EXELIXIS INC
Form 10-Q
May 07, 2009
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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 April 3, 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)

Delaware	04-3257395
(State or Other Jurisdiction of Incorporation or Organization)	(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 x 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 x	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 x

As of May 1, 2009 there were 106,448,343 shares of the registrant s common stock outstanding.

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EXELIXIS, INC.

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTERLY PERIOD ENDED APRIL 3, 2009

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PART I FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

EXELIXIS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	March 31, 2009 (unaudited)	December 31, 2008 [1]
ASSETS		
Current assets:		
Cash and cash equivalents	$ 201,425	$ 247,698
Marketable securities	4,044	
Investments held by Symphony Evolution, Inc.	12,581	14,703
Other receivables	3,712	1,457
Prepaid expenses and other current assets	8,453	7,713
Total current assets	230,215	271,571
Restricted cash and investments	4,853	4,015
Long-term marketable securities	14,831	17,769
Property and equipment, net	33,354	36,247
Goodwill	63,684	63,684
Other assets	8,168	8,336
Total assets	$ 355,105	$ 401,622
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 4,570	$ 4,946
Accrued clinical trial liabilities	20,752	22,551
Other accrued liabilities	13,915	14,007
Accrued compensation and benefits	11,383	16,142
Current portion of notes payable and bank obligations	13,919	14,911
Current portion of convertible loans	28,050	28,050
Deferred revenue	83,869	88,936
Total current liabilities	176,458	189,543
Notes payable and bank obligations	14,831	17,769
Convertible loans	56,950	56,950
Other long-term liabilities	23,103	22,620
Deferred revenue	172,711	171,001
Total liabilities	444,053	457,883
Commitments		
Stockholders deficit:		
Exelixis, Inc. stockholders deficit:		
Common stock	106	106

Additional paid-in-capital	903,069	897,423
Accumulated other comprehensive income	3	
Accumulated deficit	(990,684)	(954,504)
Total Exelixis, Inc. stockholders deficit	(87,506)	(56,975)
Noncontrolling interest	(1,442)	714
Total stockholders deficit	(88,948)	(56,261)
Total liabilities and stockholders deficit	$ 355,105	$ 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.

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EXELIXIS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(unaudited)

	Three Months Ended March 31,	
	2009	2008
Revenues:		
Contract	$ 6,706	$ 18,626
License	18,596	9,318
Total revenues	25,302	27,944
Operating expenses:		
Research and development	55,344	65,973
General and administrative	8,529	8,691
Collaboration cost sharing	(1,797)	
Total operating expenses	62,076	74,664
Loss from operations	(36,774)	(46,720)
Other income (expense):		
Interest income and other, net	554	2,511
Interest expense	(2,116)	(961)
Total other income (expense), net	(1,562)	1,550
Consolidated net loss.	(38,336)	(45,170)
Loss attributable to noncontrolling interest	2,156	3,896
Net loss attributable to Exelixis, Inc.	$ (36,180)	$ (41,274)
Net loss per share, basic and diluted, attributable to Exelixis, Inc.	$ (0.34)	$ (0.39)
Shares used in computing basic and diluted loss per share amounts	106,383	104,993

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

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EXELIXIS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Three Months Ended March 31, 2009	2008
Cash flows from operating activities:		
Consolidated net loss	$ (38,336)	$ (45,170)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,286	3,264
Stock-based compensation expense	5,092	5,674
Other	356	212
Changes in assets and liabilities:		
Other receivables	(2,255)	(3,103)
Prepaid expenses and other current assets	(740)	(1,538)
Other assets	370	95
Accounts payable and other accrued expenses	(7,021)	2,297
Other long-term liabilities	483	831
Deferred revenue	(3,357)	(1,780)
Net cash used in operating activities	(42,122)	(39,218)
Cash flows from investing activities:		
Purchases of investments held by Symphony Evolution, Inc.	(36)	(295)
Proceeds on sale of investments held by Symphony Evolution, Inc.	2,158	3,657
Purchases of property and equipment	(398)	(5,363)
Increase (decrease) in restricted cash and investments	(837)	1,905
Proceeds from maturities of marketable securities	2,938	34,299
Purchases of marketable securities	(4,048)	(4,932)
Net cash (used in) provided by investing activities	(223)	29,271
Cash flows from financing activities:		
Proceeds from exercise of stock options and warrants	2	6
Principal payments on notes payable and bank obligations	(3,930)	(3,633)
Net cash used in financing activities	(3,928)	(3,627)
Net decreases in cash and cash equivalents	(46,273)	(13,574)
Cash and cash equivalents, at beginning of period	247,698	135,457
Cash and cash equivalents, at end of period	$ 201,425	$ 121,883

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

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EXELIXIS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 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. Operating results for the three-month period ended March 31, 2009 are not necessarily indicative of the results that may be expected for the fiscal year ending January 1, 2010 or for any future period. These financial statements and notes should be read in conjunction with the consolidated financial statements and notes thereto for the fiscal year ended December 31, 2008 included in our Annual Report on Form 10-K filed with the SEC on March 10, 2009.

Exelixis has adopted a 52- or 53-week fiscal year that ends on the Friday closest to December 31st 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 March 28, 2008 and April 3, 2009 are indicated as ended March 31, 2008 and 2009, respectively.

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., for which we are the primary beneficiary as defined by Financial Accounting Standards Board (FASB) Interpretation No. 46 (revised 2003), *Consolidation of Variable Interest Entities*. All significant intercompany balances and transactions have been eliminated.

Fair Value Measurements

As of January 1, 2008, we adopted FASB Statement No. 157, *Fair Value Measurements* (SFAS 157). SFAS 157 established a framework for measuring fair value in GAAP and clarified the definition of fair value within that framework. SFAS 157 does not require any new fair value measurements in GAAP. SFAS 157 introduced, or reiterated, a number of key concepts which form the foundation of the fair value measurement approach to be utilized for financial reporting purposes. The fair value of our financial instruments reflect 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). SFAS 157 also established a fair value hierarchy that prioritizes the use of inputs used in valuation techniques into 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.

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The adoption of SFAS 157 did not have a material effect on our financial condition and results of operations, but SFAS 157 introduced new disclosures about how we value certain assets and liabilities. Much of the disclosure is focused on the inputs used to measure fair value, particularly in instances where the measurement uses significant unobservable (Level 3) inputs. Our financial instruments are valued using quoted prices in active markets or based upon other observable inputs. The following table sets forth the fair value of our financial assets for the periods ended March 31, 2009 and December 31, 2008, respectively (in thousands):

As of March 31, 2009:

	Level 1	Level 2	Level 3	Total
Cash equivalents and marketable securities	$ 221,419	$ 6,044	$	$ 227,463
Investments held by Symphony Evolution, Inc.	12,581			12,581
Total	$ 234,000	$ 6,044	$	$ 240,044

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

Collaboration Arrangements

As of January 1, 2009, we adopted Emerging Issues Task Force Issue No. 07-1, Accounting for Collaborative Arrangements (EITF 07-1). EITF 07-1 requires participants in a collaborative arrangement to present the results of collaboration activities and also requires significant disclosures related to these collaborative arrangements. Collaborative agreement reimbursement revenue or collaboration cost sharing expenses are recorded as earned or owed based on the performance requirements by both parties under the respective contracts. Under our 2007 cancer collaboration with Bristol-Myers Squibb Company (Bristol-Myers Squibb), we are not currently an active participant, as Bristol-Myers Squibb is responsible for leading all further development and commercialization of the compounds under the collaboration, and we are responsible for reimbursing Bristol-Myers Squibb for 35% of the shared costs. The presentation and disclosure requirements of EITF 07-1 are not applicable to the 2007 cancer collaboration at this time. However, under our 2008 cancer collaboration with 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 December 2007, the FASB issued SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements an amendment of Accounting Research Bulletin No. 51 (SFAS 160). SFAS 160 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. SFAS 160 also establishes disclosure requirements that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS 160 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 2009. The adoption did not have a material impact on the Company s consolidated results or operations or financial condition; however, it did slightly modify the presentation of our financial results.

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NOTE 2. Comprehensive Loss

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

	Three Months Ended March 31,	
	2009	2008
Consolidated net loss	$ (38,336)	$ (45,170)
Increase in unrealized gains on available-for-sale securities	3	752
Reclassification for losses on marketable securities recognized in earnings		(15)
Comprehensive loss	(38,333)	(44,433)
Comprehensive loss attributable to the noncontrolling interest	2,156	3,896
Comprehensive loss attributable to Exelixis, Inc.	$ (36,177)	$ (40,537)

NOTE 3. Stock-Based Compensation

Under SFAS No. 123 (revised 2004), Share-Based Payment, we recorded and allocated employee stock-based compensation expenses as follows (in thousands):

	Three Months Ended March 31,	
	2009	2008
Research and development expense	$ 3,276	$ 3,550
General and administrative expense	1,798	2,094
Total employee stock-based compensation expense	$ 5,074	$ 5,644

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

	Stock Options		Employee Stock Purchase PLan (1)	
	Three Months Ended March 31,		Three Months Ended March 31,	
	2009	2008	2009	2008
Weighted average fair value of awards	$ 2.64	$ 4.69	$ N/A	$ 3.33
Risk-free interest rate	2.23%	3.20%	N/A	3.95%
Dividend yield	0%	0%	N/A	0%
Volatility	67%	61%	N/A	53%
Expected life	5.6 years	5.2 years	N/A	0.5 years

(1) Due to the limited number of shares available for issuance under our Employee Stock Purchase Plan (ESPP), we did not incur any stock-based compensation expense under our ESPP for the three months ended March 31, 2009. We plan to seek approval from our stockholders at the Annual Meeting on May 13, 2009 in order to increase the number of shares available for purchase under the ESPP.

A summary of all stock option activity for the three months ended March 31, 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	1,068,505	4.42		
Exercised	(1,365)	1.33		
Cancelled	(607,179)	8.39		
Options outstanding at March 31, 2009	24,601,147	$ 9.47	6.6 years	$ 588,110
Exercisable at March 31, 2009	15,787,356	$ 10.45	5.4 years	$ 39,893

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As of March 31, 2009, $33.2 million of total unrecognized compensation expense related to employee stock options was expected to be recognized over a weighted-average period of 2.5 years.

NOTE 4. Bristol-Myers Squibb

2008 Cancer Collaboration. 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 requires Bristol-Myers Squibb to make additional license payments of $45.0 million in 2009, of which $20.0 million was received by us in March 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, Deerfield Private Design Fund, L.P., Deerfield Private Design International, L.P., Deerfield Partners, L.P. and Deerfield International Limited, as the same may be amended from time to time, 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 on XL281, including our activities. We are eligible for development and regulatory milestones of up to $315.0 million on XL281, sales performance milestones of up to $150.0 million and double-digit royalties on worldwide sales of XL281.

The upfront payment of $195.0 million we received upon effectiveness of the collaboration agreement, the license payment of $20.0 million received in March 2009 and the fully committed payment of $25.0 million payable to us in 2009 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 expense. However, for the three months ended March 31, 2009, we have recorded a net receivable, which results in a reduction in operating 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.

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

	Three Months Ended March 31,	
	2009	2008
Exelixis research and development expenses (1)	$ 9,860	
Net amount due from collaboration partner (2)	$ 1,780	

(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 three months ended March 31, 2009.

NOTE 5: Restructuring Charge

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 plan.

In connection with the 2008 restructuring plan, we recorded a charge of approximately $2.9 million during the year ended December 31, 2008 in accordance with Statement of Financial Accounting Standards No. 146, Accounting for Costs Associated with Exit or Disposal Activities. 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 March 31, 2009 and the components are summarized in the following table (in thousands):

	Employee Severance and Other Benefits	Legal and Other Fees	Total
Balance as of December 31, 2008	$ 1,688	$ 51	$ 1,739
Cash payments	(1,572)	(120)	(1,692)
Adjustments or non-cash credits	(73)	79	6
Balance as of March 31, 2009	$ 43	$ 10	$ 53

NOTE 6: Subsequent Event

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 is 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 shall each conduct research under a mutually agreed upon research plan until such time that we submit a compound that 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. Boehringer Ingelheim also has the right, at its own expense to conduct additional research on S1P1R agonists under the collaboration 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 pre-clinical, 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 of $15.0 million will be amortized over the estimated research term 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.

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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, 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.

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
XL147	Unpartnered	PI3K	Cancer	Phase 1b/2
XL765	Unpartnered	PI3K, mTOR	Cancer	Phase 1b/2
XL518	Genentech	MEK	Cancer	Phase 1
XL228	Unpartnered	IGF1R , ABL, SRC	Cancer	Phase 1
XL019	Unpartnered	JAK2	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

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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
XL281	Bristol-Myers Squibb	RAF	Cancer	Phase 1
XL652	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. We have refined our strategy to reflect the prolonged economic downturn and the deterioration of the capital markets. In particular, we are focused on ensuring that our expenses are in line with our cash resources, with the goal of being able to operate independently of the capital markets for a substantial period of time.

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 expect particularly to focus 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.

Control costs We are committed to managing our costs. In November 2008, we implemented a restructuring that resulted in the reduction of approximately 10% of our workforce. We will continue to analyze our expenses to ensure that they are not disproportionate to our cash resources. In addition, we will continue to be selective with respect to funding our clinical development programs. We 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. For example, we are conducting limited studies on XL019 and XL228 with the goal of making decisions to continue or halt development of these compounds during 2009. In addition, in late 2008 we discontinued development of XL820 and XL844. In the second half of 2008, we also decided not to invest any additional Exelixis resources in the development of XL647. 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.

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.

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Recent Development

Boehringer Ingelheim International GmbH Collaboration

On May 7, 2009, we entered into a collaboration agreement with Boehringer Ingelheim International GmbH, or 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 is 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 shall each conduct research under a mutually agreed upon research plan until such time that we submit a compound that 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. Boehringer Ingelheim also has the right, at its own expense to conduct additional research on S1P1R agonists under the collaboration 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 pre-clinical, 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.

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.

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.

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Liquidity

As of March 31, 2009, we had $237.7 million in cash and cash equivalents and short-term and long-term marketable securities, which included investments held by Symphony Evolution, Inc., or SEI, of $12.6 million and restricted cash and investments of $4.9 million. We anticipate that our current cash and cash equivalents, short-term and long-term marketable securities, funds available 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), and other 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. Our goal is to be able to operate independently of the capital markets for a substantial period of time. However, our future capital requirements will be substantial and depend on many factors, including the following:

- whether we repay amounts outstanding under our loan and security agreement with GlaxoSmithKline (described below) in cash or shares of our common stock;
- whether and when we draw funds under our Facility Agreement with the Deerfield Entities;
- 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 XLl84; 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 expect to particularly focus 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 requires Bristol-Myers Squibb to make additional license payments of $45.0 million in 2009, of which $20.0 million was received by us in March 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, 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 on XL281, including our activities. We are eligible for development and regulatory milestones of up to $315.0 million on XL281, sales performance milestones of up to $150.0 million and double-digit royalties on worldwide sales of XL281.

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The upfront payment of $195.0 million we received upon effectiveness of the collaboration agreement, the license payment of $20.0 million received in March 2009 and the fully committed payment of $25.0 million payable to us in 2009 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 expense. However, for the three months ended March 31, 2009, we have recorded a net receivable, which results in a reduction in operating 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.

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. Principal and accrued interest under the loan becomes due in three annual installments, beginning on October 27, 2009. 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. As of March 31, 2009, the aggregate principal and interest outstanding under our GlaxoSmithKline loan was $103.1 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, including from funds available under the Facility Agreement with the Deerfield Entities, to satisfy our repayment obligations, including the payment that is due on October 27, 2009. 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. 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 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 March 31, 2009, we had not drawn funds under the Facility Agreement.

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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. We have 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. We do not have the right to repurchase a single product candidate without also repurchasing the other two product candidates. The purchase option price, which may be paid in cash and/or shares of our common stock, at our sole discretion, would be equal to the sum of (1) the total amount of capital invested in SEI by its investors ($80.0 million) and (2) an amount equal to 25% per year on such funded capital, compounded from the time of funding. As a result, the purchase option price for the compounds licensed to SEI increases over time. The purchase option is exercisable at any time until the earlier of June 9, 2009 or the 90th day after the date on which SEI provides us with financial statements showing cash and cash equivalents of less than $5.0 million. In 2007, we discontinued the development of XL999 and completed the phase 2 trial for XL784; the phase 2 clinical development program for XL647 is ongoing. We do not intend to further develop XL647 or XL784 on our own or invest any further Exelixis resources in the development of these compounds. In light of the foregoing, we do not expect to exercise the purchase option and will allow the purchase option to expire on June 9, 2009. As a result of the expiration of the purchase option, we will be obligated to issue an additional warrant to purchase 500,000 shares of our common stock at a price per share 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 expires, with a five-year term.

Upon the expiration of the purchase option, in accordance with SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements an amendment of Accounting Research Bulletin No. 51, or SFAS 160, Exelixis will be required to deconsolidate SEI and derecognize their assets and liabilities from our financial statements. The fair value of the warrants issued plus any fees paid will be accumulated and recognized as a loss upon deconsolidation.

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.

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 recognize all non-refundable up-front license fees as revenues in accordance with the guidance provided in the SEC s Staff Accounting Bulletin No. 104. 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

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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 under Emerging Issues Task Force No. 00-21, Revenue Arrangements with Multiple Deliverables, or EITF 00-21, 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 in EITF 00-21 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 March 31, 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.

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.

Stock Option Valuation

We account for stock options under the fair value recognition provisions of Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment. Under this standard, 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

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volatility and the expected term of the award. We have limited historical information available to support the underlying estimates of certain assumptions required to value stock options. The value of a stock option is derived from its potential for appreciation. The more volatile the stock, the more valuable the option becomes because of the greater possibility of significant changes in stock price. Because there is a market for options on our common stock, we have considered implied volatilities as well as our historical realized volatilities when developing an estimate of expected volatility. The expected option term also has a significant effect on the value of the option. The longer the term, the more time the option holder has to allow the stock price to increase without a cash investment and thus, the more valuable the option. Further, lengthier option terms provide more opportunity to exploit market highs. However, empirical data shows that employees, for a variety of reasons, typically do not wait until the end of the contractual term of a nontransferable option to exercise. Accordingly, companies are required to estimate the expected term of the option for input to an option-pricing model. As required under the accounting rules, we review our valuation assumptions at each grant date and, as a result, from time to time we will likely change the valuation assumptions we use to value stock based awards granted in future periods. The assumptions used in calculating the fair value of share-based payment awards represent management s best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our stock-based compensation expense could be materially different in the future. In addition, we are required to estimate the expected forfeiture rate and recognize expense only for those shares expected to vest. If our actual forfeiture rate is materially different from our estimate, the stock-based compensation expense could be significantly different from what we have recorded in the current period. As of March 31, 2009, $33.2 million of total unrecognized compensation expense related to stock options is expected to be recognized over a weighted-average period of 2.5 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 st 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 March 28, 2008 and April 3, 2009 are indicated as ended March 31, 2008 and 2009, respectively.

Results of Operations

Revenues

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

	Three Months Ended March 31,	
	2009	2008
Contract revenue:		
Research and development funding	$ 2.0	$ 7.9
Milestones	4.7	10.7
License revenue, amortization of upfront payments, including amortization of premiums for equity purchases	18.6	9.3
Total revenues	$ 25.3	$ 27.9
Dollar decrease	$ 2.6	
Percentage decrease	9.5%	

The decrease in research and development funding for the three months ended March 31, 2009, as compared to the comparable period for the prior year, was driven primarily by the end of various collaboration agreements with GlaxoSmithKline, Inc., Genentech, Inc., Bayer CropScience, and Bristol-Myers Squibb for a combined decrease of $5.9 million.

The decrease in milestone revenues for the three months ended March 31, 2009, as compared to the comparable period for the prior year, was primarily due to the recognition of revenue in the first quarter of 2008 associated with our 2007 cancer collaboration with Bristol-Myers Squibb and our co-development collaboration with Genentech, Inc. for XL518. In addition, we concluded our collaboration with GlaxoSmithKline, Inc., in October 2008 resulting in a decrease of $1.3 million.

The increase in the amortization of upfront payments for the three months ended March 31, 2009, as compared to the comparable period for the prior year, including amortization of premiums paid for equity purchases, was primarily due to $12.0 million in revenues associated with the $240 million of license fee payments under our 2008 cancer collaboration with Bristol-Myers Squibb relating to XL184 and XL281. This increase was partially offset by $1.2 million relating to the end of 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.

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Research and Development Expenses

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

	Three Months Ended March 31, 2009	2008
Research and development expenses	$ 55.3	$ 66.0
Dollar decrease	$ 10.7	
Percentage decrease	16.1%	

Research and development expenses consist primarily of personnel expenses, clinical trials, consulting, laboratory supplies and facilities costs. The decrease for the three months ended March 31, 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 $6.4 million, or 32%, primarily due to the wind down of activities associated with XL647 and XL820 clinical trials, the transfer of XL880 to GlaxoSmithKline, completion of toxicology studies and phase 2 clinical trial activity for XL784 and the completion of toxicology studies for XL765. These decreases were partially offset by an increase in phase 3 clinical trial activity for XL184, increased phase 1 clinical trial activity for XL281 and XL228, and increased clinical trial activity for XL147.

Personnel Personnel expense, which includes salaries, bonuses, related fringe benefits, recruiting and relocation costs, decreased by $2.3 million, or 11%, primarily due to a reduction in headcount related to our restructuring in November 2008.

Lab Supplies Lab supplies decreased by $0.6 million, or 14%, due to the decrease in clinical trials activity.

Travel & Entertainment Travel and entertainment decreased by $0.6 million or 60% due to a decrease in clinical trials activity and cost saving measures.

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

In addition to reviewing the three categories of research and development expenses described above, we principally consider qualitative factors in making decisions regarding our research and development programs. Such factors include enrollment in clinical trials for our drug candidates, the results of and data from clinical trials, the potential indications for our drug candidates and the clinical and commercial potential for our drug candidates and competitive dynamics. We also make our research and development decisions in the context of our overall business strategy, which includes the pursuit of commercial collaborations with major pharmaceutical and biotechnology companies for the development of our drug candidates.

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

	Three Months Ended March 31, 2009	2008

Drug discovery	$ 23.4	$ 26.6
Development	27.4	35.5
Other	4.5	3.9
Total research and development expenses	$ 55.3	$ 66.0

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For the three months ended March 31, 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 X184, XL147, XL765, XL281 and XL228. 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, as compared to the prior year period, were as follows (dollar amounts are presented in millions):

	Three Months Ended March 31,	
	2009	2008
General and administrative expenses	$ 8.5	$ 8.7
Dollar decrease	$ 0.2	
Percentage decrease	1.9%	

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 months ended March 31, 2009, as compared to the comparable period in 2008, was primarily due to a reduction in headcount related to our restructuring in November 2008 and cost saving measures, partially offset by an increase in facilities costs.

Collaboration Cost-Sharing Expenses

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

	Three Months Ended March 31,	
	2009	2008
Collaboration cost-sharing expenses	$ (1.8)	$
Dollar change	$ (1.8)	
Percentage change	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. However, for the three months ended March 31, 2009, we have recorded a receivable, which results in a reduction in operating expense of $1.8 million for the quarter.

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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 March 31, 2009	2008
Total other income (expense), net	$ (1.6)	$ 1.6
Dollar decrease	$ (3.2)	
Percentage decrease	201%	

Total other income (expense), net consists primarily of interest income earned on cash and cash equivalents, short-term and long-term marketable securities and investments held by SEI, offset by interest expense incurred on our notes payable, bank obligations, capital lease obligations, convertible notes and loans, and Facility Agreement. The decrease in total other income for the three months ended March 31, 2009, as compared to the comparable period in 2008, was primarily due to lower average cash and investment balances and lower average interest rates resulting in a decrease in interest income of $2.1 million, and increased interest expense of $1.2 million, primarily related to our Facility Agreement with the Deerfield Entities.

Noncontrolling Interest in Symphony Evolution, Inc.

Pursuant to the agreements that we entered into with SEI and certain other parties in June 2005, we consolidate SEI s financial condition and results of operations in accordance with Financial Accounting Standards Board Interpretation No. 46 (revised 2003), *Consolidation of Variable Interest Entities*. Accordingly, we have deducted the losses attributable to the noncontrolling interest (SEI s losses) from our consolidated net loss in the consolidated statement of operations and we have also reduced the noncontrolling interest holders ownership interest in SEI in the consolidated balance sheet by SEI s losses. The noncontrolling interest holders ownership in the consolidated balance sheet was ($1.4) million as of March 31, 2009. Prior to 2009, we would not allocate SEI s losses such that the carrying value of the noncontrolling interest would be reduced below zero. However, upon the adoption of SFAS 160, on January 3, 2009, we allocated losses to the noncontrolling interest in SEI such that the noncontrolling interest resulted in a negative carrying value. The decrease in the losses attributed to the noncontrolling interest holders for the three months ended March 31, 2009, as compared to the comparable period in 2008, was primarily due to decreased development expenses associated with XL647 and XL784. We do not intend to further develop XL647 or XL784 on our own. In light of the foregoing, we do not expect to exercise the purchase option and will allow the purchase option to expire on June 9, 2009. As a result of the expiration of the purchase option, we will be obligated to issue an additional warrant to purchase 500,000 shares of our common stock at a price per share 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 expires, with a five-year term.

Liquidity and Capital Resources

Sources and Uses of Cash

The following table summarizes our cash flow activities for the three months ended March 31, 2009 and 2008, respectively (dollar amounts presented in thousands):

	Three Months Ended March 31, 2009	2008
Consolidated net loss	$ (38,336)	$ (45,170)
Adjustments to reconcile net loss to net cash provided by operating activities	8,734	9,150
Changes in operating assets and liabilities	(12,520)	(3,198)
Net cash provided by (used in) operating activities	(42,122)	(39,218)
Net cash provided by (used in) investing activities	(223)	29,271
Net cash provided by (used in) financing activities	(3,928)	(3,627)
Net (decrease) increase in cash and cash equivalents	(46,273)	(13,574)
Cash and cash equivalents, at beginning of period	247,698	135,457

Cash and cash equivalents, at end of period	$ 201,425	$ 121,883

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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 March 31, 2009, we had $237.7 million in cash and cash equivalents and short-term and long-term marketable securities, which includes investments held by SEI of $12.6 million and restricted cash and investments of $4.9 million.

Operating Activities

Our operating activities used cash of $42.1 million for the three months ended March 31, 2009, compared to cash used of $39.2 million for the comparable period in 2008. Cash used by operating activities for the 2009 period related primarily to our net loss attributable to Exelixis, Inc. of $36.2 million, in addition to $12.6 million of cash used as the result of increases in other receivables and decreases in accounts payable and other accrued expenses and deferred revenue. These increases in cash used were partially offset by non-cash charges totaling $8.4 million relating to stock-based compensation and depreciation and amortization. Cash used by operating activities for the 2008 period related primarily to our net loss of $41.3 million, partially offset by non-cash charges totaling $8.9 million relating to stock-based compensation and depreciation and amortization. In addition, cash used in operating activities increased by $6.4 million as the result of increases in other receivables, prepaid expenses and other current assets and a decrease in deferred revenue.

Cash used in our operating activities increased by $2.9 million for the three months ended March 31, 2009 as compared to the comparable period in 2008. The increase was primarily driven by $10.9 million decrease in accounts payable and other accrued expenses and deferred revenue offset by a decrease in our net loss of $5.1 million and a decrease in our loss attributable to our noncontrolling interest of $1.7 million. Decreases in accounts payable and other accrued expenses, net loss attributable to Exelixis, Inc., and loss attributable to our noncontrolling interest relate primarily to a decrease in research and development expenses. The decrease in deferred revenue relates principally to the ratable recognition of deferred revenues over the period of continuing involvement from our various collaborations.

Investing Activities

Our investing activities used cash of $0.2 million for the three months ended March 31, 2009, compared to cash provided of $29.3 million for the comparable period in 2008. Cash used by investing activities for the 2009 period was primarily driven by proceeds of $2.2 million from the sale on investments held by SEI and proceeds of $2.9 million from the maturity of long term investments. This cash inflow was offset by purchases of $4.0 million of marketable securities, a decrease in restricted cash and investments of $0.8 million, and purchases of property and equipment of $0.4. The proceeds provided by the sale and maturity of our investments were used to fund our operations. We expect to continue to make moderate investments in property and equipment to support our operations.

Cash used by investing activities for the 2008 period was primarily driven by proceeds of $34.3 million from the maturities of our marketable securities and the sale of $3.7 million of investments held by SEI. This cash inflow was partially offset by purchases of property and equipment of $5.4 million and purchases of $4.9 million of marketable securities. The proceeds provided by maturities of our marketable securities and the sale of investments by SEI were used to fund our operations. We expect to continue to make significant investments in property and equipment to support our operations.

Financing Activities

Our financing activities used cash of $3.9 million for the three months ended March 31, 2009, compared to cash used of $3.6 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 $3.9 million. Cash used by our financing activities for the 2008 period was due to principal payments on notes payable and bank obligations of $3.6 million.

We finance property and equipment purchases through equipment financing facilities, such as notes and bank obligations. Proceeds from collaboration loans and common stock issuances are used for general working capital purposes, such as research and development activities and other general corporate purposes. Over the next several years, we are required to make certain payments on notes, bank obligations and our loan from GlaxoSmithKline. 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 March 31, 2009, we had not drawn funds under the Facility Agreement.

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Cash Requirements

We have incurred net losses since inception, including a net loss attributable to Exelixis, Inc. of $36.2 million for the three months ended March 31, 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 March 31, 2009, we had $237.7 million in cash and cash equivalents and short-term and long-term marketable securities, which included investments held by SEI of $12.6 million and restricted cash and investments of $4.9 million. We anticipate that our current cash and cash equivalents, short-term and long-term marketable securities, funds available under the Facility Agreement with the Deerfield Entities, and other 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. Our goal is to be able to operate independently of the capital markets for a substantial period of time. 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. Principal and accrued interest under the loan becomes due in three annual installments, beginning on October 27, 2009. 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. As of March 31, 2009, the aggregate principal and interest outstanding under our GlaxoSmithKline loan was $103.1 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, including from funds available under the Facility Agreement with the Deerfield Entities, to satisfy our repayment obligations, including the payment that is due on October 27, 2009. 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.

whether and when we 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 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 expect to particularly focus 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

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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;

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, as part of our collaboration with GlaxoSmithKline, we entered into the loan and security agreement, which, as amended, 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) must not be less than $25.0 million and our cash and investments (total cash, cash equivalents and investments as defined by the agreement, which excludes restricted cash) must not be less than $50.0 million. As of March 31, 2009, our working capital was $287.6 million (including $150.0 million available for borrowing under the Facility Agreement) and our cash and investments were $232.9 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 $103.1 million at March 31, 2009. Principal and accrued interest under the loan becomes due in three annual installments beginning on October 27, 2009. 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

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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, 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 March 31, 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 March 31, 2009 and December 31, 2008, respectively. As of March 31, 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 $0.9 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 statements made by us or on our behalf. The risks and uncertainties described below are not the only ones facing the company. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. If any of the following risks or such other risks actually occurs, our business could be harmed.

We have marked with an asterisk (*) those risk factors below that reflect substantive changes from the risk factors included in our Annual Report on Form 10-K for the fiscal year ended December 31, 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.

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As of March 31, 2009, we had $237.7 million in cash and cash equivalents and short-term and long-term marketable securities, which included investments held by SEI of $12.6 million and restricted cash and investments of $4.9 million. We anticipate that our current cash and cash equivalents, short-term and long-term marketable securities, investments held by SEI, funds available under the Facility Agreement with the Deerfield Entities, and other 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. Our goal is to be able to operate independently of the capital markets for a substantial period of time. 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. Principal and accrued interest under the loan becomes due in three annual installments, beginning on October 27, 2009. 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. As of March 31, 2009, the aggregate principal and interest outstanding under our GlaxoSmithKline loan was $103.1 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, including from funds available under the Facility Agreement with the Deerfield Entities, to satisfy our repayment obligations, including the payment that is due on October 27, 2009. 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.

whether and when we 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 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 expect to particularly focus 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

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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;

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, as part of our collaboration with GlaxoSmithKline, we entered into the loan and security agreement, which, as amended, 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) must not be less than $25.0 million and our cash and investments (total cash, cash equivalents and investments as defined by the agreement, which excludes restricted cash) must not be less than $50.0 million. As of March 31, 2009, our working capital was $287.6 million (including $150.0 million available for borrowing under the Facility Agreement) and our cash and investments were $232.9 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 $103.1 million at March 31, 2009. Principal and accrued interest under the loan becomes due in three annual installments beginning on October 27, 2009. 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, 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.

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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 $36.2 million for the three months ended March 31, 2009. As of that date, we had an accumulated deficit of $990.7 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 may not realize the expected benefits of our initiatives to control costs.

Managing costs is a key element of our business strategy. Consistent with this element of our strategy, in November 2008 we implemented a restructuring that resulted in the reduction of approximately 10% of our workforce. We anticipate that we will incur some level of restructuring charges through the end of 2009 as we continue to implement this restructuring.

If we experience excessive unanticipated inefficiencies or incremental costs in connection with restructuring activities, such as unanticipated inefficiencies caused by reducing headcount, we may be unable to meaningfully realize cost savings and we may incur expenses in excess of what we anticipate. Either of these outcomes could prevent us from meeting our goal of being able to operate independently of the capital markets for a substantial period of time, and could adversely impact our results of operations or financial condition.

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

Our cash and cash equivalents are maintained in highly liquid investments with remaining maturities of 90 days or less at the time of purchase. Our short-term and long-term investments consist primarily of readily marketable debt securities with remaining maturities of more than 90 days at the time of purchase. While as of the date of this filing, we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents, short-term investments, or long-term investments since March 31, 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.

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;

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- 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 could suffer. Our agreements with Bristol-Myers Squibb, Genentech, 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.

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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.

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.

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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.

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.

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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.

A primary trend in the United States health care industry is toward cost containment. In December 2003, President Bush signed into law legislation creating a prescription drug benefit program for Medicare recipients. The new prescription drug program may have the effect of reducing the prices that we are able to charge for products we develop and sell through plans under the program. The new prescription drug program may also cause third-party payors other than the federal government, including the states under the Medicaid program, to discontinue coverage for products we develop or to lower the price that they will pay. In addition, members of the United States Congress have stated their desire to reduce the government s cost for reimbursements of prescription drugs by amending this legislation.

State Medicaid programs generally have outpatient prescription drug coverage, subject to state regulatory restrictions, for the population eligible for Medicaid. The availability of coverage or reimbursement for prescription drugs under private health insurance and managed care plans varies based on the type of contract or plan purchased.

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

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

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

The biotechnology industry is highly fragmented and is characterized by rapid technological change. In particular, the area of kinase-targeted therapies is a rapidly evolving and competitive field. We face, and will continue to face, intense competition from biotechnology and pharmaceutical companies, as well as academic research institutions, clinical reference laboratories and government agencies that are pursuing 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

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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 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.

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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 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

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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, pharmaceutical companies or others selling or testing our products. We have obtained limited product liability insurance coverage for our clinical trials in the amount of $10.0 million per occurrence and $10.0 million in the aggregate. However, our insurance may not reimburse us or may not be sufficient to reimburse us for expenses or losses we may suffer. Moreover, if insurance coverage becomes more expensive, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for any of our product candidates, we intend to expand our insurance coverage to include the sale of commercial products, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, juries have awarded large judgments in class action lawsuits for claims based on drugs that had unanticipated side effects. In addition, the pharmaceutical and biotechnology industries, in general, have been subject to significant medical malpractice litigation. A successful product liability claim or series of claims brought against us could harm our reputation and business and would decrease our cash reserves.

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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 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;
- 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;

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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.

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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.

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SIGNATURES

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

Date: May 7, 2009

EXELIXIS, INC.

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

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EXHIBIT INDEX

Number	Exhibit Description
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	Warrant Purchase Agreement, dated June 9, 2005, between Exelixis, Inc. and Symphony Evolution Holdings LLC. (5)
4.5	Form Warrant to Purchase Common Stock of Exelixis, Inc. issued or issuable to Deerfield Private Design Fund, L.P., Deerfield Private Design International, L.P., Deerfield Partners, L.P. and Deerfield International Limited (7)
4.6	Fourth Amended and Restated Registration Rights Agreement, dated February 26, 1999, among Exelixis, Inc. and certain Stockholders of Exelixis, Inc. (4)
4.7	Registration Rights Agreement, dated October 18, 2004, by and among Exelixis, Inc., X-Ceptor Therapeutics, Inc., and certain holders of capital stock of X-Ceptor Therapeutics, Inc. listed in Annex I thereto. (8)
4.8	Registration Rights Agreement, dated October 18, 2004, by and among Exelixis, Inc., X-Ceptor Therapeutics, Inc., and certain holders of capital stock of X-Ceptor Therapeutics, Inc. listed in Annex I thereto. (8)
4.9	Registration Rights Agreement, dated June 9, 2005, between Exelixis, Inc. and Symphony Evolution Holdings LLC. (5)
4.10	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 (7)
10.1*	Letter Agreement between Exelixis, Inc. and SmithKline Beecham Corporation d/b/a GlaxoSmithKline dated February 17, 2009.
10.2	Compensation Information for the Company s Named Executive Officers. (9)
10.3	Compensation Information for Non-Employee Directors. (10)
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).

* 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.

(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.

(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.

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(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 Current Report on Form 8-K, as filed with the Securities and Exchange Commission on June 9, 2008 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 October 21, 2004 and incorporated herein by reference.

(9) Filed as an Exhibit to Exelixis, Inc. s Current Report on Form 8-K, as filed with the Securities and Exchange Commission on March 3, 2009 and incorporated herein by reference.

(10) Filed as an Exhibit to Exelixis, Inc. s Annual Report on Form 10-K, filed with the Securities and Exchange Commission on march 10, 2009 and incorporated herein by reference.