

EXELIXIS INC
Form 10-Q
August 07, 2007
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 29, 2007

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: 0-30235

Exelixis, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

170 Harbor Way
P.O. Box 511

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

Edgar Filing: EXELIXIS INC - Form 10-Q

South San Francisco, CA 94083

(Address of principal executive offices, including zip code)

(650) 837-7000

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer

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

As of July 27, 2007, 97,404,804 shares of the registrant's common stock, \$0.001 par value, were outstanding.

Table of Contents

EXELIXIS, INC.

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTERLY PERIOD ENDED JUNE 29, 2007

INDEX

	Page
Part I. Financial Information	
Item 1. <u>Condensed Consolidated Balance Sheets - June 30, 2007 and December 31, 2006</u>	3
<u>Condensed Consolidated Statements of Operations - Three Months and Six Months Ended June 30, 2007 and 2006</u>	4
<u>Condensed Consolidated Statements of Cash Flows - Six Months Ended June 30, 2007 and 2006</u>	5
<u>Notes to Condensed Consolidated Financial Statements</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	9
Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	18
Item 4. <u>Controls and Procedures</u>	18
Part II. Other Information	19
Item 1A. <u>Risk Factors</u>	19
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	32
Item 6. <u>Exhibits</u>	32
<u>SIGNATURES</u>	33

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

	June 30,	December 31,
	2007	2006 ⁽¹⁾
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 105,607	\$ 123,369
Marketable securities	78,236	55,516
Investments held by Symphony Evolution, Inc.	44,709	55,087
Other receivables	2,855	22,197
Prepaid expenses and other current assets	9,478	6,082
Total current assets	240,885	262,251
Restricted cash and investments	8,917	9,635
Long-term marketable securities	15,537	19,573
Property and equipment, net	34,621	32,294
Goodwill	67,364	67,364
Other intangibles, net	2,461	2,605
Other assets	2,003	1,695
Total assets	\$ 371,788	\$ 395,417
LIABILITIES, NONCONTROLLING INTEREST AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 5,004	\$ 3,699
Accrued clinical trial liabilities	17,811	12,209
Other accrued liabilities	9,657	7,018
Accrued compensation and benefits	10,580	11,456
Current portion of notes payable and bank obligations	12,628	13,579
Deferred revenue	60,141	63,476
Total current liabilities	115,821	111,437
Notes payable and bank obligations	17,713	23,074
Convertible loans	85,000	85,000
Other long-term liabilities	23,255	20,491
Deferred revenue	86,193	64,804
Total liabilities	327,982	304,806
Noncontrolling interest in Symphony Evolution, Inc.	24,022	38,071
Commitments		
Stockholders' equity:		
Common stock	97	96
Additional paid-in-capital	776,617	756,568
Accumulated other comprehensive income	1,102	1,145
Accumulated deficit	(758,032)	(705,269)

Edgar Filing: EXELIXIS INC - Form 10-Q

Total stockholders' equity	19,784	52,540
Total liabilities, noncontrolling interest and stockholders' equity	\$ 371,788	\$ 395,417

⁽¹⁾ The condensed consolidated balance sheet at December 31, 2006 has been derived from the audited consolidated financial statements at that date but does not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements.

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

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2007	2006	2007	2006
Revenues:				
Contract	\$ 16,378	\$ 17,016	\$ 31,544	\$ 29,262
License	12,881	10,224	25,851	16,097
Total revenues	29,259	27,240	57,395	45,359
Operating expenses:				
Research and development	56,306	47,399	106,516	87,296
General and administrative	11,183	9,984	22,394	18,991
Amortization of intangible assets	72	240	144	512
Total operating expenses	67,561	57,623	129,054	106,799
Loss from operations	(38,302)	(30,383)	(71,659)	(61,440)
Other income (expense):				
Interest income and other, net	3,284	1,961	6,878	3,911
Interest expense	(1,004)	(1,338)	(2,031)	(2,872)
Total other income	2,280	623	4,847	1,039
Loss before noncontrolling interest in Symphony Evolution, Inc.	(36,022)	(29,760)	(66,812)	(60,401)
Loss attributed to noncontrolling interest in Symphony Evolution, Inc.	7,460	5,770	14,049	9,288
Net loss	\$ (28,562)	\$ (23,990)	\$ (52,763)	\$ (51,113)
Net loss per share, basic and diluted	\$ (0.29)	\$ (0.29)	\$ (0.55)	\$ (0.61)
Shares used in computing basic and diluted loss per share amounts	96,976	84,054	96,694	83,867

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

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

	Six Months Ended June 30,	
	2007	2006
Cash flows from operating activities:		
Net loss	\$ (52,763)	\$ (51,113)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	5,141	8,673
Loss attributed to noncontrolling interest	(14,049)	(9,288)
Stock-based compensation expense	9,721	9,079
Amortization of intangible assets	144	512
Loss from the sale of equipment	6	38
Other	317	310
Changes in assets and liabilities:		
Other receivables	19,342	5,735
Prepaid expenses and other current assets	(3,396)	(714)
Other assets	(484)	(28)
Accounts payable and other accrued liabilities	10,734	1,806
Other long-term liabilities	2,764	3,379
Deferred revenue	18,054	10,399
Net cash used in operating activities	(4,469)	(21,212)
Cash flows from investing activities:		
Purchases of investments held by Symphony Evolution, Inc.	(1,280)	(40,783)
Proceeds on sale of investments held by Symphony Evolution, Inc.	11,658	9,786
Purchases of property and equipment	(9,401)	(6,797)
Proceeds from sale of equipment		4
Changes in restricted cash and investments	717	1,678
Proceeds from maturities of marketable securities	91,455	69,471
Purchases of marketable securities	(108,194)	(30,401)
Net cash provided by (used in) investing activities	(15,045)	2,958
Cash flows from financing activities:		
Proceeds from exercise of stock options and warrants	6,392	2,360
Proceeds from employee stock purchase plan	1,741	1,267
Payments on capital lease obligations		(98)
Proceeds from notes payable and bank obligations		2,424
Principal payments on notes payable and bank obligations	(6,312)	(36,330)
Proceeds from purchase of noncontrolling interest by preferred stockholders in Symphony Evolution, Inc.		40,000
Net cash provided by financing activities	1,821	9,623
Effect of foreign exchange rate changes on cash and cash equivalents	(69)	55

Edgar Filing: EXELIXIS INC - Form 10-Q

Net decrease in cash and cash equivalents	(17,762)	(8,576)
Cash and cash equivalents, at beginning of period	123,369	81,328
Cash and cash equivalents, at end of period	\$ 105,607	\$ 72,752

Supplemental cash flow disclosure:

Warrants issued in conjunction with the Symphony Evolution, Inc. transaction	\$	\$ 3,984
--	----	----------

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

Table of Contents

EXELIXIS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2007

(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.

We believe that our proprietary technologies and drug discovery engine are also valuable to other industries whose products can be enhanced by an understanding of DNA or proteins, including the agrochemical and agricultural industries. We also maintain operations in Germany, which are engaged in activities dedicated towards the provision of transgenic mouse generation services, tools and related licenses to the industrial and academic communities.

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 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- and six-month periods ended June 30, 2007 are not necessarily indicative of the results that may be expected for the fiscal year ending December 28, 2007 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 29, 2006 included in our Annual Report on Form 10-K filed with the SEC on February 27, 2007.

In 2006, Exelixis adopted a 52- or 53-week fiscal year that ends on the last Friday in December, and the fiscal quarters end on the last Friday of the quarter. Fiscal year 2006, a 52-week year, ended on December 29, 2006, and fiscal year 2007, a 52-week year, will end on December 28, 2007. For convenience, references in these Condensed Consolidated Financial Statements and Notes as of and for the fiscal year ended December 29, 2006 are indicated on a calendar year basis, ending December 31, 2006, and as of and for the three- and six-month periods ended June 29, 2007 are indicated as ending June 30, 2007.

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* (FIN 46R). All significant intercompany balances and transactions have been eliminated. We have determined that our subsidiary located in Germany, Artemis Pharmaceuticals, is an operating segment and it has been aggregated into one reportable segment with Exelixis.

Net Loss Per Share

Basic and diluted net loss per share are computed by dividing the net loss for the period by the weighted average number of shares of common stock outstanding during the period. The calculation of diluted net loss per share excludes potential common stock because their effect is antidilutive. Potential common stock consists of incremental common shares issuable upon the exercise of stock options and warrants and shares issuable upon conversion of the convertible loans.

Reclassification

Certain prior period amounts have been reclassified to conform to the current period presentation.

Recent Accounting Pronouncements

We adopted FASB Interpretation 48, Accounting for Uncertainty in Income Taxes (FIN 48), on January 1, 2007. As a result of the implementation of FIN 48, we did not recognize any adjustment for uncertain tax positions and therefore did not record any adjustment to the beginning balance of retained earnings on the balance sheet. As of the date of adoption, we had

Table of Contents

a \$17.8 million reduction to the deferred tax assets for unrecognized tax benefits, all of which was offset by a full valuation allowance. Therefore, we did not record any adjustment to the beginning balance of retained earnings in our condensed consolidated balance sheet.

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 and foreign currency cumulative translation adjustments, not reflected in the consolidated statements of operations. Comprehensive loss was as follows (in thousands):

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2007	2006	2007	2006
Net loss	\$ (28,562)	\$ (23,990)	\$ (52,763)	\$ (51,113)
Increase in unrealized gains on available-for-sale securities	51	96	26	164
Decrease in foreign cumulative translation adjustment	(29)	(75)	(69)	(109)
Comprehensive loss	\$ (28,540)	\$ (23,969)	\$ (52,806)	\$ (51,058)

NOTE 3. Stock-Based Compensation

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2007	2006	2007	2006
Research and development expense	\$ 2,992	\$ 2,886	\$ 5,440	\$ 5,995
General and administrative expense	1,784	1,521	3,562	2,988
Total employee stock-based compensation expense	\$ 4,776	\$ 4,407	\$ 9,002	\$ 8,983

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

	Stock Options		ESPP	
	Three Months Ended June 30, 2007	Three Months Ended June 30, 2006	Three Months Ended June 30, 2007	Three Months Ended June 30, 2006
Weighted average fair value of awards	\$ 5.87	\$ 6.14	\$ 2.97	\$ 2.67
Risk-free interest rate	4.72%	4.96%	5.07%	4.57%
Dividend yield	0%	0%	0%	0%
Volatility	59%	63%	52%	54%
Expected life	4.9 years	4.7 years	0.5 years	0.5 years

	Stock Options	ESPP
	Six Months Ended June 30,	Six Months Ended June 30,

Edgar Filing: EXELIXIS INC - Form 10-Q

	2007	2006	2007	2006
Weighted average fair value of awards	\$ 5.14	\$ 5.34	\$ 2.89	\$ 2.45
Risk-free interest rate	4.69%	4.34%	5.09%	4.36%
Dividend yield	0%	0%	0%	0%
Volatility	60%	64%	52%	54%
Expected life	4.9 years	4.7 years	0.5 years	0.5 years

Table of Contents

A summary of all stock option activity for the six months ended June 30, 2007 is presented below:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Options outstanding at December 31, 2006	17,210,626	\$ 10.34		
Granted	3,624,075	9.37		
Exercised	(854,333)	7.48		
Cancelled	(820,807)	9.42		
Options outstanding at June 30, 2007	19,159,561	10.32	7.4 years	\$ 53,348,673
Exercisable at June 30, 2007	9,575,225	11.47	5.9 years	\$ 25,267,726

As of June 30, 2007, \$45.4 million of total unrecognized compensation expense related to stock options was expected to be recognized over a weighted-average period of 2.8 years.

NOTE 4. Bristol-Myers Squibb

In December 2006, we entered into a worldwide collaboration with Bristol-Myers Squibb Company, which became effective in January 2007, to collaborate in the discovery, development and commercialization of novel targeted therapies for the treatment of cancer. We are responsible for discovery and preclinical development of small molecule drug candidates directed against mutually selected targets. In January 2007, Bristol-Myers Squibb made an upfront payment of \$60.0 million to us for which we granted Bristol-Myers Squibb the right to select up to three IND candidates from six future Exelixis compounds. We are recognizing the upfront payment as revenue over the estimated four-year research term.

For each IND candidate selected we are entitled to receive a \$20.0 million selection milestone from Bristol-Myers Squibb. Once selected, Bristol-Myers Squibb will lead the further development and commercialization of the selected IND candidates, and we and Bristol-Myers Squibb will equally share all development costs, promotion responsibilities and profits in the United States. However, we may opt out of the co-development in which case we would be entitled to receive milestone payments and royalties in lieu of profits from sales in the United States, if any. Outside of the United States, Bristol-Myers Squibb will have primary responsibility for development activities and we will be entitled to receive royalties on any product sales. After exercising its co-development option, Bristol-Myers Squibb may, upon notice to us, terminate the agreement as to any product containing or comprising the selected candidate. 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 certain collaboration compounds that were discovered.

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

The following discussion and analysis contains forward-looking statements. These statements are based on our current expectations, assumptions, estimates and projections about our business and our industry, and involve known and unknown risks, uncertainties and other factors that may cause our or our industry's results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied in, or contemplated by, the forward-looking statements. Words such as believe, anticipate, expect, intend, plan, will, determine, may, could, 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, the financial statements and accompanying notes thereto included in our Annual Report on Form 10-K for the fiscal year ended December 29, 2006, filed with the Securities and Exchange Commission on February 27, 2007. 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 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.

Utilizing our library of more than four million compounds, we integrate high-throughput processes, medicinal chemistry, bioinformatics, structural biology and early *in vivo* testing in parallel to characterize thousands of compounds, a process that is designed to enable us to move quickly in research and development. This approach allows us to select highly qualified drug candidates that meet our extensive development criteria from a large pool of compounds.

To date, we have filed 14 investigational new drug applications, or INDs. We believe that our deep pool of drug candidates will enable us to continue to file multiple new INDs each year for the foreseeable future. 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 product 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.

We have established collaborations with major pharmaceutical and biotechnology companies based on the strength of our expertise in biology, drug discovery and development that allow us to retain economic participation in compounds and support additional development of our proprietary products. Through these collaborations, we obtain license fees, research funding, a share of the profits and the opportunity to receive milestone payments and royalties (as applicable) from research results and subsequent product development activities. We also have collaborations in which we retain the right to co-promote products in the United States. We have ongoing commercial collaborations with several leading pharmaceutical and biotechnology companies, including GlaxoSmithKline, Bristol-Myers Squibb Company and Genentech, Inc. We expect to continue to use corporate partnering as a strategic tool to cultivate our assets, fund our operations and expand the therapeutic and commercial potential of our pipeline.

Our current development portfolio includes the following compounds, for which we are leading development:

Compound	Principal Targets	Indication	Stage of Development
XL647*	EGFR, HER2, VEGFR2	Cancer	Phase 2
XL784*	ADAM10, MMP2	Diabetic nephropathy	Phase 2
XL880	MET, VEGFR2	Cancer	Phase 2
XL999*	VEGFR2, PDGFR, FGFR, FLT3	Cancer	Phase 1
XL820	KIT, VEGFR2, PDGFR	Cancer	Phase 1
XL184	MET, VEGFR2, RET	Cancer	Phase 1

Table of Contents

Compound	Principal Targets	Indication	Stage of Development
XL844	CHK1, CHK2	Cancer	Phase 1
XL518**	MEK	Cancer	Phase 1
XL418	AKT, S6K	Cancer	Phase 1
XL281	RAF	Cancer	Phase 1
XL228	ABL, SRC, IGF1R	Cancer	Phase 1
XL147	PI3K	Cancer	Phase 1
XL765	PI3K, mTOR	Cancer	Phase 1
XL019	JAK2	Cancer	Phase 1

* Out-licensed to Symphony Evolution, Inc. and subject to a repurchase option as described elsewhere in this report.

** In co-development collaboration with Genentech, Inc.

Pursuant to a product development and commercialization agreement between Exelixis and GlaxoSmithKline, GlaxoSmithKline has the option, after completion of clinical proof-of-concept by Exelixis, to elect to develop up to three compounds in Exelixis' product pipeline, which may include XL784 and the cancer compounds identified in the table above except XL518, XL147, XL765 and XL019. As described under "Recent Developments", on July 26, 2007, we announced that GlaxoSmithKline decided not to exercise this option with respect to XL647.

In addition to the compounds identified in the above table, we have compounds in various stages of development that are being developed by our partners, such as Bristol-Myers Squibb, Daiichi Sankyo Company Limited and Wyeth Pharmaceuticals. We also have compounds in preclinical development that we are developing internally.

Recent Developments*Decision by GlaxoSmithKline Not to Exercise Development Option for XL647*

In April 2007, we notified GlaxoSmithKline of our determination that we achieved clinical proof-of-concept for XL647 based on data from a phase 2 clinical trial, thereby triggering a 90-day review period in which GlaxoSmithKline could exercise its option under the product development and commercialization agreement between us and GlaxoSmithKline to license XL647 for further development and commercialization. On July 26, 2007, we announced that GlaxoSmithKline decided not to exercise this option. As a result of the decision by GlaxoSmithKline not to exercise this option, we retain the right to develop and commercialize XL647 either independently or in collaboration with third parties, subject to our obligations under our clinical development financing arrangement with Symphony Evolution, Inc., or SEI, referred to below. We intend to move forward with the full development of XL647 in patients with non-small cell lung cancer and potentially other indications. GlaxoSmithKline's sole remaining right with respect to XL647 is its right to receive a royalty of 3% on net sales of XL647, which we will be required to pay if the compound is successfully commercialized.

XL647 is part of our clinical development financing arrangement with SEI. In 2005, we licensed three of our compounds, XL784, XL647 and XL999, to SEI in return for \$80.0 million for the clinical development of these compounds and an exclusive option to reacquire the compounds from SEI's investors at a specified purchase price. We are responsible for the development of these compounds in accordance with specified development plans and related development budgets. As of June 30, 2007, SEI had \$44.7 million of cash, which we anticipate will be used to advance the clinical trial programs for XL647 in addition to XL784 and XL999, subject to our option to repurchase the compounds.

Certain Factors That May Affect Our Business*Industry-wide Factors*

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.

Table of Contents*Company-specific Factors*

Our financial performance is driven by many factors, including:

Clinical Trials. We currently have multiple compounds in clinical development and expect to continue to advance more compounds into clinical trials. 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 exceedingly difficult and our trials may be delayed due to many factors, including those 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 to the next stage of clinical development, whereas expenses will end for compounds that do not warrant further clinical development.

Liquidity. As of June 30, 2007, we had \$253.0 million in cash and cash equivalents and short-term and long-term marketable securities, which included investments held by SEI of \$44.7 million and restricted cash and investments of \$8.9 million. We anticipate that our current cash and cash equivalents, short-term and long-term marketable securities, investments held by SEI 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. However, our future capital requirements will be substantial and depend on many factors, including the timing of key events in our agreements with GlaxoSmithKline and SEI that may require us to consume available capital significantly sooner than we currently anticipate. We will have to obtain additional funding in order to support our plans for the aggressive development of our broad clinical and preclinical pipelines. Our minimum liquidity needs are also determined by certain financial covenants contained in our loan and security agreement with GlaxoSmithKline, which require us to maintain working capital of at least \$25.0 million and cash and investments of at least \$50.0 million. 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.

Reliance on Partners. We currently have no pharmaceutical products that have received marketing approval, and we have generated no revenues from the sale of such products. We do not expect to generate product 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 and milestone 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.

GlaxoSmithKline Compound Selection. Pursuant to our product development and commercialization agreement with GlaxoSmithKline, GlaxoSmithKline has the option, after completion of clinical proof-of-concept by us, to elect to develop up to three compounds in our product pipeline, which may include XL784, XL999, XL880, XL184, XL820, XL844, XL281, XL418 and XL228. As described below, XL784, XL647 and XL999 have been licensed to SEI. A compound selection by GlaxoSmithKline could potentially trigger significant milestone payments to Exelixis. The size of these milestone payments depends on how quickly we can advance compounds to clinical proof-of-concept, how many compounds GlaxoSmithKline selects and whether a selected compound was funded through our agreement with SEI. Any future delays in obtaining clinical proof-of-concept for compounds subject to GlaxoSmithKline's election rights may decrease the size of any GlaxoSmithKline milestone payments and negatively affect our financial position, including in relation to the amount of additional funds that we would need to raise in order to exercise our SEI purchase option, as discussed below. In April 2007, we notified GlaxoSmithKline of our determination that we had achieved clinical proof-of-concept for XL647. As described under *Recent Developments*, on July 26, 2007, we announced that GlaxoSmithKline decided not to exercise its option under our product development and commercialization agreement to elect to develop and commercialize XL647 at clinical proof-of-concept.

Symphony Evolution, Inc. In 2005, we licensed three of our lead compounds (XL784, XL647 and XL999) to SEI in return for an \$80.0 million investment for the clinical development of these compounds. We continue to be primarily responsible for the development of these compounds in accordance with specified development plans and related development budgets. We have retained an exclusive option to reacquire the compounds from SEI's investors at a specified purchase price. We may repurchase the compounds for cash, shares of our common stock or a combination of cash and shares of our common stock, at our sole discretion.

Edgar Filing: EXELIXIS INC - Form 10-Q

The purchase price for the compounds increases over the length of the option period. If GlaxoSmithKline selects any of the compounds licensed to SEI for further development and commercialization or we determine to enter into a collaboration agreement with a third party with respect to these compounds, we would be required to repurchase all of the compounds from SEI's investors. If we repurchase the compounds, we would need to raise additional funds to cover the purchase price or issue to SEI's investors a substantial number of shares of our common stock.

Table of Contents**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 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. There have been no changes during the six months ended June 30, 2007 to the items that we disclosed as our critical accounting estimates in Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the fiscal year ended December 29, 2006.

Fiscal Year Convention

In 2006, Exelixis adopted a 52- or 53-week fiscal year that ends on the last Friday in December, and the fiscal quarters end on the last Friday of the quarter. Fiscal year 2006, a 52-week year, ended on December 29, 2006 and fiscal year 2007, a 52-week year, will end on December 28, 2007. For convenience, references in this report as of and for the fiscal year ended December 29, 2006 are indicated on a calendar year basis, ending December 31, 2006, and as of and for the three- and six-month periods ended June 29, 2007 are indicated as ending June 30, 2007.

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		Six Months Ended	
	June 30, 2007	June 30, 2006	June 30, 2007	June 30, 2006
Contract revenue:				
Research and development services	\$ 13.6	\$ 11.6	\$ 25.9	\$ 22.5
Milestones	2.8	5.4	5.6	6.8
License revenue:				
Amortization of upfront payments, including premiums paid on equity purchases	12.9	10.2	25.9	16.1
Total revenues	\$ 29.3	\$ 27.2	\$ 57.4	\$ 45.4
Dollar increase	\$ 2.0		\$ 12.0	
Percentage increase	7%		27%	

The increase in research and development services for the three months ended June 30, 2007, as compared to the comparable period for the prior year, was primarily the result of increases in research and development services of \$1.1 million attributable to our German subsidiary, Artemis Pharmaceuticals, and \$0.9 million from a new collaboration with Agrigenetics, Inc. for the development of plant traits in corn and other crops.

The increase in research and development services for the six months ended June 30, 2007, as compared to the comparable period for the prior year, was primarily the result of increases in research and development services of \$2.0 million attributable to Artemis Pharmaceuticals, \$1.0 million from our agreement with Daiichi-Sankyo and \$0.9 million from our collaboration with Agrigenetics. These increases are partially offset by a decrease of \$0.5 million in funding from one of our Bristol-Myer Squibb collaborations.

Table of Contents

The decrease in milestone revenues for the three months ended June 30, 2007, as compared to the comparable period for the prior year, was primarily due to \$4.0 million in revenues in 2006 associated with a milestone achieved under our collaboration with Helsinn Healthcare S.A., which was partially offset by \$1.3 million in revenues in 2007 associated with a milestone achieved under our new collaboration with Genentech.

The decrease in milestone revenues for the six months ended June 30, 2007, as compared to the comparable period for the prior year, was primarily due to \$4.0 million in revenues in 2006 associated with a milestone achieved under our collaboration with Helsinn Healthcare S.A., which was partially offset by \$2.5 million in revenues in 2007 associated with a milestone achieved under our new collaboration with Genentech.

The increase in the amortization of upfront payments, including amortization of premiums paid for equity purchases, for the three months ended June 30, 2007, as compared to the comparable period in the prior year, was driven primarily by upfront payments from our new oncology collaboration with Bristol-Myers Squibb, resulting in increased revenue of \$3.8 million; and the XL518 co-development collaboration with Genentech, resulting in increased revenues of \$2.1 million. This increase was partially offset by a decrease of \$2.5 million related to the conclusion in December 2006 of the amortization of the upfront payment from Wyeth Pharmaceuticals.

The increase in the amortization of upfront payments, including amortization of premiums paid for equity purchases, for the six months ended June 30, 2007, as compared to the comparable period in the prior year, was driven primarily by upfront payments from our new oncology collaboration with Bristol-Myers Squibb, resulting in increased revenue of \$7.1 million; the XL518 co-development collaboration with Genentech, resulting in increased revenues of \$4.2 million; and the mineralocorticoid collaboration with Daiichi-Sankyo, resulting in increased revenues of \$3.6 million. This increase was partially offset by a decrease of \$5.0 million related to the conclusion in December 2006 of the amortization of the upfront payment from Wyeth.

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		Six Months Ended	
	June 30,		June 30,	
	2007	2006	2007	2006
Research and development expenses	\$ 56.3	\$ 47.4	\$ 106.5	\$ 87.3
Dollar increase	\$ 8.9		\$ 19.2	
Percentage increase	19%		22%	

Research and development expenses consist primarily of personnel expenses, clinical trials, consulting, laboratory supplies and facilities costs. The increase for the three months ended June 30, 2007, as compared to the comparable period in 2006, resulted primarily from the following:

Personnel Personnel expense, which includes salaries, bonuses, related fringe benefits, recruiting and relocation costs, increased by \$4.0 million, or 29%, primarily due to the expanded workforce supporting drug development operations to advance our clinical and preclinical development programs and, to a lesser degree, an increased investment in drug discovery to ensure the continued growth of our pipeline.

Clinical Trials Clinical trial and preclinical expenses, which include services performed by third-party contract research organizations and other vendors, increased by \$1.8 million, or 14%, primarily due to phase 2 clinical trial activity for XL784, XL880 and XL647 and phase 1 clinical trial activity for XL999, XL844, XL820, XL228, XL281, XL518 and XL184, as well as preclinical activity for XL418, XL147, XL765 and XL019, partially offset by a decrease in phase 2 trial activity for XL999 during 2007.

Edgar Filing: EXELIXIS INC - Form 10-Q

Lab Supplies Lab supplies expense increased by \$1.7 million, or 36%, primarily due to an increase in our drug discovery activities to ensure the continued growth of our pipeline and, to a lesser degree, development activities related to our phase 1 and phase 2 clinical trials.

The increase for the six months ended June 30, 2007, as compared to the comparable period in 2006, resulted primarily from the following:

Clinical Trials Clinical trial and preclinical expenses increased by \$7.8 million, or 40%, primarily due to phase 2 clinical trial activity for XL784, XL880 and XL647 and phase 1 clinical trial activity for XL999, XL844, XL820, XL228, XL281, XL518 and XL184 as well as preclinical activity for XL418, XL147, XL765 and XL019.

Table of Contents

Personnel Personnel expense increased by \$6.8 million, or 25%, primarily due to the expanded workforce supporting drug development operations to advance our clinical and preclinical development programs and, to a lesser degree, an increased investment in drug discovery to ensure the continued growth of our pipeline.

Lab Supplies Lab supplies expense increased by \$2.7 million, or 30%, primarily due to an increase in our drug discovery activities to ensure the continued growth of our pipeline.

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 product candidate, the clinical trial design and the ability to enroll suitable patients. We expect that research and development expenses will continue to increase as we advance our compounds through development.

We currently do not have 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 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		Six Months Ended	
	June 30,		June 30,	
	2007	2006	2007	2006
General and administrative expenses	\$ 11.2	\$ 10.0	\$ 22.4	\$ 19.0
Dollar increase	\$ 1.2		\$ 3.4	
Percentage increase	12%		18%	

General and administrative expenses consist primarily of personnel expenses, employee stock-based compensation expense, facility costs and consulting and professional expenses, such as legal and accounting fees. The increase in expenses for the three months ended June 30, 2007, as compared to the comparable period in 2006, resulted primarily from increases of \$0.6 million in stock-based compensation expense and \$0.4 million in personnel expenses. The increase in expenses for the six months ended June 30, 2007, as compared to the comparable period in 2006, resulted primarily from increases of \$1.8 million in personnel expenses, \$1.2 million in stock-based compensation expense and \$0.4 million in legal and accounting expenses. These increases are primarily to support our expanding general operating activities.

Amortization of Intangibles

Total amortization of intangible assets, as compared to the prior year period, was as follows (dollar amounts are presented in millions):

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2007	2006	2007	2006
Amortization of intangible assets	\$ 0.1	\$ 0.2	\$ 0.1	\$ 0.5
Dollar decrease	\$ 0.2		\$ 0.4	
Percentage decrease	70%		72%	

Edgar Filing: EXELIXIS INC - Form 10-Q

Intangible assets result from our acquisitions of X-Ceptor Therapeutics, Genomica, Artemis Pharmaceuticals and Agritope (renamed Exelixis Plant Sciences). The decrease in amortization of intangibles expense for the three- and six-month periods ended June 30, 2007, as compared to the comparable periods in 2006, were due to fully amortized expenses for the assembled workforce related to our acquisition of X-Ceptor Therapeutics and the developed technology related to our acquisition of Artemis Pharmaceuticals.

Table of Contents**Total Other Income**

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

	Six Months			
	Three Months		Ended	
	Ended		June 30,	
	2007	2006	2007	2005
Total other income	\$ 2.3	\$ 0.6	\$ 4.8	\$ 1.0
Dollar increase	\$ 1.7		\$ 3.8	
Percentage increase	266%		367%	

Total other income consists primarily of interest income earned on cash and cash equivalents, short-term and long-term marketable securities and investments held by SEI, partially offset by interest expense incurred on our notes payable, bank obligations, capital lease obligations and convertible notes and loans. The increase in total other income for the three months ended June 30, 2007, as compared to the comparable period in 2006, and six months ended June 30, 2007, as compared to the comparable period in 2006, were primarily due to an increase in interest income as a result of higher cash and investment balances and higher average interest rates. The increases are also attributable to a decrease in interest expense as a result of the repayment of our \$30.0 million convertible promissory note to PDL BioPharma, Inc. in May 2006.

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 FIN 46R. Accordingly, we have deducted the losses attributable to the noncontrolling interest (SEI's losses) from our 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. SEI's losses consist primarily of the development expenses for XL647, XL784 and XL999. The noncontrolling interest holders' ownership in the consolidated balance sheet was \$24.0 million as of June 30, 2007. Once SEI's losses are in excess of the noncontrolling interest holders' ownership, SEI's losses will no longer be deducted from our net losses. For the three months ended June 30, 2007, the loss attributed to the noncontrolling interest holders was \$7.5 million, as compared to \$5.8 million for the comparable period in 2006, and for the six month period ended June 30, 2007 the loss attributed to the noncontrolling interest holders was \$14.0 million, as compared to \$9.3 million for the comparable period in 2006. The increases in the losses attributed to the noncontrolling interest holders were due primarily to the increase in clinical trial activity for XL647, XL784 and XL999.

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

The following table summarizes our cash flow activities for the six-month periods ended June 30, 2007 and 2006, respectively (dollar amounts are presented in thousands):

	Six Months Ended June 30,	
	2007	2006
Net loss	\$ (52,763)	\$ (51,113)
Adjustments to reconcile net loss to net cash used in operating activities	1,280	9,324
Changes in operating assets and liabilities	47,014	20,577
Net cash used in operating activities	(4,469)	(21,212)
Net cash provided by (used in) investing activities	(15,045)	2,958
Net cash provided by financing activities	1,821	9,623
Effect of foreign exchange rate changes on cash and cash equivalents	(69)	55

Edgar Filing: EXELIXIS INC - Form 10-Q

Net decrease in cash and cash equivalents	(17,762)	(8,576)
Cash and cash equivalents, at beginning of period	123,369	81,328
Cash and cash equivalents, at end of period	\$ 105,607	\$ 72,752

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 June 30, 2007, we had \$253.0 million in cash and cash equivalents and short-term and long-term marketable securities, which includes investments held by SEI of \$44.7 million and restricted cash and investments of \$8.9 million.

Table of Contents*Operating Activities*

Our operating activities used cash of \$4.5 million for the six month period ended June 30, 2007, compared to \$21.2 million for the comparable period in 2006. Cash provided by operating activities for the 2007 period related primarily to changes in deferred revenues from collaborators, receivables and accounts payable and other accrued expenses. The cash provided was partially offset by our net loss and losses attributed to the noncontrolling interest. While cash used in operating activities is primarily driven by our net loss, operating cash flows differ from our net loss as a result of differences in the timing of cash receipts and earnings recognition, expenses related to the noncontrolling interest and non-cash charges.

The decrease of \$16.7 million in cash used in our operating activities for the six month period ended June 30, 2007, as compared to the comparable period in 2006, was primarily driven by increases in deferred revenues and accounts payable and other accrued expenses and a decrease in receivables. The increase in deferred revenues of \$18.1 million was primarily related to \$60.0 million that we received from Bristol-Myers Squibb and \$15.0 million that we received from Genentech during the six months ended June 30, 2007. We expect to recognize the Bristol-Myers Squibb payment as revenue over a four-year period and the Genentech payment over a three-year period, commencing upon the effective date of the relevant collaboration agreement.

Investing Activities

Our investing activities used cash of \$15.0 million for the six month period ended June 30, 2007, compared to cash provided of \$3.0 million for the comparable period in 2006. Cash used in investing activities for the 2007 period was primarily driven by purchases of marketable securities of \$108.2 million and purchases of property and equipment of \$9.4 million. These uses of cash were partially offset by proceeds of \$91.5 million from the maturities of marketable securities and \$11.7 million from the sales of investments held by SEI. The proceeds provided by maturities of our marketable securities and the sale of investments by SEI were principally used to fund our operations. We expect to continue to make significant investments in property and equipment to support our expanding operations.

Cash provided by investing activities for the 2006 period was primarily driven by the proceeds of \$69.5 million provided by maturities of our marketable securities and \$9.8 million from the sales of investments held by SEI. The cash provided was partially offset by purchases of investments held by SEI of \$40.8 million, marketable securities of \$30.4 million and property and equipment of \$6.8 million.

Financing Activities

Our financing activities provided cash of \$1.8 million for the six month period ended June 30, 2007, compared to \$9.6 million for the comparable period in 2006. Cash provided by our financing activities for the 2007 period was due to proceeds of \$6.4 million from the exercise of stock options and proceeds of \$1.7 million from our employee stock purchase plan, which was partially offset by \$6.3 million of principal payments on notes payable and bank obligations. Cash provided by our financing activities for the 2006 period was primarily due to the proceeds from the purchase of noncontrolling interest by preferred shareholders in SEI of \$40.0 million, proceeds of \$2.4 million from notes payable and bank obligations and \$2.4 million from the exercise of stock options, which was partially offset by \$36.3 million of principal payments on notes payable and bank obligations.

We finance property and equipment purchases through equipment financing facilities, such as capital leases, 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 loans from collaborators.

Cash Requirements

We have incurred net losses since inception, including a net loss of \$28.6 million for the three-month period ended June 30, 2007 and \$52.8 million for the six-month period ended June 30, 2007, and 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. We anticipate that our current cash and cash equivalents, short-term and long-term marketable securities, investments held by SEI 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. However, our future capital requirements will be substantial and will depend on many factors that may require us to consume available capital resources significantly sooner than we currently anticipate. These factors include:

Table of Contents

the timing and progress of the clinical development of our product candidates XL647, XL999 and XL784, which are out-licensed to SEI. If any of the phase 2 clinical trials for XL647, XL999 or XL784 show positive results that support further clinical development of any such product candidate, in order for us or GlaxoSmithKline to pursue further development of such product candidate(s), we would be required to reacquire all three product candidates (XL647, XL999 and XL784) from SEI's investors through the exercise of our exclusive purchase option, which is described in this report. Under our amended purchase option agreement with SEI, we cannot repurchase a single product candidate without also repurchasing the other two product candidates. The purchase 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 (i) the total amount of capital invested in SEI by its investors (\$80.0 million) and (ii) an amount equal to 25% per year on such funded capital;

whether and when GlaxoSmithKline selects at clinical proof-of-concept for further development XL999 or XL784, which would require us to repurchase all three product candidates through the exercise of our purchase option. GlaxoSmithKline has the right to select for further clinical development at clinical proof-of-concept XL999 and XL784, two of the product candidates licensed to SEI. If GlaxoSmithKline selects any of these product candidates, it would be necessary for us to repurchase all three product candidates licensed to SEI through the exercise of our purchase option in order to satisfy our contractual obligations to GlaxoSmithKline. GlaxoSmithKline has decided not to exercise this right at clinical proof-of-concept for XL647;

the amount of any selection milestones received from GlaxoSmithKline as a result of a product candidate selection by GlaxoSmithKline compared to the amount we are required to pay to reacquire XL647, XL999 and XL784 from SEI's investors through the exercise of our purchase option. Under our product development and commercialization agreement with GlaxoSmithKline, a product candidate selection by GlaxoSmithKline would trigger milestone payments. The size of these milestone payments depends largely on how quickly we can advance product candidates to clinical proof-of-concept. As described under Recent Developments, on July 26, 2007, we announced that GlaxoSmithKline decided not to exercise its option under our product development and commercialization agreement to elect to develop and commercialize XL647 at clinical proof-of-concept. Since GlaxoSmithKline did not select XL647, if it later selects XL999 or XL784, and there are delays in obtaining clinical proof-of-concept for XL999 or XL784, the amount of any GlaxoSmithKline milestone payments would be significantly decreased due to the delays and would therefore cover only a small portion of the purchase price with respect to SEI. In addition, the selection milestone payment for the first compound selected by GlaxoSmithKline will be reduced by \$36.0 million to account for a milestone payment that GlaxoSmithKline advanced to us in 2005 as part of an amendment to the product development and commercialization agreement;

whether any future milestone payments from GlaxoSmithKline relate to product candidates licensed to SEI. Under our product development and commercialization agreement with GlaxoSmithKline, any milestone payments relating to product candidates not licensed to SEI must be used to pay down our loan with GlaxoSmithKline as long as the loan is outstanding. As of June 30, 2007, the aggregate principal and interest outstanding under our GlaxoSmithKline loan was \$96.9 million;

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

the progress and scope of our collaborative and independent clinical trials and other research and development projects;

future clinical trial results;

our need to expand our product and clinical development efforts;

Edgar Filing: EXELIXIS INC - Form 10-Q

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.

Table of Contents

In addition, we will have to obtain additional funding in order to stay in compliance with financial covenants contained in our collaboration with GlaxoSmithKline. Our loan and security agreement with GlaxoSmithKline dated October 28, 2002, as amended, contains financial covenants pursuant to which our working capital must not be less than \$25.0 million and our cash and investments must not be less than \$50.0 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 outstanding obligations thereunder.

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. We currently have shelf registration statements on file with the SEC that allow us to offer for sale from time to time common stock, preferred stock, debt securities and warrants, either individually or in units. 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 have contractual obligations in the form of operating leases, notes payable and licensing agreements. The following chart details our contractual obligations as of June 30, 2007 (in thousands):

	Payments Due by Period				
	Total	Less than 1 year(2)	1-3 years(2)	4-5 years	More than 5 years
Contractual Obligations					
Licensing and other agreements	\$ 1,881	\$ 1,432	\$ 444	\$ 5	\$
Notes payable and bank obligations	30,341	11,691	17,132	1,518	
Convertible loans (1)	96,884		31,972	64,912	
Operating leases	142,544	15,536	28,302	27,535	71,171
Total contractual cash obligations	\$ 271,650	\$ 28,659	\$ 77,850	\$ 93,970	\$ 71,171

- (1) Includes interest payable on the convertible loans of \$11.9 million. The debt and interest payable can be repaid in cash or common stock at our election.
- (2) If GlaxoSmithKline were to select one of the compounds licensed by us to SEI for further clinical development, we would be required to exercise our option to repurchase all three compounds licensed to SEI in order to be able to satisfy our obligations under our agreements with GlaxoSmithKline. In April 2007, we notified GlaxoSmithKline of our determination that we had achieved clinical proof-of-concept for XL647. As described under *Recent Developments*, on July 26, 2007, we announced that GlaxoSmithKline decided not to exercise its option under our product development and commercialization agreement to elect to develop and commercialize XL647 at clinical proof-of-concept.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our market risks at June 30, 2007 have not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 29, 2006 on file with the Securities and Exchange Commission. Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio and our long-term debt.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures. Based on the evaluation of our disclosure controls and procedures (as defined in Securities Exchange Act of 1934 Rules 13a-15(e) and 15d-15(e)) required by Securities Exchange Act Rules 13a-15(b) or 15d-15(b), 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.

Edgar Filing: EXELIXIS INC - Form 10-Q

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.

Table of Contents

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 filed with the Securities and Exchange Commission on February 27, 2007.*

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

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

We will need to raise additional capital to:

fund our operations and clinical trials;

continue our research and development efforts; and

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

As of June 30, 2007, we had \$253.0 million in cash and cash equivalents and short-term and long-term marketable securities, which included investments held by SEI of \$44.7 million and restricted cash and investments of \$8.9 million. We anticipate that our current cash and cash equivalents, short-term and long-term marketable securities, investments held by SEI 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. However, our future capital requirements will be substantial and will depend on many factors that may require us to consume available capital resources significantly sooner than we currently anticipate. These factors include:

the timing and progress of the clinical development of our product candidates XL647, XL999 and XL784, which are out-licensed to SEI. If any of the phase 2 clinical trials for XL647, XL999 or XL784 show positive results that support further clinical development of any such product candidate, in order for us or GlaxoSmithKline to pursue further development of such product candidate(s), we would be required to reacquire all three product candidates (XL647, XL999 and XL784) from SEI's investors through the exercise of our exclusive purchase option, which is described in this report. Under our amended purchase option agreement with SEI, we cannot repurchase a single product candidate without also repurchasing the other two product candidates. The purchase 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 (i) the total amount of capital invested in SEI by its investors (\$80.0 million) and (ii) an amount equal to 25% per year on such funded capital;

whether and when GlaxoSmithKline selects at clinical proof-of-concept for further development XL999 or XL784, which would require us to repurchase all three product candidates through the exercise of our purchase option. GlaxoSmithKline has the right to select for further clinical development at clinical proof-of-concept XL999 and XL784, two of the product candidates licensed to SEI. If GlaxoSmithKline selects any of these product candidates, it would be necessary for us to repurchase all three product candidates licensed to SEI through the exercise of our purchase option in order to satisfy our contractual obligations to GlaxoSmithKline.

Edgar Filing: EXELIXIS INC - Form 10-Q

GlaxoSmithKline has decided not to exercise this right at clinical proof-of-concept for XL647;

the amount of any selection milestones received from GlaxoSmithKline as a result of a product candidate selection by GlaxoSmithKline compared to the amount we are required to pay to reacquire XL647, XL999 and XL784 from SEI's investors through the exercise of our purchase option. Under our product development and commercialization agreement with GlaxoSmithKline, a product candidate selection by GlaxoSmithKline would trigger milestone payments. The size of these milestone payments depends largely on how quickly we can advance product candidates to clinical proof-of-concept. As described under Recent Developments, on July 26, 2007, we announced that GlaxoSmithKline decided not to exercise its option under our product development and commercialization agreement to elect to develop and commercialize XL647 at clinical proof-of-concept. Since GlaxoSmithKline did not select XL647, if it later selects XL999 or XL784, and there are delays in obtaining clinical proof-of-concept for XL999 or XL784, the amount of any GlaxoSmithKline milestone payments would be significantly decreased due to the delays and would therefore cover only a small portion of the purchase price.

Table of Contents

with respect to SEI. In addition, the selection milestone payment for the first compound selected by GlaxoSmithKline will be reduced by \$36.0 million to account for a milestone payment that GlaxoSmithKline advanced to us in 2005 as part of an amendment to the product development and commercialization agreement;

whether any future milestone payments from GlaxoSmithKline relate to product candidates licensed to SEI Under our product development and commercialization agreement with GlaxoSmithKline, any milestone payments relating to product candidates not licensed to SEI must be used to pay down our loan with GlaxoSmithKline as long as the loan is outstanding. As of June 30, 2007, the aggregate principal and interest outstanding under our GlaxoSmithKline loan was \$96.9 million;

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

the progress and scope of our collaborative and independent clinical trials and other research and development projects;

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 consume available capital resources significantly sooner than we anticipate. If our capital resources are insufficient to meet future capital requirements, we will have to raise additional funds. 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 existing 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 unfavorable to our stockholders or us. If we are unable to obtain adequate funds on reasonable terms, we may be required to curtail operations

Edgar Filing: EXELIXIS INC - Form 10-Q

significantly or obtain funds by entering into financing, supply or collaboration agreements on unattractive terms. If we raise additional funds through collaboration arrangements with third parties, it will be necessary to relinquish some rights to our technologies or product candidates, or we may be required to grant licenses on terms that are unfavorable to us.

In addition, 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 a loan and security agreement, dated October 28, 2002, 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) 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 June 30, 2007, our working capital was \$125.1 million and our cash and investments were \$244.1 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 \$96.9 million at June 30, 2007.

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.

Table of Contents

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

We have incurred net losses since inception, including a net loss of \$28.6 million for the three month period ended June 30, 2007 and \$52.8 million for the six month period ended June 30, 2007. As of that date, we had an accumulated deficit of \$758.0 million. We expect these losses to continue 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 German subsidiary, Artemis Pharmaceuticals, our only revenues to date are license revenues and revenues under contracts with our partners. 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 that our operations will continue to increase, 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 have licensed the intellectual property, including commercialization rights, to our product candidates XL647, XL999 and XL784 to SEI and will not receive any future royalties or revenues with respect to these product candidates unless we exercise our option to acquire these product candidates in the future. We may not have the financial resources to exercise this option or sufficient clinical data in order to determine whether we should exercise this option.*

We have licensed to SEI our intellectual property rights, including commercialization rights, to our product candidates XL647, XL999 and XL784 in exchange for SEI's investment of \$80.0 million to advance the clinical development of XL647, XL999 and XL784. In exchange for this investment and for five-year warrants to purchase shares of our common stock, we received an exclusive purchase option to acquire all of the equity of SEI, thereby allowing us to reacquire the product candidates, including any associated intellectual property rights and commercialization rights. We may, at our sole discretion, exercise this purchase option at any time until the earlier of June 9, 2009 or the 90th day after the date that SEI provides us with financial statements showing cash and cash equivalents of less than \$5.0 million. The purchase option exercise price is equal to the sum of: (i) the total amount of capital invested in SEI by its investors and (ii) an amount equal to 25% per year on such funded capital. The option exercise price may be paid in cash and/or shares of our common stock, at our sole discretion.

If we elect to exercise the purchase option, we will be required to make a substantial cash payment and/or to issue a substantial number of shares of our common stock, or enter into a financing arrangement or license arrangement with one or more third parties, or some combination of the foregoing. A payment in cash would reduce our capital resources. A payment in shares of our common stock could result in dilution to our stockholders at that time. Other financing or licensing alternatives may be expensive or impossible to obtain. If we do not exercise the purchase option prior to its expiration, our rights to purchase all of the equity in SEI and to reacquire XL647, XL999 and XL784 will terminate. We may not have the financial resources to exercise the option, which may result in our loss of these rights. Additionally, we may not have sufficient clinical data in order to determine whether we should exercise the option.

In addition, under our collaboration with GlaxoSmithKline, GlaxoSmithKline may continue to select at clinical proof-of-concept for further development one or more of the product candidates licensed to SEI, in which case we would be required under our amended purchase option agreement with SEI to repurchase all product candidates licensed to SEI through the exercise of our purchase option. If, after receiving any selection milestones from GlaxoSmithKline, we are unable to pay the purchase option exercise price in cash and/or delivery of our shares of our common stock, we could be in breach of our product development and commercialization agreement with GlaxoSmithKline. In the event of such breach, GlaxoSmithKline could terminate the collaboration and, among other remedies, declare all amounts under our loan facility with GlaxoSmithKline immediately due and payable, which would have a significant adverse effect on our business, operating results and financial condition.

Risks Related to Development of Product Candidates

Clinical testing of our product candidates is a lengthy, costly and uncertain process and may fail to demonstrate safety and efficacy, which could prevent or significantly delay regulatory approval.

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

Table of Contents

observed in earlier-stage trials or preliminary studies. Although we have established timelines for manufacturing and clinical development based on existing knowledge of our compounds in development and industry metrics, we may not be able to meet those timelines.

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

our product candidates may not prove to be efficacious or may cause harmful side effects;

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

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 and our ability to generate revenue from the affected product candidates could be impaired, which would 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.

Our research and clinical testing may be delayed or abandoned if we or our competitors subsequently discover other compounds that we believe show significantly improved safety or efficacy compared to our product candidates, which 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.

*Any serious adverse cardiovascular events observed in our phase 1 clinical trial evaluating XL999 in patients with NSCLC may result in significant delays or termination of clinical testing, which could harm our business, operating results and financial condition.**

Edgar Filing: EXELIXIS INC - Form 10-Q

In April 2007, we were notified by the FDA that it had completed its review of a clinical trial protocol for a phase 1 dose-escalation trial of XL999 in patients with NSCLC and agreed that the trial may be initiated. XL999 was previously evaluated in phase 1 and 2 clinical trials in which cardiovascular adverse events were observed. These observations caused us to suspend new patient enrollment in the ongoing XL999 clinical trials in November 2006. The FDA subsequently placed the clinical program on partial clinical hold in December 2006. The previous phase 1 and 2 clinical trials will not be re-initiated at this time. Given acceptance by the FDA of the new clinical trial protocol for XL999 in patients with NSCLC, the XL999 development program will now focus on this indication.

We may experience a number of events that could continue to delay or prevent development of XL999, including:

analysis of data from the new XL999 clinical trial may show that XL999 cannot be administered safely at a therapeutic dose;

failure to enroll patients in the new XL999 clinical trial in a timely manner or at all;

regulators or institutional review boards may not authorize or may delay, suspend or terminate the clinical trial program for XL999 due to the observed adverse cardiovascular or other effects; and

any disagreements between SEI and the company regarding the further clinical development of XL999.

Table of Contents

In addition, because the size of acceptance milestones is reduced over time under our agreement with GlaxoSmithKline, delays in the clinical development of XL999 may result in reduced acceptance milestone payments if GlaxoSmithKline selects XL999 for further clinical development. The occurrence of any of the foregoing events could delay or prevent commercialization of XL999 and harm our business, operating results and financial condition.

Risks Related to Our Relationships with Third Parties

Disagreements between SEI and us regarding the development of our product candidates XL647, XL999 and XL784 may cause significant delays and other impediments in the development of these product candidates, which could negatively affect the value of these product candidates.

We have licensed to SEI our intellectual property rights, including commercialization rights, to our product candidates XL647, XL999 and XL784 in exchange for SEI's investment of \$80.0 million to advance the clinical development of XL647, XL999 and XL784. We are responsible for developing XL647, XL999 and XL784 in accordance with a specified development plan and related development budget. Our development activities are supervised by SEI's development committee, which is comprised of an equal number of representatives from Exelixis and SEI. If the development committee cannot resolve a particular development issue, the issue will be referred to the chief executive officers of Exelixis and SEI. Any disagreements between SEI and us regarding a development decision may cause significant delays in the development and commercialization of our product candidates XL647, XL999 and XL784 as well as lead to development decisions that do not reflect our interests. Any such delays or development decisions not in our interest could negatively affect the value of XL647, XL999 and XL784.

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 these agreements or agreements with other partners are not renewed or are 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 collaboration with GlaxoSmithKline is scheduled to expire in October 2008 but became subject to earlier termination at the discretion of GlaxoSmithKline starting in 2005. Our agreements with Bristol-Myers Squibb and Wyeth also 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. For example, in March 2005, we agreed with Bayer CropScience LP to terminate the research term under our collaboration with Bayer CropScience in order to allow us to focus on our core business. We may not be able to enter into new collaboration agreements on similar or superior financial terms to offset the loss of revenue from the termination or expiration of any of our existing arrangements, and the timing of new collaboration agreements may have a material adverse effect on our ability to continue to successfully meet our objectives.

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

We are conducting proprietary research programs in specific disease, therapeutic modality and agricultural product areas that are not covered by our collaboration agreements. Our pursuit of opportunities in pharmaceutical and agricultural markets could result in conflicts with our collaborators in the event that any of our collaborators takes the position that our internal activities overlap with those areas that are exclusive to our collaboration agreements, and we should be precluded from such internal activities. Moreover, disagreements with our collaborators could develop over 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

Table of Contents

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.

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

Table of Contents

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.

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.

Table of Contents

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.

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 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

Table of Contents

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.

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.

Table of Contents

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 be a distraction to management. 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 attract and retain 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. Recruiting and retaining 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. As our operations expand, we will need to continue to manage multiple locations and additional relationships with various collaborative partners, suppliers and other third parties. Our ability to manage our operations and growth effectively requires us to continue to improve our reporting systems and procedures as well as our operational, financial and management controls. In addition, rules and regulations implemented by the Securities and Exchange Commission have increased the internal control and regulatory requirements under which we operate. We may not be able to successfully implement improvements to our management information and control systems in an efficient or timely manner to meet future requirements.

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

Given our headquarters location in South San Francisco, California, 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

Table of Contents

maintain may not be adequate to cover our losses. If any disaster were to occur, our ability to operate our business at our facilities could be seriously, or potentially completely, impaired. In addition, the unique nature of our research activities could cause significant delays in our programs and make it difficult for us to recover from a disaster. Accordingly, an earthquake or other disaster could materially and adversely harm our ability to conduct business.

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

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

Risks Related to Environmental and Product Liability

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

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

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

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

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

Risks Related to Our Common Stock

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

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;

Table of Contents

payments of non-refundable upfront or licensing fees 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. In addition, we expect operating expenses to increase significantly as we move more compounds into clinical development. Accordingly, 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 stock market 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:

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;

Edgar Filing: EXELIXIS INC - Form 10-Q

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;

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

Table of Contents

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.

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) 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. For example, following an acquisition, a significant number of shares of our common stock held by new stockholders may become freely tradable or holders of registration rights could cause us to register their shares for resale. Sales of these shares of common stock held by existing stockholders could cause the market price of our common stock to decline.

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

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

enter into transactions or agreements that would not be widely viewed as beneficial.

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

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

a classified Board of Directors;

a prohibition on actions by our stockholders by written consent;

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

Table of Contents

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 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

At our 2007 annual meeting of stockholders held on May 1, 2007, the stockholders were asked to vote upon:

1. The election of three Class II directors for a three-year term until the 2010 annual meeting of stockholders. The nominees for election to these positions were Alan M. Garber, M.D., Ph.D., Vincent T. Marchesi, M.D., Ph.D., and Carl B. Feldbaum, Esq; and
2. The ratification of the selection of Ernst & Young LLP to serve as the Company's independent registered public accounting firm for the fiscal year ending December 28, 2007.

The results of the matters presented at the annual meeting, based on the presence in person or by proxy of holders of record of 82,653,457 shares of the 96,631,531 shares of our common stock entitled to vote, were as follows:

1. The election of each of Drs. Garber and Marchesi and Mr. Feldbaum as directors of the Company until the 2010 annual meeting of stockholders, and until his successor is elected and qualified, or until his earlier death, resignation or removal, was approved as follows:

	For	Withheld
Alan M. Garber, M.D., Ph.D.	81,661,281	992,176
Vincent T. Marchesi, M.D., Ph.D.	73,392,963	9,260,494
Carl B. Feldbaum, Esq.	81,676,781	976,676

Our Class I directors, Charles Cohen, Ph.D., George Poste, D.V.M., Ph.D., and Jack Wyszomierski, will each continue to serve on the Board of Directors until the 2009 annual meeting of stockholders and until his successor is elected and qualified, or until his earlier death, resignation or removal. Our Class III directors, Stelios Papadopoulos, Ph.D., George A. Scangos, Ph.D., Frank McCormick, Ph.D., and Lance Willsey, M.D., will each continue to serve on the Board of Directors until the 2008 annual meeting of stockholders and until his successor is elected and qualified, or until his earlier death, resignation or removal.

2. The ratification of Ernst & Young LLP as the Company's independent registered public accounting firm for the fiscal year ending December 28, 2007 was approved as follows:

Edgar Filing: EXELIXIS INC - Form 10-Q

For	Against	Abstain	Broker Non-Vote
82,479,053	119,375	55,029	0

ITEM 6. EXHIBITS

(a) Exhibits

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

Table of Contents

SIGNATURES

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

Date: August 7, 2007

EXELIXIS, INC.

/s/ Frank Karbe
Frank Karbe

Executive Vice President, Chief Financial Officer

(Principal Financial and Accounting Officer)

Table of Contents

EXHIBIT INDEX

Number	Exhibit Description
10.1*	First Amendment to Collaboration Agreement, effective as of June 5, 2007, between Exelixis, Inc. and Daiichi Sankyo Company Limited (formerly known as Sankyo Company Limited).
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.