose significant restrictions on the indicated uses, conditions for use, labeling, distribution, advertising, promotion, marketing and/or production of such product 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 Products

The commercial success of any products that we may develop will depend upon the degree of market acceptance of our products among physicians, patients, health care payors, private health insurers and the medical community.

Our ability to commercialize any products that we may develop will be highly dependent upon the extent to which these products gain 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 these products do 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 our product candidates, if approved for commercial sale, will depend upon a number of factors, including:

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

Edgar Filing: EXELIXIS INC - Form 10-Q

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

potential advantages over alternative treatments;

the ability to offer our products for sale at competitive prices;

relative convenience and ease of administration;

Table of Contents

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 our product candidates, 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 currently 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 any products that we develop 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 any products that we may develop, our revenues and prospects for profitability will suffer.

Our ability to commercialize any products that we may develop will be highly dependent on the extent to which coverage and reimbursement for our products 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 some or all of the products that we may develop 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 any products that we may develop, our revenues and prospects for profitability will suffer. In addition, even if third-party payors provide some coverage or reimbursement for our products, the availability of such coverage or reimbursement for prescription drugs under private health insurance and managed care plans often varies based on the type of contract or plan purchased.

In recent years, there have been numerous legislative proposals to change the healthcare system in the United States that could significantly affect our business. Such proposals reflect the primary trend in the United States health care industry toward cost containment and include measures that may have the effect of reducing the prices that we are able to charge for any products we develop and sell and cause a reduction in the coverage and reimbursement of such products. If approved, such reform could limit our ability to successfully commercialize our potential products.

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 any products that we may develop, 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 our product candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in the commercialization of our product candidates. 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 any products that we may develop. Cost-control initiatives could decrease the price we might establish for products that we may develop, which would result in lower product revenues to us.

Our competitors may develop products and technologies that make our products and technologies 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

Edgar Filing: EXELIXIS INC - Form 10-Q

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 our product candidates could allow our competitors to bring products to market before us, which would impair our ability to commercialize our product candidates. 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

Table of Contents

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 our drug candidates. In addition, any drug candidate that we successfully develop may compete with existing therapies that have long histories of use, such as chemotherapy and radiation treatments in cancer indications. Examples of potential competition for XL184 include AstraZeneca's development-stage VEGFR and EGFR inhibitor, vandetanib, other VEGF pathway inhibitors, including Genentech's bevacizumab, and other MET inhibitors, including ArQule Inc.'s ARQ197, GlaxoSmithKline's foretinib (XL880) and Genentech's Met MAb. Examples of potential competition for XL147 and XL765 include early-stage development programs of various pharmaceutical and biotechnology companies, including Genentech, Novartis, Pfizer, Calistoga Pharmaceuticals and Semafore Pharmaceuticals.

We may not be able to manufacture our product candidates in commercial quantities, which would prevent us from commercializing our product candidates.

To date, our product candidates have been manufactured in small quantities for preclinical and clinical trials. If any of these product candidates are approved by the FDA or other regulatory agencies for commercial sale, we will need to manufacture them 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 any of our product candidates 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 a product candidate, the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in supply. Our product candidates require 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 currently 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.

Table of Contents

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

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

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 do not currently have sufficient clinical development personnel to fully 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 of the company that we implemented on March 8, 2010 and our recent change in the position of President and Chief Executive Officer 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 maybe 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.

Table of Contents

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

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

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

Risks Related to Environmental and Product Liability

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

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

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

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

We may be held liable if any product we or our collaborators develop causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing or sale. Regardless of merit or eventual outcome, product liability claims could result in decreased demand for our product candidates, injury to our reputation, withdrawal of patients from our clinical trials, substantial monetary awards to trial participants and the inability to commercialize any products that we may develop. These claims might be made directly by consumers, health 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 any of our product candidates, 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.

Table of Contents

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

the scope of our research and development activities;

recognition of upfront licensing or other fees or revenue;

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

acceptance of our technologies and platforms;

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

the introduction of new technologies or products by our competitors;

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

our ability to enter into new collaborative relationships;

the termination or non-renewal of existing collaborations;

the timing and amount of expenses incurred for clinical development and manufacturing of our product candidates;

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 the restructuring of the company implemented on March 8, 2010; 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.

Edgar Filing: EXELIXIS INC - Form 10-Q

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 our 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 drug candidates;

actions taken by regulatory agencies with respect to our drug candidates or our clinical trials;

the announcement of new products by us or 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;

Table of Contents

developments in the biotechnology or pharmaceutical industry;

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

departures of key personnel or board members;

developments concerning current or future collaborations;

FDA or international regulatory actions;

third-party reimbursement policies;

acquisitions of other companies or technologies;

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. As with the stock of many other public companies, the market price of our common stock has been particularly volatile during the recent period of upheaval in the capital markets and world economy. This 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 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.

Table of Contents

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: November 4, 2010

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				
Exhibit			Exhibit/			
				Appendix		Filed
Number	Exhibit Description	Form	File Number	Reference	Filing Date	Herewith
2.1*	Asset Purchase and License Agreement, dated as of September 4, 2007, by and among Agrigenetics, Inc., Mycogen Corporation, Exelixis Plant Sciences, Inc., Agrinomics, LLC and Exelixis, Inc.	10-Q	000-30235	10.1	11/5/2007	
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 9, 2005, to purchase 750,000 shares of Exelixis, Inc. common stock in favor of Symphony Evolution Holdings LLC.	10-Q	000-30235	4.1	8/9/2005	
4.3	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	
4.4	Warrant Purchase Agreement, dated June 9, 2005, between Exelixis, Inc. and Symphony Evolution Holdings LLC.	10-Q	000-30235	4.4	8/5/2010	
4.5*	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	Fourth Amended and Restated Registration Rights Agreement, dated February 26, 1999, among Exelixis, Inc. and certain Stockholders of Exelixis, Inc.	S-1,	333-96335	4.2	2/7/2000	
		as amended				
4.7	Registration Rights Agreement, dated October 18, 2004, by and among Exelixis, Inc., X-Ceptor Therapeutics, Inc., and certain holders of capital stock of X-Ceptor Therapeutics, Inc. listed in Annex I thereto.	8-K	000-30235	10.1	10/21/2004	
4.8	Registration Rights Agreement, dated October 18, 2004, by and among Exelixis, Inc., X-Ceptor Therapeutics, Inc., and certain holders of capital stock of X-Ceptor Therapeutics, Inc. listed in Annex I thereto.	8-K	000-30235	10.2	10/21/2004	
4.9	Registration Rights Agreement, dated June 9, 2005, between Exelixis, Inc. and Symphony Evolution Holdings LLC.	10-Q	000-30235	4.9	8/5/2010	
4.10	Registration Rights Agreement between Exelixis, Inc. and Deerfield Private Design Fund, L.P., Deerfield Private Design International, L.P.,	8-K	000-30235	4.10	6/9/2008	

Edgar Filing: EXELIXIS INC - Form 10-Q

Deerfield Partners, L.P. and Deerfield International Limited dated June 4, 2008.

4.11	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			

Table of Contents

4.12	Form of Common Stock Agreement and Warrant Certificate	S-3,	333-158792	4.17	4/24/2009	
		as amended				
4.13	Form of Preferred Stock Agreement and Warrant Certificate	S-3,	333-158792	4.18	4/24/2009	
		as amended				
4.14	Form of Debt Securities Warrant Agreement and Warrant Certificate	S-3,	333-158792	4.19	4/24/2009	
		as amended				
4.15	Form of Senior Debt Indenture	S-3,	333-158792	4.13	5/28/2009	
		as amended				
4.16	Form of Subordinated Debt Indenture	S-3,	333-158792	4.14	5/28/2009	
		as amended				
4.17	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)	
4.18	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)	
10.1	Resignation Agreement dated July 22, 2010 by and between Exelixis, Inc. and George A. Scangos					X
10.2	Fourth Amendment dated July 9, 2010 to Lease Agreement, dated September 14, 2007, by and between ARE-San Francisco No. 12, LLC and Exelixis, Inc.					X
10.3	Consent to Sublease dated July 9, 2010 by and among ARE-San Francisco No. 12, LLC, Exelixis, Inc. and Onyx Pharmaceuticals, Inc.					X
10.4	Sublease Agreement, dated July 9, 2010, by and between Exelixis, Inc. and Onyx Pharmaceuticals, Inc.					X
31.1	Certification required by Rule 13a-14(a) or Rule 15d-14(a).					X
31.2	Certification required by Rule 13a-14(a) or Rule 15d-14(a).					X
32.1 ⁺⁺	Certification by the Chief Executive Officer and the Chief Financial Officer of Exelixis, Inc., as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).					X

* 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.