

EXELIXIS INC  
Form 10-Q  
October 29, 2009  
[Table of Contents](#)

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

Washington, D.C. 20549

**FORM 10-Q**

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

**For the quarterly period ended October 2, 2009**

**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.)

**249 East Grand Ave.**

**P.O. Box 511**

**South San Francisco, CA 94083-0511**

(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 23, 2009 there were 107,386,717 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 2, 2009**

**INDEX**

<b><u>Part I. Financial Information</u></b>	3
Item 1. <u>Financial Statements</u>	3
<u>Condensed Consolidated Balance Sheets September 30, 2009 and December 31, 2008</u>	3
<u>Condensed Consolidated Statements of Operations Three Months and Nine Months Ended September 30, 2009 and</u>	
<u>2008</u>	4
<u>Condensed Consolidated Statements of Cash Flows Nine Months Ended September 30, 2009 and 2008</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>	14
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	28
Item 4. <u>Controls and Procedures</u>	28
<b><u>Part II. Other Information</u></b>	28
Item 1A. <u>Risk Factors</u>	28
Item 6. <u>Exhibits</u>	41
<b><u>SIGNATURES</u></b>	42
<b><u>EXHIBITS</u></b>	43
<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>	
<u>Exhibit 99.1</u>	
<u>Exhibit 99.2</u>	

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

	<b>September 30, 2009 (unaudited)</b>	<b>December 31, 2008 (1)</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 170,570	\$ 247,698
Marketable securities	115,737	
Investments held by Symphony Evolution, Inc.		14,703
Other receivables	9,594	1,457
Prepaid expenses and other current assets	10,621	7,713
Total current assets	306,522	271,571
Restricted cash and investments	4,744	4,015
Long-term marketable securities	9,976	17,769
Property and equipment, net	28,481	36,247
Goodwill	63,684	63,684
Other assets	7,695	8,336
Total assets	\$ 421,102	\$ 401,622
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 4,048	\$ 4,946
Accrued clinical trial liabilities	18,982	22,551
Other accrued liabilities	18,742	14,007
Accrued compensation and benefits	15,215	16,142
Current portion of notes payable and bank obligations	11,459	14,911
Current portion of convertible loans	28,050	28,050
Deferred revenue	118,499	88,936
Total current liabilities	214,995	189,543
Notes payable and bank obligations	9,976	17,769
Convertible loans	56,950	56,950
Other long-term liabilities	23,907	22,620
Deferred revenue	258,044	171,001
Total liabilities	563,872	457,883
Commitments		
Stockholders' deficit:		
Exelixis, Inc. stockholders' deficit:		
Common stock	107	106

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

Additional paid-in-capital	917,916	897,423
Accumulated other comprehensive income	96	
Accumulated deficit	(1,060,889)	(954,504)
Total Exelixis, Inc. stockholders' deficit	(142,770)	(56,975)
Noncontrolling interest		714
Total stockholders' deficit	(142,770)	(56,261)
Total liabilities and stockholders' deficit	\$ 421,102	\$ 401,622

- (1) The condensed consolidated balance sheet at December 31, 2008 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)**

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
Revenues:				
Contract	\$ 24,608	\$ 16,665	\$ 37,615	\$ 52,047
License	30,368	13,267	70,066	36,240
Total revenues	54,976	29,932	107,681	88,287
Operating expenses:				
Research and development	60,186	65,670	170,567	200,512
General and administrative	8,643	8,867	25,910	27,786
Collaboration cost sharing	2,965		2,807	
Total operating expenses	71,794	74,537	199,284	228,298
Loss from operations	(16,818)	(44,605)	(91,603)	(140,011)
Other income (expense):				
Interest income and other, net	355	1,090	1,276	5,072
Interest expense	(2,122)	(2,171)	(6,356)	(4,386)
Gain on sale of business		4,500	1,800	4,500
Loss on deconsolidation of Symphony Evolution, Inc.			(9,826)	
Total other income (expense), net	(1,767)	3,419	(13,106)	5,186
Consolidated loss before taxes	(18,585)	(41,186)	(104,709)	(134,825)
Tax provision	(6,860)		(6,014)	
Consolidated net loss	(25,445)	(41,186)	(110,723)	(134,825)
Loss attributable to noncontrolling interest.		2,680	4,337	9,920
Net loss attributable to Exelixis, Inc.	\$ (25,445)	\$ (38,506)	\$ (106,386)	\$ (124,905)
Net loss per share, basic and diluted, attributable to Exelixis, Inc.	\$ (0.24)	\$ (0.36)	\$ (1.00)	\$ (1.19)
Shares used in computing basic and diluted loss per share amounts	107,336	105,548	106,853	105,294

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

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

	<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>
Cash flows from operating activities:		
Consolidated net loss	\$ (110,723)	\$ (134,825)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	9,558	9,822
Stock-based compensation expense	17,512	17,081
Gain on sale of business		(4,500)
Loss on deconsolidation of Symphony Evolution, Inc.	9,826	
Other	621	1,009
Changes in assets and liabilities:		
Other receivables	(8,035)	(233)
Prepaid expenses and other current assets	(2,909)	(609)
Other assets	1,111	(3,191)
Accounts payable and other accrued expenses	1,305	5,790
Other long-term liabilities	1,287	2,414
Deferred revenue	116,606	(56,336)
Net cash provided by (used in) operating activities	36,159	(163,578)
Cash flows from investing activities:		
Purchases of investments held by Symphony Evolution, Inc.	(49)	(601)
Proceeds on sale of investments held by Symphony Evolution, Inc.	4,497	13,063
Purchases of property and equipment	(1,592)	(13,925)
Proceeds on sale of business	1,800	9,000
Increase (decrease) in restricted cash and investments	(729)	2,384
Proceeds from maturities of marketable securities	5,998	51,172
Proceeds from sale of marketable securities	7,793	32,571
Purchases of marketable securities	(121,889)	(5,619)
Net cash (used in) provided by investing activities	(104,171)	88,045
Cash flows from financing activities:		
Proceeds from exercise of stock options and warrants	4	299
Proceeds from employee stock purchase plan	2,150	2,142
Proceeds from note payable and bank obligations		13,619
Principal payments on notes payable and bank obligations	(11,245)	(11,754)
Repayments, net from deconsolidation of Symphony Evolution, Inc.	(25)	
Net cash (used in) provided by financing activities	(9,116)	4,306
Net decreases in cash and cash equivalents	(77,128)	(71,227)
Cash and cash equivalents, at beginning of period	247,698	135,457
Cash and cash equivalents, at end of period	170,570	\$ 64,230

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

### Non-cash investing and financing activities:

Warrants issued in conjunction with Deerfield financing agreement	\$	3,438
---	----	-------

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, 2009**

**(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 and other serious diseases. 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 molecules in cancer.

**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 31<sup>st</sup> of each year. Fiscal year 2008, a 53-week year, ended on January 2, 2009, and fiscal year 2009, a 52-week year, will end on January 1, 2010. For convenience, references in these Condensed Consolidated Financial Statements and Notes as of and for the fiscal year ended January 2, 2009 are indicated on a calendar year basis ended December 31, 2008 and as of and for the fiscal quarters ended September 26, 2008 and October 2, 2009 are indicated as ended September 30, 2008 and 2009, respectively. We have evaluated subsequent events through October 29, 2009, the date on which the financial statements being presented were issued.

Operating results for the three-month and nine-month periods ended September 30, 2009 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2009 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, 2008 included in our Annual Report on Form 10-K filed with the SEC on March 10, 2009.

**Basis of Consolidation**

The consolidated financial statements include the accounts of Exelixis and our wholly owned subsidiaries as well as one variable interest entity, Symphony Evolution, Inc. ( SEI ), for which we were the primary beneficiary. As of June 9, 2009, our purchase option for SEI expired and as a result, we were no longer considered to be the primary beneficiary. (Refer to Note 6). 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.

Investments held by SEI consisted of investments in money market funds. As of December 31, 2008, we had investments held by SEI of \$14.7 million. As of September 30, 2009, following the deconsolidation of SEI, we no longer record any SEI investments.

All marketable securities are classified as available-for-sale and are carried at fair value. We view our available-for-sale portfolio as available for use in current operations. Accordingly, we have classified certain investments as short-term marketable securities, even though the stated maturity date may be one year or more beyond the current balance sheet date. Available-for-sale securities are stated at fair value based upon

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

quoted market prices of the securities. We have classified certain investments as cash and cash equivalents or marketable securities that collateralize loan balances. However, they are not restricted to withdrawal. Unrealized gains and losses on available-for-sale investments are 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, 2009****(unaudited)**

The following summarizes available-for-sale securities included in cash and cash equivalents and restricted cash and investments as of September 30, 2009 (in thousands):

	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>
Money market funds	\$ 168,600	\$	\$	\$ 168,600
Commercial paper	34,991	1	(2)	34,990
Corporate bonds	28,868	89	(35)	28,922
U.S. Government agency securities	16,604	11		16,615
Government sponsored enterprises	55,745	38	(5)	55,778
Total	\$ 304,808	\$ 139	\$ (42)	\$ 304,905

The following summarizes available-for-sale securities included in cash and cash equivalents and restricted cash and investments as of December 31, 2008 (in thousands):

	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>
Money market funds	\$ 270,147	\$	\$	\$ 270,147
Total	\$ 270,147	\$	\$	\$ 270,147

The following summarizes available-for-sale securities included in cash and cash equivalents and restricted cash and investments as of September 30, 2009 by contractual maturity (in thousands):

	<b>Amortized Cost</b>	<b>Fair Value</b>
Mature in less than one year	\$ 286,475	\$ 286,585
Mature in one to three years	18,333	18,320
Total	\$ 304,808	\$ 304,905

**Fair Value Measurements**

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

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, 2009 and December 31, 2008, respectively (in thousands):

As of September 30, 2009:

	Level 1	Level 2	Level 3	Total
Cash equivalents and marketable securities	\$ 168,600	\$ 136,305	\$	\$ 304,905
Total	\$ 168,600	\$ 136,305	\$	\$ 304,905

As of December 31, 2008:

	Level 1	Level 2	Level 3	Total
Cash equivalents and marketable securities	\$ 270,147	\$	\$	\$ 270,147
Investments held by Symphony Evolution, Inc.	14,703			14,703
Total	\$ 284,850	\$	\$	\$ 284,850

**Table of Contents****EXELIXIS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****September 30, 2009****(unaudited)**

We have estimated the fair value of our long-term debt instruments 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. We have outstanding balances associated with our loan from GlaxoSmithKline and various equipment lines of credit. The estimated fair value of our outstanding debt was as follows (in thousands):

	<b>September 30, 2009</b>	<b>December 31, 2008</b>
GlaxoSmithKline loan	\$ 76,824	\$ 77,121
Equipment lines of credit	21,244	30,388
<b>Total</b>	<b>\$ 98,068</b>	<b>\$ 107,509</b>

At September 30, 2009 and December 31, 2008, we had debt outstanding of \$106.4 million and \$117.7 million, respectively. Our payment commitments associated with these debt instruments are fixed during the corresponding terms and are comprised of interest payments, principal payments or a combination thereof. The fair value of our debt will fluctuate with movements of interest rates, increasing in periods of declining rates of interest, and declining in periods of increasing rates of interest.

**Collaboration Cost-Sharing**

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 are actively involved with compound development and certain research and development expenses are 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 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 annual periods when net research and development funding payments are payable to Bristol-Myers Squibb, these payments will be presented as collaboration cost-sharing expense.

**Recent Accounting Pronouncements**

In June 2009, the Financial Accounting Standards Board ( FASB ) established the FASB Accounting Standards Codification ( FASB ASC ) as the source of authoritative accounting principles recognized by the FASB. The FASB will issue new standards in the form of Accounting Standards Updates ( FASB ASUs ). FASB ASC is effective for financial statements issued for interim and annual periods ending after September 15, 2009 and therefore was effective for us in the third quarter of fiscal year 2009. The issuance of FASB ASC does not change GAAP and therefore the adoption of FASB ASC only affects the specific references to GAAP literature in the notes to our consolidated financial statements.

In December 2007, the FASB issued FASB ASC 810, Consolidation, 10 Overall, paragraph 65-1 Transition ( FASB ASC Paragraph 810-10-65-1 ). FASB ASC Paragraph 810-10-65-1 establishes accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income attributed to the parent and to the noncontrolling interest, changes in a parent's ownership interest and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. FASB ASC Paragraph 810-10-65-1 also establishes disclosure requirements that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. FASB ASC Paragraph 810-10-65-1 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and was adopted by us in the first quarter of fiscal year 2009. The adoption did not have a material impact on our

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

consolidated results or operations or financial condition; however, it did modify the presentation of our financial results.

**Table of Contents****EXELIXIS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****September 30, 2009****(unaudited)****NOTE 2. Comprehensive Loss**

Comprehensive loss represents net loss plus the results of certain stockholders' deficit 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):

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
Consolidated net loss	\$ (25,445)	\$ (41,186)	\$ (110,723)	\$ (134,825)
Increase in unrealized gains (losses) on available-for-sale securities	76	(424)	96	(321)
Comprehensive loss	(25,369)	(41,610)	(110,627)	(135,146)
Comprehensive loss attributable to the noncontrolling interest		2,680	4,337	9,920
Comprehensive loss attributable to Exelixis	\$ (25,369)	\$ (38,930)	\$ (106,290)	\$ (125,226)

**NOTE 3. Stock-Based Compensation**

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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
Research and development expense	\$ 3,979	\$ 3,773	\$ 11,789	\$ 10,985
General and administrative expense	1,951	1,990	5,689	6,021
Total employee stock-based compensation expense	\$ 5,930	\$ 5,763	\$ 17,478	\$ 17,006

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

	<b>Stock Options</b>		<b>ESPP</b>	
	<b>Three Months Ended September 30,</b>		<b>Three Months Ended September 30,</b>	
	<b>2009 (1)</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
Weighted average fair value of awards	\$ 3.54	\$ 3.48	\$ 1.37	\$ 2.42

# Edgar Filing: EXELIXIS INC - Form 10-Q

Risk-free interest rate	2.5%	3.25%	0.30%	1.73%
Dividend yield	0%	0%	0%	0%
Volatility	67%	61%	61%	59%
Expected life	5.6 years	5.2 years	0.44 years	0.5 years

	Stock Options		ESPP	
	Nine Months Ended September 30, 2009 (1)	2008	Nine Months Ended September 30, 2009	2008
Weighted average fair value of awards	\$ 2.93	\$ 4.53	\$ 1.67	\$ 2.83
Risk-free interest rate	2.3%	3.20%	0.18%	2.72%
Dividend yield	0%	0%	0%	0%
Volatility	67%	61%	65%	56%
Expected life	5.6 years	5.2 years	0.17 years	0.5 years

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



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

On July 7, 2009, we commenced a stock option exchange program approved by our stockholders on May 14, 2009. The exchange program was open to all eligible employees who, at the start of the exchange program, were employed by us or one of our subsidiaries and remained employed through August 5, 2009, the date that the replacement stock options were granted. As a result of the exchange, 9.9 million options were cancelled, of which 7.3 million and 2.6 million were vested and unvested, respectively. Of the 7.2 million replacement options that were granted, 5.1 million were issued in exchange for vested options and 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.

**Table of Contents****EXELIXIS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****September 30, 2009****(unaudited)**

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

A summary of all stock option activity for the nine-month period ended September 30, 2009 is presented below:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Options outstanding at December 31, 2008	24,141,186	\$ 9.67		
Granted	9,088,759	\$ 5.48		
Exercised	(1,811)	\$ 2.19		
Cancelled	(11,686,952)	\$ 10.43		
Options outstanding at September 30, 2009	21,541,182	\$ 7.49	6.37 years	\$ 6,525,830
Exercisable at September 30, 2009	8,953,655	\$ 9.67	5.13 years	\$ 231,360

As of September 30, 2009, \$26.0 million of total unrecognized compensation expense related to employee stock options was expected to be recognized over a weighted-average period of 1.93 years.

**NOTE 4. Collaborations*****Global License Agreement and Collaboration with sanofi-aventis***

On May 27, 2009, we entered into a global license agreement with sanofi-aventis for two of our cancer programs, XL147 and XL765, and a broad collaboration for the discovery of inhibitors of phosphoinositide-3 kinase ( PI3K ) for the treatment of cancer. The license agreement and collaboration agreement became effective on July 7, 2009. In connection with the effectiveness of the license and collaboration, on July 20, 2009, we received upfront payments of \$140.0 million (\$120.0 million for the license and \$20.0 million for the collaboration), less applicable withholding taxes of \$7.0 million, for a net receipt of \$133.0 million.

Under the license, sanofi-aventis received a worldwide exclusive license to XL147 and XL765, which are currently in phase 1 and phase 1b/2 clinical trials, respectively, and has sole responsibility for all subsequent clinical, regulatory, commercial and manufacturing activities. We will participate in conducting 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 discovery collaboration, the parties will combine efforts in establishing several preclinical PI3K programs and will jointly share responsibility for research and preclinical activities related to isoform-selective inhibitors of PI3K alpha and beta. Sanofi-aventis will provide guaranteed research and development funding to cover

our expenses and is responsible for funding all development activities for each product following approval of the investigational new drug application filed with the United States Food and Drug Administration, or the foreign equivalent thereof, 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 also entitled to receive guaranteed research funding of \$21.0 million over three years. For both the license and the collaboration, 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. 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 collaboration.

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.

**Table of Contents**

**EXELIXIS, INC.**

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

**September 30, 2009**

**(unaudited)**

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 autoimmune disease therapies. The collaboration is focused on the discovery of sphingosine-1-phosphate type 1 receptor ( S1P1R ) agonists, a central mediator of multiple pathways implicated in a variety of autoimmune diseases.

Under the terms of the agreement, Boehringer Ingelheim was required to pay us an upfront cash payment of \$15.0 million for the development and commercialization rights to our S1P1R agonist program. We and Boehringer Ingelheim will 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 shall each be 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 will be amortized over the estimated research term of approximately 11 months and recorded as license revenue from the effective date of the 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.

***Bristol-Myers Squibb***

In December 2008, we entered into a worldwide collaboration with Bristol-Myers Squibb for XL184 and XL281. Upon effectiveness of the 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, of which \$20.0 million was received on April 1, 2009 and \$25.0 million was received on July 1, 2009.

We and Bristol-Myers Squibb have agreed to co-develop XL184, which may include a backup program for XL184. The companies will share worldwide (except for Japan) development costs for XL184. We are responsible for 35% of such costs and Bristol-Myers Squibb is responsible for 65% of such costs, except that we are responsible for funding the initial \$100.0 million of combined costs and have the option to defer payments for development costs above certain thresholds. In return, we will share 50% of the commercial profits and losses (including pre-launch commercialization expenses) in the United States and have the option to co-promote XL184 in the United States. We have the right to defer payment for certain early commercialization and other related costs above certain thresholds. We are eligible to receive sales performance milestones of up to \$150.0 million and double-digit royalties on sales on XL184 outside the United States. The clinical development of XL184 is directed by a joint committee. It is anticipated that we will conduct certain clinical development activities for XL184. We may opt out of the co-development for XL184, in which case we would instead be eligible to receive development and regulatory milestones

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

of up to \$295.0 million, double-digit royalties on XL184 product sales worldwide and sales performance milestones. Our co-development and co-promotion rights may be terminated in the event that we have cash reserves below \$80.0 million and we are unable to increase such cash reserves to \$80.0 million or more within 90 days, in which case we would receive development and regulatory milestones, sales milestones and double-digit royalties instead of sharing product profits on XL184 in the United States. For purposes of the agreement, cash reserves includes our total cash, cash equivalents and investments (excluding any restricted cash), plus the amount then available for borrowing by us under the Facility Agreement dated June 4, 2008 among us, Deerfield Private Design Fund, L.P., Deerfield Private Design International, L.P.,

**Table of Contents****EXELIXIS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****September 30, 2009****(unaudited)**

Deerfield Partners, L.P. and Deerfield International Limited, as the same may be amended from time to time (which will remain available until December 2009), and any other similar financing arrangements. Our co-promotion rights on XL184 in the United States, and possibly our right to share product profits on XL184, may be terminated in the event we undergo certain change of control transactions. Bristol-Myers Squibb may, upon certain prior notice to us, terminate the agreement as to products containing XL184 or XL281. In the event of such termination election, Bristol-Myers Squibb's license relating to such product would terminate and revert to us, and we would receive, subject to certain terms and conditions, licenses from Bristol-Myers Squibb to research, develop and commercialize such products.

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 of XL281, including our activities. We are eligible for development and regulatory milestones of up to \$315.0 million, 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 we received upon effectiveness of the collaboration agreement and the license payments of \$20.0 million and \$25.0 million we received on April 1, 2009 and on July 1, 2009, respectively, will be amortized over the estimated development term of five years, and recorded as license revenue, from the effective date of the agreement in December 2008. Any milestone payments that we may receive under the agreement will be amortized over the same period but recorded as contract revenue. We will record as operating expense 100% of the cost incurred for work performed by Exelixis on the two programs. During the term of the collaboration, so long as we have not opted out of the co-development of XL184, there may be periods during which Bristol-Myers Squibb will partially reimburse us for certain research and development expenses, and other periods during which we will 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. To the extent that net research and development funding payments are received from Bristol-Myers Squibb, these payments will be presented as collaboration revenue. In periods when net research and development funding payments are payable to Bristol-Myers Squibb, these payments will be presented as collaboration cost sharing expense. Net amounts due from or payable to Bristol-Myers Squibb will be determined and reflected on an annual basis. For the year ending December 31, 2009, we expect to incur a net payable to Bristol-Myers Squibb, which has resulted in a net increase in operating expenses year-to-date. Generally, the direction of cash flows will depend on the level of development activity by either party, which may change during the development term. Our capital requirements will be impacted by the level of our expenses for the development activity conducted by us and the degree to which we will be required to make payments to, or we will receive payments from, Bristol-Myers Squibb. If we opt out of the co-development of XL184, we would have no further unreimbursed cost obligations with respect to that compound.

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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009 (2)</b>	<b>2008</b>
Exelixis research and development expenses (1)	\$ 15,218	\$	\$ 34,987	\$
Net amount (owed to) due from collaboration partner	\$ (2,965)	\$	\$ (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 due from the collaborative partner is classified as a reduction in operating expenses for the nine-month period ended September 30, 2009.

**NOTE 5: Restructuring Charge**

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

In November 2008, we implemented a restructuring plan that resulted in a reduction in force of 78 employees, or approximately 10% of our workforce. All actions associated with the 2008 restructuring plan were completed in the first quarter of 2009, and we do not anticipate incurring any further costs under the 2008 restructuring plan.

**Table of Contents****EXELIXIS, INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****September 30, 2009****(unaudited)**

In connection with the 2008 restructuring plan, we recorded a charge of approximately \$2.9 million during the year ended December 31, 2008. This charge consisted primarily of severance, health care benefits and legal and outplacement services fees. The current balance of the liability is included in Other Accrued Expenses on our Condensed Consolidated Balance Sheet as of September 30, 2009 and the components are summarized in the following table (in thousands):

	<b>Employee Severance and Other Benefits</b>	<b>Legal and Other Fees</b>	<b>Total</b>
Balance as of December 31, 2008	\$ 1,688	\$ 51	\$ 1,739
Cash payments	(1,602)	(129)	(1,731)
Adjustments or non-cash credits	(86)	92	6
Balance as of September 30, 2009	\$	\$ 14	\$ 14

**NOTE 6. 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. As a result of the expiration of the purchase option, we issued a warrant to Symphony Evolution Holdings LLC to purchase 500,000 shares of our common stock at a price of \$6.05 per share, which is equal to 125% of the average closing price of our common stock on the NASDAQ Global Select Market over a continuous period of 60 trading days immediately preceding the second trading day prior to the business day immediately following the date the purchase option expired, with a five-year term.

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

**NOTE 7. Sale of Plant Trait Business**

In 2007, we entered into arrangements with Agrigenetics, Inc. ( Agrigenetics ), a wholly-owned subsidiary of The Dow Chemical Company, for (1) the sale of assets used for crop trait discovery and granted to Agrigenetics licenses to certain other related assets and intellectual property and (2) to perform contract research. In the second quarter of 2009, we signed an amendment to this arrangement upon the execution of which we were entitled to receive \$1.8 million. The \$1.8 million payable has been recorded as an adjustment to the gain on the sale of our plant trait business originally recorded in 2007. We are entitled to receive additional payments of up to \$7.2 million if we achieve specified development milestones, which will also be recorded as adjustments to the 2007 gain, in the period that they are achieved.

**NOTE 8. Income Taxes**

As a result of our collaboration with sanofi-aventis, we were subject to \$7.0 million withholding tax payable to the French taxing authorities. As a result of this withholding, we have recorded a tax provision for this amount which was paid upon the effective date of the collaboration. In addition, as a result of the Housing and Economic Recovery Act of 2008, we are eligible to claim a refund of previously generated tax credits and have recorded a total tax benefit of approximately \$1.0 million.





## **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, could, would, estimate, 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, 2008, filed with the Securities and Exchange Commission, or SEC, on March 10, 2009. 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 developing innovative therapies for cancer and other serious diseases. 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. Our most advanced pharmaceutical programs focus on discovery and development of small molecule drugs for cancer.

Utilizing our library of more than 4.5 million compounds, we have integrated high-throughput processes, medicinal chemistry, bioinformatics, structural biology and early *in vivo* testing into a process that allows us to efficiently and rapidly identify highly qualified drug candidates that meet our extensive development criteria.

Since our inception, we have filed 16 investigational new drug applications, or INDs, with the United States Food and Drug Administration, or FDA. As our compounds advance into clinical development, we expect to generate a critical mass of data that will help us to understand the full clinical and commercial potential of our drug candidates. In addition to guiding the potential commercialization of our innovative therapies, these data may contribute to the understanding of disease and help improve treatment outcomes.

Based on the strength of our expertise in biology, drug discovery and development, we have established collaborations with leading pharmaceutical and biotechnology companies, including Bristol-Myers Squibb Company, sanofi-aventis, Genentech, Inc. and GlaxoSmithKline, that allow us to retain economic participation in compounds and support additional development of our pipeline. Our collaborations generally fall 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 only to receive milestones and royalties 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. We maintain exclusive ownership of those compounds in our pipeline that we are developing ourselves. We are responsible for all development costs for these compounds and are entitled to 100% of profits if the compounds are commercialized.

**Table of Contents**

The following table sets forth those compounds in clinical development that we are developing internally or are co-developing with a partner:

Compound	Partner	Principal Targets	Indication	Stage of Development
XL184	Bristol-Myers Squibb	MET, VEGFR2, RET	Cancer	Phase 3
XL518	Genentech	MEK	Cancer	Phase 1
XL228	Unpartnered	IGF1R , ABL, SRC	Cancer	Phase 1
XL139	Bristol-Myers Squibb	Hedgehog	Cancer	Phase 1
XL413	Bristol-Myers Squibb	CDC7	Cancer	Phase 1
XL888	Unpartnered	HSP90	Cancer	Phase 1

The following table sets forth those compounds in preclinical and clinical development that we have out-licensed to third parties for further development and commercialization:

Compound	Partner	Principal Targets	Indication	Stage of Development
XL880	GlaxoSmithKline	MET, VEGFR2	Cancer	Phase 2
XL147	sanofi-aventis	PI3K	Cancer	Phase 1b/2
XL765	sanofi-aventis	PI3K, mTOR	Cancer	Phase 1b/2
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
XL550	Daiichi-Sankyo	MR	Metabolic and cardiovascular diseases	Preclinical
FXR	Wyeth	FXR	Metabolic and liver disorders	Preclinical

**Our Strategy**

Our business strategy is to leverage our biological expertise and integrated drug discovery capabilities to generate a pipeline of diverse development compounds with first-in-class or best-in-class potential that fulfill unmet medical needs in the treatment of cancer and potentially other serious diseases.

Our strategy is centered around three principal elements:

**Focus development** While we have historically pursued an approach to drug discovery intended to generate a significant number of development candidates to fuel our pipeline, for the foreseeable future we intend to direct our discovery efforts more towards generating development candidates under existing and future discovery collaborations with third parties. Our objective is to fund a significant portion of our discovery costs by entering into such collaborations. We are also focusing our later stage clinical development efforts on a limited number of programs. We believe that the most attractive compounds to develop ourselves or to co-develop with a partner have a lower-cost, lower-risk route to the market, usually for a niche indication, with the possibility of substantially expanding the market into major indications. Our most advanced clinical asset, XL184, which we are co-developing with Bristol-Myers Squibb, represents such a compound. We are focusing our later stage development efforts on XL184, which is being studied in a variety of tumor types, with the goal of rapidly commercializing the compound.

**Partner compounds** We are seeking new collaborations with leading pharmaceutical and biotechnology companies for the development and ultimate commercialization of some of our preclinical and clinical assets, particularly those drug candidates for which we believe that the capabilities and bandwidth of a partner can accelerate development and help to fully realize their therapeutic and commercial potential. Collaborations also provide us with a means of shifting a portion or all of the development costs related to such drug candidates. Consistent with this element of our strategy, in December 2008 we entered into a worldwide collaboration with Bristol-Myers Squibb on two of our cancer programs: one associated with XL184 and the other associated with XL281, and in May 2009 we entered into a license agreement with sanofi-aventis for XL147 and XL765 and also launched a broad collaboration with sanofi-aventis for the discovery of phosphoinositide-3 kinase, or PI3K, inhibitors. In May 2009, we also entered into a collaboration agreement with Boehringer Ingelheim International GmbH focused on the discovery of sphingosine-1-phosphate type 1 receptor agonists. We expect that over the next several years an increasingly greater portion of our development expenses will be funded by our partners.

**Control costs** We are committed to managing our costs and continually analyze our expenses to ensure that they are not disproportionate to our cash resources. We are selective with respect to funding our clinical development programs and have established definitive go/no-go criteria with respect to our development programs to ensure that we commit our resources only to those programs with the greatest commercial and therapeutic potential. To control costs, we may decide in the future to pursue collaborations for the development of drug candidates that we had initially determined to develop ourselves. We also retain the right to opt-out of the development of certain drug candidates that we are currently co-developing with partners.

## **Table of Contents**

We make decisions regarding whether and how to develop particular drug candidates we have generated through our discovery efforts based on a variety of factors, including preclinical and clinical data, our available financial resources, estimates of the costs to develop and commercialize the drug candidate, our bandwidth and our expertise. Ultimately, our decision-making is intended to maximize the value and productivity of our resources and to focus our efforts on those drug candidates that are commercially attractive and have the potential to be first-in-class or best-in-class therapeutics.

## **Recent Developments**

### ***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, 2009, we paid \$34.7 million in cash to GlaxoSmithKline as the first of three annual installments of principal and accrued interest due under the loan agreement. After giving effect to the payment, as of October 27, 2009, the aggregate principal and interest outstanding under the loan was \$70.4 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 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 program for our compounds. 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 and for a portion of development costs for those compounds that we are co-developing with partners. We share development costs with partners in our co-development collaborations and have no unreimbursed cost obligations with respect to compounds that we have out-licensed. We expect that over the next several years an increasingly greater portion of our development expenses will be funded by our partners.

### ***Liquidity***

As of September 30, 2009, we had \$301.0 million in cash and cash equivalents and short-term and long-term marketable securities, which included restricted cash and investments of \$4.7 million. We anticipate that our current cash and cash equivalents, short-term and long-term marketable securities and funding that we expect to receive from collaborators, which assumes a moderate level of 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:

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

whether we repay amounts outstanding under our loan and security agreement with GlaxoSmithKline (described below) in cash or shares of our common stock;

our expectation that we will not draw funds under the Facility Agreement among us, Deerfield Private Design Fund, L.P., Deerfield Private Design International, L.P., Deerfield Partners, L.P. and Deerfield International Limited (collectively, the Deerfield Entities );

## **Table of Contents**

our plans for the aggressive development of our broad clinical and preclinical pipelines;

our obligations under our collaboration agreements, including, in particular, our collaboration agreement with Bristol-Myers Squibb for XL184; and

whether we generate funds from existing or new collaborations for the development of any of our compounds.

Our minimum liquidity needs are also determined by financial covenants in our loan and security agreement, as amended, with GlaxoSmithKline, the Facility Agreement with the Deerfield Entities and our collaboration agreement with Bristol-Myers Squibb for XL184, as well as other factors, which are described under **Liquidity and Capital Resources** **Cash Requirements** .

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

### ***2008 Cancer Collaboration with Bristol-Myers Squibb***

We are focusing our later stage development efforts on XL184, which is being studied in a variety of tumor types, with the goal of rapidly commercializing the compound. In December 2008, we entered into a worldwide collaboration with Bristol-Myers Squibb for XL184 and XL281. Upon effectiveness of the 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, of which \$20.0 million was received in the first quarter of 2009 and \$25.0 million was received in the second quarter of 2009.

We and Bristol-Myers Squibb have agreed to co-develop XL184, which may include a backup program for XL184. The companies will share worldwide (except for Japan) development costs for XL184. We are responsible for 35% of such costs and Bristol-Myers Squibb is responsible for 65% of such costs, except that we are responsible for funding the initial \$100.0 million of combined costs and have the option to defer payments for development costs above certain thresholds. In return, we will share 50% of the commercial profits and losses (including pre-launch commercialization expenses) in the United States and have the option to co-promote XL184 in the United States. We have the right to defer payment for certain early commercialization and other related costs above certain thresholds. We are eligible to receive sales performance milestones of up to \$150.0 million and double-digit royalties on sales on XL184 outside the United States. The clinical development of XL184 is directed by a joint committee. It is anticipated that we will conduct certain clinical development activities for XL184. We may opt out of the co-development for XL184, in which case we would instead be eligible to receive development and regulatory milestones of up to \$295.0 million, double-digit royalties on XL184 product sales worldwide and sales performance milestones. Our co-development and co-promotion rights may be terminated in the event that we have cash reserves below \$80.0 million and we are unable to increase such cash reserves to \$80.0 million or more within 90 days, in which case we would receive development and regulatory milestones, sales milestones and double-digit royalties, instead of sharing product profits on XL184 in the United States. For purposes of the agreement, cash reserves includes our total cash, cash equivalents and investments (excluding any restricted cash), plus the amount then available for borrowing by us under the Facility Agreement dated June 4, 2008 among us and the Deerfield Entities, as the same may be amended from time to time (which will remain available until December 2009), and any other similar financing arrangements. Our co-promotion rights on XL184 in the United States, and possibly our right to share product profits on XL184, may be terminated in the event we undergo certain change of control transactions. Bristol-Myers Squibb may, upon certain prior notice to us, terminate the agreement as to products containing XL184 or XL281. In the event of such termination election, Bristol-Myers Squibb's license relating to such product would terminate and revert to us, and we would receive, subject to certain terms and conditions, licenses from Bristol-Myers Squibb to research, develop and commercialize such products.

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 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.

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 we received in the first quarter and second quarter of 2009, respectively, will be amortized over the estimated development term of five years, and recorded as license revenue, from the effective date of the agreement in December 2008. Any milestone payments that we may receive under the agreement will be amortized over the same period but recorded as contract revenue. We will record as operating expense 100% of the cost incurred for work performed by Exelixis on the two programs. During the term of the collaboration, so long as we have not opted out of the co-development of XL184, there may be periods during which Bristol-Myers Squibb will partially reimburse us for certain

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

research and development expenses, and other periods during which we will 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. To the extent that net research and development funding payments are received from Bristol-Myers Squibb, these payments will be presented as collaboration revenue. In periods when net research and development funding payments are payable to Bristol-Myers Squibb, these payments will be presented



**Table of Contents**

as collaboration cost sharing expense. Net amounts due from or payable to Bristol-Myers Squibb will be determined and reflected on an annual basis. For the year ending December 31, 2009, we expect to incur a net payable to Bristol-Myers Squibb. Generally, the direction of cash flows will depend on the level of development activity by either party, which may change during the development term. Our capital requirements will be impacted by the level of our expenses for the development activity conducted by us and the degree to which we will be required to make payments to, or we will receive payments from, Bristol-Myers Squibb. If we opt out of the co-development of XL184, we would have no further unreimbursed cost obligations with respect to that compound.

***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. As of September 30, 2009, the aggregate principal and interest outstanding under our GlaxoSmithKline loan was \$104.8 million. Repayment of all or any of the amounts advanced to us under this agreement may, at our election, be in the form of our common stock at fair market value, subject to certain conditions, or cash. On October 27, 2009, we paid \$34.7 million in cash to GlaxoSmithKline as the first of three annual installments of principal and accrued interest due under our loan. After giving effect to the payment, as of October 27, 2009, the aggregate principal and interest outstanding under the loan was \$70.4 million. 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 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.

***Deerfield Facility***

In June 2008, we entered into the Facility Agreement with the Deerfield Entities pursuant to which the Deerfield Entities agreed to loan to us up to \$150.0 million, subject to certain conditions. We may draw down on the facility in \$15.0 million increments at any time until December 2009. If we draw down the facility, the outstanding principal and interest under the loan, if any, would be due by June 4, 2013, and, at our option, could be repaid at any time with shares of our common stock, subject to certain restrictions, or in cash. Interest under the loan does not accrue until we draw down on the facility, at which time interest will begin to accrue at a rate of 6.75% per annum compounded annually on the outstanding principal amount of the facility. The Deerfield Entities also have limited rights to accelerate repayment of the loan upon certain changes of control of Exelixis or an event of default. Pursuant to the Facility Agreement, we paid the Deerfield Entities a one time transaction fee of \$3.8 million, or 2.5% of the loan facility, and we are obligated to pay an annual commitment fee of \$3.4 million, or 2.25% of the loan facility, payable quarterly. We also issued warrants to the Deerfield Entities to purchase an aggregate of 1,000,000 shares of our common stock at an exercise price of \$7.40 per share. If we draw down under the Facility Agreement, we would be required to issue to the Deerfield Entities additional warrants to purchase shares of our common stock. If we draw down under the Facility Agreement, there is no assurance that the conditions to our ability to repay the loan in shares of our common stock would be satisfied at the time that any outstanding principal and interest under the loan is due, in which case we would be obligated to repay the loan in cash, or that events permitting acceleration of the loan will not occur, in which event we would be required to repay any outstanding principal and interest sooner than anticipated. As of September 30, 2009, we had not drawn funds under the Facility Agreement and we do not expect to draw funds under the Facility Agreement prior to the expiration of our ability to do so in December 2009.

***Critical Accounting Estimates***

Our consolidated financial statements and related notes are prepared in accordance with U.S. generally accepted accounting principles, or GAAP, which requires 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.

## **Table of Contents**

### ***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. 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 have estimated our term to be five years, or through the completion of certain phase 3 trials. We estimate that this is the longest possible period that we could be obligated to perform services and therefore the appropriate term with which to amortize any license fees. However, if we submit a New Drug Approval application earlier than anticipated, or Bristol-Myers Squibb decides to take over management of trials prior to their completion, the estimated term of our obligation would be shortened, resulting in an increase in revenue recognition in the period in which our estimated term changes.

Although milestone payments are generally non-refundable once the milestone is achieved, we recognize the milestone revenues on a straight-line basis over the expected research term of the arrangement. This typically results in a portion of the 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.

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, certain research and development expenses are partially reimbursable to us. On an annual basis, the amounts that Bristol-Myers Squibb owes us, net of amounts reimbursable to Bristol-Myers Squibb by us on those projects, are recorded as 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 annual periods when net research and development funding payments are payable to Bristol-Myers Squibb, these payments will be presented as collaboration cost-sharing expense.

Some of our research and licensing arrangements have multiple deliverables in order to meet our customers' needs. For example, the arrangements may include a combination of up-front fees, license payments, research and development services, milestone payments and future royalties. 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.

### ***Goodwill Impairment***

As of September 30, 2009, our consolidated balance sheet included \$63.7 million of goodwill. Under GAAP, we evaluate goodwill for impairment on an annual basis and on an interim basis if events or changes in circumstances between annual impairment tests indicate that the asset might be impaired. The impairment tests for goodwill are performed at the reporting unit level and require us to perform a two-step impairment test. Our reporting units have been determined to be consistent with our operating segments. In the first step, we compare the fair value of our reporting units to their respective carrying values. If the fair value of the reporting unit exceeds the carrying value of the net assets assigned to that unit, goodwill is not impaired and we are not required to perform further testing. If the carrying value of the net assets assigned to the reporting unit exceeds the fair value of the reporting unit, we perform the second step of the impairment test in order to determine the implied fair value of the reporting unit's goodwill. If the carrying value of a reporting unit's goodwill exceeds its fair value, then we record an impairment loss equal to the difference.



**Table of Contents*****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. For example, in 2007 we recorded a reduction of \$2.6 million to our accrued clinical trial liabilities and research and development expenses related to our phase 2 clinical trial for XL784.

***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.

During the quarter ended September 30, 2009, we completed a stock option exchange program that required us to fair value both our under-water pre-exchange options and the replacement options. We will record the incremental expense difference, if any, over the vesting period of the new options. Replacement options that were granted in exchange for fully vested surrendered options shall be 100% vested on the one-year anniversary following the date the replacement options were granted. Replacement options that were granted in exchange for surrendered options that are not fully vested shall be 33% vested on the one-year anniversary following the date the replacement options were granted and the balance of the shares shall vest in a series of twenty-four successive equal monthly installments. The replacement options have a maximum term of 6.2 years. In valuing the replacement awards, we used the mid-point between the vesting period and the maximum term to estimate the expected life of the award. In association with the option exchange, we expect to recognize incremental compensation cost of approximately \$0.8 million ratably over the new vesting periods, of which we have recognized approximately \$0.1 million during the quarter ended September 30, 2009.

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, 2009, \$26.0 million of total unrecognized compensation expense related to stock options is expected to be recognized over a weighted-average period of 1.93 years. See Note 3 to the Condensed 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 31<sup>st</sup> of each year. Fiscal year 2008, a 53-week year, ended on January 2, 2009, and fiscal year 2009, a 52-week year, will end on January 1, 2010. For convenience, references in these Condensed Consolidated Financial Statements and Notes as of and for the fiscal year ended January 2, 2009 are indicated on a calendar year basis ended December 31, 2008 and as of and for the fiscal quarters ended September 26, 2008 and October 2, 2009 are indicated as ended September 30,

2008 and 2009, respectively.

**Table of Contents****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,	
	2009	2008	2009	2008
Contract revenue:				
Research and development funding	\$ 8.6	\$ 6.3	\$ 12.2	\$ 21.6
Milestones	6.4	10.3	15.8	30.5
Collaboration reimbursements	9.6		9.6	
License revenue, amortization of upfront payments, including amortization of premiums for equity purchases	30.4	13.3	70.1	36.2
Total revenues	\$ 55.0	\$ 29.9	\$ 107.7	\$ 88.3
Dollar increase	\$ 25.1		\$ 19.4	
Percentage increase	84%		22%	

The increase in research and development funding for the three-months ended September 30, 2009, as compared to the comparable period for the prior year, was driven primarily by an increase of \$7.1 million resulting from our new collaboration with sanofi-aventis partially offset by a decrease of \$4.4 million resulting from the conclusion of the development term under our collaboration agreement with GlaxoSmithKline and \$0.5 million from the reduction in the number of full-time equivalents related to certain collaborations with Bristol-Myers Squibb.

The decrease in research and development funding for the nine-months ended September 30, 2009, as compared to the comparable period for the prior year, was driven primarily by the conclusion of the development term under our collaboration agreement with GlaxoSmithKline, which resulted in a decrease of \$12.6 million. In addition, there was a decline of \$2.3 million relating to the conclusion of the research term under certain of our collaboration agreements with Genentech and Bristol-Myers Squibb as well as a decline of \$1.4 million relating to fewer full-time equivalents under our LXR program with Bristol-Myers Squibb. These decreases were partially offset by an increase of \$7.1 million resulting from our new collaboration with sanofi-aventis.

The decrease in milestone revenues for the three months ended September 30, 2009, as compared to the comparable period for the prior year, was primarily due to the conclusion of the development term under our collaboration agreement with GlaxoSmithKline in October 2008, which resulted in a decrease of \$5.7 million, in addition to the conclusion of the research term under one of our collaborations with Bristol-Myers Squibb, which resulted in a decrease of \$1.2 million. These decreases were partially offset by an increase of \$3.2 million in revenue recognition relating to various other collaboration agreements with Bristol-Myers Squibb.

The decrease in milestone revenues for the nine months ended September 30, 2009, as compared to the comparable period for the prior year, was primarily due to the conclusion of the development term under our collaboration agreement with GlaxoSmithKline in October 2008, which resulted in a decrease of \$12.7 million, as well as a decrease of \$2.2 million from the reduction in revenue recognition from various collaboration agreements with Bristol-Myers Squibb and a decrease of \$1.1 million from our MEK collaboration with Genentech. These decreases were partially offset by an increase of \$1.3 million relating to our LXR agreement with Bristol-Myers Squibb.

The increase in collaboration reimbursements for the three and nine-months ended September 30, 2009, as compared to the comparable period for the prior year, of \$9.6 million was due to our 2009 collaboration agreement with sanofi-aventis for the discovery of inhibitors of phosphoinositide-3 kinase, or PI3K.

The increase in the amortization of upfront payments for the three months ended September 30, 2009, as compared to the comparable period for the prior year, was primarily due to \$12.0 million in revenues associated with our 2008 cancer collaboration with Bristol-Myers Squibb relating to XL184 and XL281 in addition to \$8.2 million in revenues associated with our collaboration with sanofi-aventis for XL147 and XL765 and \$4.2 million in revenues associated with our 2009 collaboration with Boehringer Ingelheim. This increase was partially offset by a decrease of \$5.5 million relating to the conclusion of the development term under our collaboration with GlaxoSmithKline and \$1.2 million due to the deceleration of revenue recognition under our Bristol-Myers Squibb LXR collaboration as a result of extending the collaboration term.

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

The increase in the amortization of upfront payments for the nine months ended September 30, 2009, as compared to the comparable period for the prior year, was primarily due to \$36.0 million in revenues associated with our 2008 cancer collaboration with Bristol-Myers Squibb relating to XL184 and XL281, in addition to \$8.2 million in revenues associated with our collaboration



**Table of Contents**

with sanofi-aventis for XL147 and XL765 and \$6.7 million in revenues associated with our 2009 collaboration with Boehringer Ingelheim. This increase was partially offset by \$12.1 million relating to the conclusion of the development term under our collaboration with GlaxoSmithKline and \$3.6 million due to the deceleration of revenue recognition under our Bristol-Myers Squibb LXR collaboration as a result of extending the collaboration term. In addition, there was a decrease of \$1.0 million due to the conclusion of the research term under our 2005 cancer collaboration agreement with Genentech.

**Research and Development Expenses**

Total research and development expenses for the three-month and nine-month period ended September 30, 2009, 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,	
	2009	2008	2009	2008
Research and development expenses	\$ 60.2	\$ 65.7	\$ 170.6	\$ 200.5
Dollar decrease	\$ 5.5		\$ 29.9	
Percentage decrease	8%		15%	

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, 2009, as compared to the comparable period in 2008, resulted primarily from the following:

**Clinical Trials** Clinical trial expenses, which include services performed by third-party contract research organizations and other vendors, decreased by \$1.3 million, or 6%, primarily due to the wind down of activities associated with XL647, XL820 and XL844 clinical trials, a decline in preclinical activity on XL888 compared to 2008, the discontinued development of XL999, the transfer of XL518 to Genentech in March 2009 and non-clinical toxicology studies conducted in 2008 on XL019. These decreases were partially offset by an increase in phase 2 and 3 clinical trial activity for XL184.

**Personnel** Personnel expense, which includes salaries, bonuses, related fringe benefits, recruiting and relocation costs, decreased by \$2.1 million, or 10%, primarily due to a reduction in headcount.

The decrease for the nine months ended September 30, 2009, as compared to the comparable period in 2008, resulted primarily from the following:

**Clinical Trials** Clinical trial expenses, which include services performed by third-party contract research organizations and other vendors, decreased by \$17.6 million, or 28%, primarily due to the wind down of activities associated with XL647, XL820, XL784 and XL844 clinical trials, the transfer of XL880 to GlaxoSmithKline in 2008, the transfer of XL518 to Genentech in March 2009, and non-clinical toxicology studies conducted in 2008 on XL019. These decreases were partially offset by an increase in phase 3 clinical trial activities for XL184, increased phase 1 clinical trial activity for XL281, non-clinical activity for XL388, and increased phase 1 activity related to XL139.

**Personnel** Personnel expense, which includes salaries, bonuses, related fringe benefits, recruiting and relocation costs, decreased by \$6.5 million, or 11%, primarily due to a reduction in headcount.

**Lab Supplies** Lab supplies decreased by \$2.7 million, or 19%, primarily due to the decrease in headcount and other cost cutting measures.

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

**Cost Reimbursement** As a result of our contract research agreement with Agrigenetics, Inc., or Agrigenetics, we received an increase in research and development funding of \$1.5 million that was recognized as a reduction to research and development expense.

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 expenses, 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

**Table of Contents**

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 expenses (dollar amounts are presented in millions):

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
Drug discovery	\$ 21.5	\$ 25.6	\$ 66.2	\$ 78.3
Development	33.9	35.6	88.7	109.8
Other	4.8	4.5	15.7	12.4
Total research and development expenses	\$ 60.2	\$ 65.7	\$ 170.6	\$ 200.5

For the three months ended September 30, 2009, the programs representing the greatest portion of our research and development expenses (in approximate order of magnitude), based on estimates of the allocation of our research and development efforts and expenses among specific programs, were XL184, XL765, XL147 and XL228. The expenses for these programs are included in the development category of our research and development expenses.

For the nine months ended September 30, 2009, the programs representing the greatest portion of our research and development expenses (in approximate order of magnitude), based on estimates of the allocation of our research and development efforts and expenses among specific programs, were XL184, XL765, XL147, XL228 and XL281. The expenses for these programs are included in the development category of our research and development expenses.

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. 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 for the three-month and nine-month period ended September 30, 2009, as compared to the prior year period, were as follows (dollar amounts are presented in millions):

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
General and administrative expenses	\$ 8.6	\$ 8.9	\$ 25.9	\$ 27.8
Dollar decrease	\$ 0.3		\$ 1.9	
Percentage decrease	3%		7%	

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

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 decrease in expenses for the three-month and nine-month periods ended September 30, 2009, as compared to the comparable periods in 2008, was primarily due to a reduction in headcount related to our restructuring in November 2008 and other cost saving measures.

**Table of Contents****Collaboration Cost-Sharing Expenses**

Total collaboration cost-sharing expenses for the three-month and nine-month period ended September 30, 2009, 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,	
	2009	2008	2009	2008
Collaboration cost-sharing expenses	\$ 3.0	\$	\$ 2.8	\$
Dollar change	\$ 3.0		\$ 2.8	
Percentage change	100%		100%	

Total collaboration cost-sharing expenses consist 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 research and development funding payments are received from Bristol-Myers Squibb, these payments will be presented as collaboration revenue. In periods when net research and development funding payments are payable to Bristol-Myers Squibb, these payments will be presented as collaboration cost sharing expense. Net amounts due from or payable to Bristol-Myers Squibb will be determined and reflected on an annual basis. For the year ending December 31, 2009, we expect to incur a net expense. For the three-month and nine-month periods ended September 30, 2009, we have recorded a payable, which results in an increase in operating expenses of \$3.0 million and \$2.8 million, respectively.

**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,	
	2009	2008	2009	2008
Total other (expense) income, net	\$ (1.8)	\$ 3.4	\$ (13.1)	\$ 5.2
Dollar change	\$ (5.2)		\$ (18.3)	
Percentage decrease	Not meaningful		Not meaningful	

The change in total other income (expense), net for the three-month period ended September 30, 2009, as compared to the comparable period in 2008, resulted primarily from the recording of a \$4.5 million adjustment in 2008 related to the gain on the sale of our plant trait business originally recorded in 2007.

The change in total other income (expense), net for the nine-month period ended September 30, 2009, as compared to the comparable period in 2008, resulted primarily from the recording of a \$9.8 million loss upon deconsolidation of SEI as a result of the expiration of our purchase option for SEI in June 2009. In addition, we recorded a net adjustment of \$2.7 million to the gain on the sale of our plant trait business which is the difference between the \$4.5 million recorded in 2008 and the \$1.8 million recorded in 2009.

**Income Tax Provision**

The income tax provision for the three-month period ended September 30, 2009 is a result of \$7.0 million of withholding tax associated with the payments received from sanofi-aventis.

The income tax provision for the nine-month period ended September 30, 2009 is a result of \$7.0 million of withholding tax associated with the payments received from sanofi-aventis, partially offset by a \$1.0 million tax credit recorded as a result of the Housing and Economic Recovery Act of 2008.

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

The following table summarizes our cash flow activities for the nine months ended September 30, 2009 and 2008, respectively (dollar amounts are presented in thousands):

	<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>
Consolidated net loss	\$ (110,723)	\$ (134,825)
Adjustments to reconcile net loss to net cash used in operating activities	37,517	23,412
Changes in operating assets and liabilities	109,365	(52,165)
Net cash provided by (used in) operating activities	36,159	(163,578)
Net cash (used in) provided by investing activities	(104,171)	88,045
Net cash (used in) provided by financing activities	(9,116)	4,306
Net decrease in cash and cash equivalents	(77,128)	(71,227)
Cash and cash equivalents, at beginning of period	247,698	135,457
Cash and cash equivalents, at end of period	\$ 170,570	\$ 64,230

To date, we have financed our operations primarily through the sale of equity, payments and loans from collaborators, equipment financing facilities and interest income. We have also financed certain of our research and development activities under our agreements with SEI. As of September 30, 2009, we had \$301.0 million in cash and cash equivalents and short-term and long-term marketable securities, which included restricted cash and investments of \$4.7 million. In addition, as of September 30, 2009, approximately \$22.7 million of cash and cash equivalents and marketable securities served as collateral for bank lines of credit.

***Operating Activities***

Our operating activities provided cash of \$36.2 million for the nine months ended September 30, 2009, compared to cash used of \$163.6 million for the comparable period in 2008. 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. Cash used by operating activities for the 2008 period related primarily to our net loss of \$134.8 million, losses attributed to noncontrolling interest and to a decrease in cash received from collaborators, which caused a decrease in deferred revenues of \$56.3 million. In addition to the decrease in cash received in 2008, the decline in deferred revenues also reflects the acceleration of \$17.3 million in previously deferred revenue relating to the conclusion of the development term under our collaboration with GlaxoSmithKline on October 27, 2008. These uses of cash by operating activities were partially offset by non-cash charges of stock-based compensation expense and depreciation and amortization expense.

Cash provided in our operating activities increased by \$199.7 million for the nine months ended September 30, 2009 as compared to the comparable period in 2008. The increase was primarily driven by an increase in deferred revenue, the loss on our deconsolidation of SEI, and a decrease in our net loss attributable to Exelixis, Inc. partially offset by an increase in trade receivables and a decrease in accounts payable and accrued expenses. The increase in deferred revenue of \$172.9 million related principally to an increase in cash received in December 2008 and year-to-date in 2009 relating to our collaborations with Bristol-Myers Squibb, sanofi-aventis, and Boehringer Ingelheim, partially offset by the ratable recognition of deferred revenues over the period of continuing involvement from our various collaborations. Decreases in accounts payable and other accrued expense and our net loss attributable to Exelixis, Inc. relate primarily to a decrease in research and development expenses.

***Investing Activities***

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

Our investing activities used cash of \$104.2 million for the nine months ended September 30, 2009, compared to cash provided of \$88.0 million for the comparable period in 2008. 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 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. The purchases of marketable securities were related to payments received from our collaborations with Bristol-Myers Squibb, sanofi-aventis and Boehringer Ingelheim. The proceeds provided by sale and maturities of our marketable securities, the sale of investments held by SEI and proceeds related to the sale of our plant trait business were used to fund our operations. We expect to continue to make moderate investments in property and equipment to support our expanding operations.

Cash provided by investing activities for the 2008 period was primarily driven by proceeds of \$83.7 million from the sale and maturities of our marketable securities and the sale of \$13.1 million of investments held by SEI. In addition, in September 2008 we

## **Table of Contents**

received the \$4.5 million anniversary payment plus an additional \$4.5 million of contingent consideration in association with our transaction with Agrigenetics. This cash inflow was partially offset by purchases of property and equipment of \$13.9 million and marketable securities purchases of \$5.6 million. The proceeds provided by maturities or sale of our marketable securities and the sale of investments by SEI were used to fund our operations. We expect to continue to make moderate investments in property and equipment to support our expanding operations.

### *Financing Activities*

Our financing activities used cash of \$9.1 million for the nine months ended September 30, 2009, compared to cash provided of \$4.3 million for the comparable period in 2008. 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. Cash provided by our financing activities for the 2008 period was primarily due to proceeds of \$13.6 million from our notes payable and bank obligations and \$2.4 million from the exercise of stock options and the issuance of stock under the employee stock purchase plan. These increases were partially offset by principal payments on notes payable and bank obligations of \$11.8 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 additional payments on our loan from GlaxoSmithKline. In June 2008, we entered into the Facility Agreement with Deerfield Entities for which the Deerfield Entities agreed to loan us up to \$150.0 million, subject to certain conditions. We may draw down on the facility in \$15.0 million increments at any time until December 2009. The outstanding principal and interest under the loan, if any, is due by June 4, 2013, and, at our option, can be repaid at any time with shares of our common stock, subject to certain restrictions, or in cash. As of September 30, 2009, we had not drawn funds under the Facility Agreement and we do not expect to draw funds under the Facility Agreement prior to the expiration of our ability to do so in December 2009.

### *Cash Requirements*

We have incurred net losses since inception, including a net loss attributable to Exelixis, Inc. of \$25.4 million for the three months ended September 30, 2009 and \$106.4 million for the nine months ended September 30, 2009, and we expect to incur substantial losses for at least the next several years as we continue our research and development activities, including manufacturing and development expenses for compounds in preclinical and clinical studies. As of September 30, 2009, we had \$301.0 million in cash and cash equivalents and short-term and long-term marketable securities, which included restricted cash and investments of \$4.7 million. We anticipate that our current cash and cash equivalents, short-term and long-term marketable securities and funding that we expect to receive from collaborators, which assumes a moderate level of 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:

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. As of September 30, 2009, the aggregate principal and interest outstanding under our GlaxoSmithKline loan was \$104.8 million. Repayment of all or any of the amounts advanced to us under this agreement may, at our election, be in the form of our common stock at fair market value, subject to certain conditions, or cash. On October 27, 2009, we paid \$34.7 million in cash to GlaxoSmithKline as the first of three annual installments of principal and accrued interest due under our loan. After giving effect to the payment, as of October 27, 2009, the aggregate principal and interest outstanding under the loan was \$70.4 million. 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 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.



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

our expectation that we will not draw funds under our Facility Agreement with the Deerfield Entities. In June 2008, we entered into the Facility Agreement with the Deerfield Entities pursuant to which the Deerfield Entities agreed to loan to us up to \$150.0 million, subject to certain conditions. We may draw down on the facility in \$15.0 million increments at any time until December 2009. The outstanding principal and interest under the loan, if any, is due by June 4, 2013, and,

## **Table of Contents**

at our option, can be repaid at any time with shares of our common stock, subject to certain restrictions, or in cash. Interest under the loan does not accrue until we draw down on the facility, at which time interest will begin to accrue at a rate of 6.75% per annum compounded annually on the outstanding principal amount of the facility. The Deerfield Entities also have limited rights to accelerate repayment of the loan upon certain changes of control of Exelixis or an event of default. Pursuant to the Facility Agreement, we paid the Deerfield Entities a one time transaction fee of \$3.8 million, or 2.5% of the loan facility, and we are obligated to pay an annual commitment fee of \$3.4 million, or 2.25% of the loan facility, payable quarterly. If we draw down under the Facility Agreement, we would be required to issue to the Deerfield Entities additional warrants to purchase shares of our common stock. If we draw funds under the Facility Agreement, there is no assurance that the conditions to our ability to repay the loan in shares of our common stock would be satisfied at the time that any outstanding principal and interest under the loan is due, in which case we would be obligated to repay the loan in cash, or that events permitting acceleration of the loan will not occur, in which event we would be required to repay any outstanding principal and interest sooner than anticipated;

the progress and scope of our collaborative and independent clinical trials and other research and development projects, including with respect to XL184, our most advanced asset. We are focusing our later stage development efforts on XL184, which is being studied in a variety of tumor types, with the goal of rapidly commercializing the compound. As described under Certain Factors Important to Understanding Our Financial Condition and Results of Operations 2008 Cancer Collaboration with Bristol-Myers Squibb, in December 2008, we entered into a worldwide co-development collaboration with Bristol-Myers Squibb for the development and commercialization of XL184. The companies will share worldwide (except for Japan) development costs for XL184. We are responsible for 35% of such costs and Bristol-Myers Squibb is responsible for 65% of such costs, except that we are responsible to fund the initial \$100 million of combined costs and have the option to defer payments for development costs above certain thresholds. In return, we will share 50% of the commercial profits and losses (including pre-launch commercialization expenses) in the United States and have the option to co-promote XL184 in the United States. We have the right to defer payment for certain early commercialization and other related costs above certain thresholds. During the term of the collaboration, so long as we have not opted out of the co-development of XL184, there may be periods during which Bristol-Myers Squibb will partially reimburse us for certain research and development expenses, and other periods during which we will 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. On an annual basis, to the extent that net research and development funding payments are received from Bristol-Myers Squibb, these payments will be presented as collaboration revenue. In annual periods when net research and development funding payments are payable to Bristol-Myers Squibb, these payments will be presented as collaboration cost sharing expense. Generally, the direction of cash flows will depend on the level of development activity by either party, which may change during the development term. Our capital requirements will be impacted by the level of our expenses for the development activity conducted by us and the degree to which we will be required to make payments to, or we will receive payments from, Bristol-Myers Squibb. If we opt out of the co-development of XL184, we would have no further unreimbursed cost obligations for that compound;

the level of payments received under existing collaboration agreements, licensing agreements and other arrangements as well as our ability to enter into new collaboration agreements, licensing agreements and other arrangements that provide additional payments;

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;

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

the cost and timing of establishing or contracting for sales, marketing and distribution capabilities.

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 strategic partnerships 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

## **Table of Contents**

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 will have to obtain additional funding in order to stay in compliance with financial covenants contained in agreements with third parties. For example, 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, but includes amounts available for borrowing under the Facility Agreement with the Deerfield Entities (which will cease to be available in December 2009)) 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, 2009, our working capital was \$360.0 million (including \$150.0 million available for borrowing until December 2009 under the Facility Agreement) and our cash and investments were \$296.3 million. If we were to 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 \$104.8 million at September 30, 2009. The second and third installments of principal and accrued interest under the loan are due on October 27, 2010 and October 27, 2011, respectively. In addition, if our cash and cash equivalents and marketable securities on the last day of any calendar quarter are less than \$75.0 million, then we would be in default under the Facility Agreement with the Deerfield Entities, and the Deerfield Entities would have the right, among other remedies, to declare immediately due and payable any amounts accrued or payable under the Facility Agreement. If our cash reserves fall below \$80.0 million and we are unable to increase such cash reserves to \$80.0 million or more within 90 days, our co-development and co-promotion rights with respect to XL184 under our 2008 collaboration agreement with Bristol-Myers Squibb may be terminated. Cash reserves for purposes of our 2008 collaboration agreement with Bristol-Myers Squibb includes our total cash, cash equivalents and investments (excluding any restricted cash), plus the amount then available for borrowing by us under the Facility Agreement with the Deerfield Entities (which will cease to be available in December 2009), as the same may be amended from time to time, and any other similar financing arrangements. If we cannot raise additional capital in order to remain in compliance with our financial covenants or if we are unable to renegotiate such covenants and the lender exercises its remedies under the agreement, we would not be able to operate under our current operating plan.

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

Our market risks at September 30, 2009 have not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2008, filed with the Securities and Exchange Commission on March 10, 2009. Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio and our long-term debt. We have estimated the effects on our interest rate sensitive assets and liabilities based on a one percentage point hypothetical adverse change in interest rates as of September 30, 2009 and December 31, 2008, respectively. As of September 30, 2009 and December 31, 2008, 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 \$0.2 million and \$1.3 million, respectively.

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

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

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

## **PART II. OTHER INFORMATION**

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

*In addition to the factors discussed elsewhere in this report and our other reports filed with the Securities and Exchange Commission, the following are important factors that could cause actual results or events to differ materially from those contained in any forward-looking*

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

*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, 2008 filed with the Securities and Exchange Commission on March 10, 2009.*

### **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, 2009, we had \$301.0 million in cash and cash equivalents and short-term and long-term marketable securities, which included restricted cash and investments of \$4.7 million. We anticipate that our current cash and cash equivalents, short-term and long-term marketable securities and funding that we expect to receive from collaborators, which assumes a moderate level of 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:

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. As of September 30, 2009, the aggregate principal and interest outstanding under our GlaxoSmithKline loan was \$104.8 million. Repayment of all or any of the amounts advanced to us under this agreement may, at our election, be in the form of our common stock at fair market value, subject to certain conditions, or cash. On October 27, 2009, we paid \$34.7 million in cash to GlaxoSmithKline as the first of three annual installments of principal and accrued interest due under our loan. After giving effect to the payment, as of October 27, 2009, the aggregate principal and interest outstanding under the loan was \$70.4 million. 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 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;

our expectation that we will not draw funds under our Facility Agreement with the Deerfield Entities In June 2008, we entered into the Facility Agreement with the Deerfield Entities pursuant to which the Deerfield Entities agreed to loan to us up to \$150.0 million, subject to certain conditions. We may draw down on the facility in \$15.0 million increments at any time until December 2009. The outstanding principal and interest under the loan, if any, is due by June 4, 2013, and, at our option, can be repaid at any time with shares of our common stock, subject to certain restrictions, or in cash. Interest under the loan does not accrue until we draw down on the facility, at which time interest will begin to accrue at a rate of 6.75% per annum compounded annually on the outstanding principal amount of the facility. The Deerfield Entities also have limited rights to accelerate repayment of the loan upon certain changes of control of Exelixis or an event of default. Pursuant to the Facility Agreement, we paid the Deerfield Entities a one time

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

transaction fee of \$3.8 million, or 2.5% of the loan facility, and we are obligated to pay an annual commitment fee of \$3.4 million, or 2.25% of the loan facility, payable quarterly. If we draw down under the Facility Agreement, we would be required to issue to the Deerfield Entities additional warrants to purchase shares of our common stock. If we draw funds under the Facility Agreement, there is no assurance that the conditions to our ability to repay the loan in shares of our common stock would be satisfied at the time that any outstanding principal and interest under the loan is due, in which case we would be obligated to repay the loan in cash, or that events permitting acceleration of the loan will not occur, in which event we would be required to repay any outstanding principal and interest sooner than anticipated;

the progress and scope of our collaborative and independent clinical trials and other research and development projects, including with respect to XL184, our most advanced asset. We are focusing our later stage development efforts on XL184, which is being studied in a variety of tumor types, with the goal of rapidly commercializing the compound. As described under Certain Factors Important to Understanding Our Financial Condition and Results of Operations 2008 Cancer

## **Table of Contents**

Collaboration with Bristol-Myers Squibb in December 2008, we entered into a worldwide co-development collaboration with Bristol-Myers Squibb for the development and commercialization of XL184. The companies will share worldwide (except for Japan) development costs for XL184. We are responsible for 35% of such costs and Bristol-Myers Squibb is responsible for 65% of such costs, except that we are responsible to fund the initial \$100 million of combined costs and have the option to defer payments for development costs above certain thresholds. In return, we will share 50% of the commercial profits and losses (including pre-launch commercialization expenses) in the United States and have the option to co-promote XL184 in the United States. We have the right to defer payment for certain early commercialization and other related costs above certain thresholds. During the term of the collaboration, so long as we have not opted out of the co-development of XL184, there may be periods during which Bristol-Myers Squibb will partially reimburse us for certain research and development expenses, and other periods during which we will 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. On an annual basis, to the extent that net research and development funding payments are received from Bristol-Myers Squibb, these payments will be presented as collaboration revenue. In annual periods when net research and development funding payments are payable to Bristol-Myers Squibb, these payments will be presented as collaboration cost sharing expense. Generally, the direction of cash flows will depend on the level of development activity by either party, which may change during the development term. Our capital requirements will be impacted by the level of our expenses for the development activity conducted by us and the degree to which we will be required to make payments to, or we will receive payments from, Bristol-Myers Squibb. If we opt out of the co-development of XL184, we would have no further unreimbursed cost obligations for that compound;

the level of payments received under existing collaboration agreements, licensing agreements and other arrangements as well as our ability to enter into new collaboration agreements, licensing agreements and other arrangements that provide additional payments;

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;



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

the cost and timing of establishing or contracting for sales, marketing and distribution capabilities.

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 strategic partnerships 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 will have to obtain additional funding in order to stay in compliance with financial covenants contained in agreements with third parties. For example, 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, but includes amounts available for borrowing under the Facility Agreement with the Deerfield Entities (which will cease to be available in December 2009)) 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, 2009, our working capital was \$360.0 million (including \$150.0 million available for borrowing until December 2009 under the Facility Agreement) and our cash and investments were \$296.3 million. If we were to default on the financial covenants under the loan and security agreement, GlaxoSmithKline may, among other remedies, declare immediately due

**Table of Contents**

and payable all obligations under the loan and security agreement. Outstanding borrowings and accrued interest under the loan and security agreement totaled \$104.8 million at September 30, 2009. The second and third installments of principal and accrued interest under the loan are due on October 27, 2010 and October 27, 2011, respectively. In addition, if our cash and cash equivalents and marketable securities on the last day of any calendar quarter are less than \$75.0 million, then we would be in default under the Facility Agreement with the Deerfield Entities, and the Deerfield Entities would have the right, among other remedies, to cancel our right to request disbursements and declare immediately due and payable any amounts accrued or payable under the Facility Agreement. If our cash reserves fall below \$80.0 million and we are unable to increase such cash reserves to \$80.0 million or more within 90 days, our co-development and co-promotion rights with respect to XL184 under our 2008 collaboration agreement with Bristol-Myers Squibb may be terminated. Cash reserves for purposes of our 2008 collaboration agreement with Bristol-Myers Squibb includes our total cash, cash equivalents and investments (excluding any restricted cash), plus the amount then available for borrowing by us under the Facility Agreement with the Deerfield Entities (which will cease to be available in December 2009), as the same may be amended from time to time, and any other similar financing arrangements. If we cannot raise additional capital in order to remain in compliance with our financial covenants or if we are unable to renegotiate such covenants and the lender exercises its remedies under the agreement, we would not be able to operate under our current operating plan.

***We have 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 \$25.4 million for the three months ended September 30, 2009 and \$106.4 million for the nine months ended September 30, 2009. As of that date, we had an accumulated deficit of \$1,060.9 million. We expect our losses in 2009 to increase as compared to 2008 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. Except for revenues associated with the transgenic mouse business of our former German subsidiary, Artemis Pharmaceuticals, GmbH, or Artemis, our only revenues to date are license revenues and revenues under contracts with our partners. In November 2007, we sold 80.1% of our ownership interest in Artemis. 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 product candidates in various stages of clinical development and we anticipate filing additional IND applications for additional product candidates 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. Even if we do increase our revenues and achieve profitability, we may not be able to maintain or increase profitability.

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

Most of our foreign expenses incurred are associated with establishing and conducting clinical trials for 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 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. We currently do not hedge against our foreign currency risks.

***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, 2009, 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.

## **Table of Contents**

### **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 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 lower 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 these events 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.

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. We do not know whether our planned clinical trials will begin on time, will be completed on schedule, or at all, will be sufficient for registration of these compounds or will 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.

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. If we are unable to achieve milestones, develop products or renew or enter into new collaborations, our revenues may decrease and our activities may fail to lead to commercialized 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, the achievement of milestones and royalties we earn from any future products developed from the collaborative research. If we are unable to successfully achieve milestones or our collaborators fail to develop successful products, we will not earn the revenues contemplated under such collaborative agreements. In addition, some of our collaborations are exclusive and preclude us from entering into additional collaboration arrangements with other parties in the area or field of exclusivity. Future collaborations may require us to relinquish some important rights, such as marketing and distribution rights.

If any of these agreements is not renewed or is terminated early, whether unilaterally or by mutual agreement, or if we are unable to enter into new collaboration agreements on commercially acceptable terms, our revenues and product development efforts

**Table of Contents**

could suffer. Our agreements with Bristol-Myers Squibb, sanofi-aventis, Genentech, Boehringer Ingelheim, Daiichi-Sanko and Wyeth contain early termination provisions. In addition, from time to time we review and assess certain aspects of our collaborations, partnerships and agreements and may amend or terminate, either by mutual agreement or pursuant to any applicable early termination provisions, such collaborations, partnerships or agreements if we deem them to be no longer in our economic or strategic interests. We may not be able to enter into new collaboration agreements on similar or superior financial terms to offset the loss of revenue from the termination or expiration of any of our existing arrangements, and the timing of new collaboration agreements may have a material adverse effect on our ability to continue to successfully meet our objectives.

***Conflicts with our collaborators could jeopardize the outcome of our collaboration agreements and our ability to commercialize products.***

We are conducting proprietary research programs in specific disease, therapeutic modality and agricultural product areas that are not covered by our collaboration agreements. Our pursuit of opportunities in pharmaceutical and agricultural markets could result in conflicts with our collaborators in the event that any of our collaborators takes the position that our internal activities overlap with those areas that are exclusive to our collaboration agreements, and we should be precluded from such internal activities. Moreover, disagreements with our collaborators could develop over, among other things, development plans and budgets, the parties' respective research and development activities and rights to our intellectual property. In addition, our collaboration agreements may have provisions that give rise to disputes regarding the respective rights and obligations of the parties, including the rights of collaborators with respect to our internal programs and disease area research. Any conflict with or among our collaborators could lead to the termination of our collaborative agreements, delay collaborative activities, impair our ability to renew agreements or obtain future collaboration agreements or result in litigation or arbitration and would negatively impact our relationship with existing collaborators. If our collaborators fail to develop or commercialize any of our compounds or product candidates, we would not receive any future royalties or milestone payments for such compounds or product candidates. We have limited or no control over the resources that our collaborators may choose to devote to our joint efforts. Our collaborators may breach or terminate their agreements with us or fail to perform their contractual obligations. Also, our collaboration agreements may be subject to early termination by mutual agreement. Further, our collaborators may elect not to develop products arising out of our collaboration arrangements, may experience financial difficulties, may undertake business combinations or significant changes in business strategy that adversely affect their willingness or ability to complete their obligations under any arrangement with us or may fail to devote sufficient resources to the development, manufacture, marketing or sale of such products. Certain of our collaborators could also become competitors in the future. If our collaborators develop competing products, preclude us from entering into collaborations with their competitors, fail to obtain necessary regulatory approvals, terminate their agreements with us prematurely or fail to devote sufficient resources to the development and commercialization of our products, our product development efforts could be delayed or otherwise adversely effected and may fail to lead to commercialized products.

***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.



## **Table of Contents**

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.***

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 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 a new drug application can be filed with the FDA, the product candidate must undergo extensive clinical trials, which can take many years and may require 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, which could delay, limit or prevent regulatory approval. 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, 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.

## **Table of Contents**

### **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;

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;

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.



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

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

## **Table of Contents**

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 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 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. In addition, there may be product candidates of which we are not aware at an earlier stage of development that may compete with our product candidates.

### ***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

## **Table of Contents**

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

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

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

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, Growth 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. 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

## **Table of Contents**

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.

### ***Difficulties we may encounter managing our growth may divert resources and limit our ability to successfully expand our operations.***

We have experienced a period of rapid and substantial growth that has placed, and our anticipated growth in the future will continue to place, a strain on our research, development, administrative and operational infrastructure. We will need to continue to manage multiple locations and additional relationships with various collaborative partners, suppliers and other third parties. Our ability to manage our operations and growth effectively requires us to continue to improve our reporting systems and procedures as well as our operational, financial and management controls. In addition, rules and regulations implemented by the Securities and Exchange Commission have increased the internal control and regulatory requirements under which we operate. We may not be able to successfully implement improvements to our management information and control systems in an efficient or timely manner to meet future requirements.

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

Our headquarters are located in South San Francisco, California, and therefore our facilities are vulnerable to damage from earthquakes. We 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,

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

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

## **Table of Contents**

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.*

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 and stock price to volatility, including:

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 discovery efforts leading to milestone payments and royalties;

the introduction of new technologies or products by our competitors;

the timing and willingness of collaborators to 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;

the impairment of acquired goodwill and other assets; 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



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

anticipated levels of revenues could therefore significantly harm our operating results for a particular fiscal period.

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

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

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

adverse results or delays in 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 announcement of new products by us or our competitors;

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

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;

**Table of Contents**

financing transactions;

developments in the biotechnology or pharmaceutical industry;

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

departures of key personnel or board members;

developments concerning current or future collaborations;

FDA or international regulatory actions;

third-party reimbursement policies;

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.

***We are exposed to risks associated with acquisitions.***

We have made, and may in the future make, acquisitions of, or significant investments in, businesses with complementary products, services and/or technologies. Acquisitions involve numerous risks, including, but not limited to:

difficulties and increased costs in connection with integration of the personnel, operations, technologies and products of acquired companies;

diversion of management's attention from other operational matters;

the potential loss of key employees;

the potential loss of key collaborators;

lack of synergy, or the inability to realize expected synergies, resulting from the acquisition; and

acquired intangible assets becoming impaired as a result of technological advancements or worse-than-expected performance of the acquired company.

Mergers and acquisitions are inherently risky, and the inability to effectively manage these risks could materially and adversely affect our business, financial condition and results of operations.

***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.

## **Table of Contents**

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

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

a classified Board of Directors;

a prohibition on actions by our stockholders by written consent;

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

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

limitations on the removal of directors; and

advance notice requirements for director nominations and stockholder proposals.

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

## **ITEM 6. EXHIBITS**

### **(a) Exhibits**

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

**Table of Contents**

**SIGNATURES**

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

Date: October 29, 2009

EXELIXIS, INC.

/s/ FRANK KARBE  
**Frank Karbe**  
**Executive Vice President and Chief Financial Officer**  
*(Principal Financial and Accounting Officer)*

**Table of Contents**

**EXHIBIT INDEX**

<b>Number</b>	<b>Exhibit Description</b>
3.1	Amended and Restated Certificate of Incorporation of Exelixis, Inc. (1)
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Exelixis, Inc. (2)
3.3	Amended and Restated Bylaws of Exelixis, Inc. (3)
4.1	Specimen Common Stock Certificate. (4)
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. (5)
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. (6)
4.4	Form of Warrant, dated June 10, 2009, to purchase 500,000 shares of Exelixis, Inc. common stock in favor of Symphony Evolution Holdings LLC. (7)
4.5	Warrant Purchase Agreement, dated June 9, 2005, between Exelixis, Inc. and Symphony Evolution Holdings LLC. (5)
4.6	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)
4.7	Fourth Amended and Restated Registration Rights Agreement, dated February 26, 1999, among Exelixis, Inc. and certain Stockholders of Exelixis, Inc. (4)
4.8	Registration Rights Agreement, dated June 9, 2005, between Exelixis, Inc. and Symphony Evolution Holdings LLC. (5)
4.9	Registration Rights Agreement between Exelixis, Inc. and Deerfield Private Design Fund, L.P., Deerfield Private Design International, L.P., Deerfield Partners, L.P. and Deerfield International Limited dated June 4, 2008. (8)
10.1	Compensation Information for Non-Employee Directors
10.2*	Amendment No. 2, effective September 1, 2009, to the Collaboration Agreement, dated December 11, 2008, by and between Exelixis, Inc. and Bristol-Myers Squibb Company.
10.3*	Amendment No. 2, effective October 1, 2009, to the Collaboration Agreement, dated December 15, 2006, by and between Exelixis, Inc. and Bristol-Myers Squibb Company.
10.4*	Fifth Amendment, dated October 1, 2009, to the Contract Research Agreement, dated September 4, 2007, by and among Agrigenetics, Inc., Mycogen Corporation, Exelixis Plant Sciences, Inc. and Exelixis, Inc.
31.1	Certification required by Rule 13a-14(a) or Rule 15d-14(a).
31.2	Certification required by Rule 13a-14(a) or Rule 15d-14(a).
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).
99.1	Exelixis, Inc. 401(k) Plan.
99.2	Exelixis, Inc. 401(k) Plan Adoption Agreement.

\* Confidential treatment requested 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.

(1) Filed as an Exhibit to Exelixis, Inc.'s Registration Statement on Form S-3 (File No. 333-152166), as filed with the Securities and Exchange Commission on April 24, 2009, as amended, and incorporated herein by reference.

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

- (2) Filed as an Exhibit to Exelixis, Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, filed with the Securities and Exchange Commission on August 5, 2004 and incorporated herein by reference.

**Table of Contents**

- (3) Filed as an Exhibit to Exelixis, Inc. s Current Report on Form 8-K, as filed with the Securities and Exchange Commission on October 4, 2007 and incorporated herein by reference.
- (4) Filed as an Exhibit to Exelixis, Inc. s Registration Statement on Form S-1 (File No. 333-96335), as filed with the Securities and Exchange Commission on February 7, 2000, as amended, and incorporated herein by reference.
- (5) Filed as an Exhibit to Exelixis, Inc. s Quarterly Report on Form 10-Q for the quarter ended June 30, 2005, filed with the Securities and Exchange Commission on August 9, 2005 and incorporated herein by reference.
- (6) Filed as an Exhibit to Exelixis, Inc. s Current Report on Form 8-K, as filed with the Securities and Exchange Commission on June 15, 2006 and incorporated herein by reference.
- (7) Filed as an Exhibit to Exelixis, Inc. s Quarterly Report on Form 10-Q for the quarter ended July 3, 2009, filed with the Securities and Exchange Commission on July 30, 2009, and incorporated herein by reference.
- (8) Filed as an Exhibit to Exelixis, Inc. s Current Report on Form 8-K, as filed with the Securities and Exchange Commission on June 9, 2008 and incorporated herein by reference.