

EXELIXIS INC
Form 10-Q
October 27, 2008
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 26, 2008

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)

Edgar Filing: EXELIXIS INC - Form 10-Q

Delaware
(State or other jurisdiction of
incorporation or organization)

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

249 East Grand Ave.

P.O. Box 511

South San Francisco, CA 94083-0511

(Address of principal executive offices, 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, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer
(Do not check if a smaller

Smaller reporting company

reporting company)

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

As of October 17, 2008 there were 105,599,680 shares of the registrant's common stock outstanding.

Table of Contents

EXELIXIS, INC.

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 26, 2008

INDEX

Part I. Financial Information

Item 1.	Financial Statements	
	<u>Condensed Consolidated Balance Sheets - September 30, 2008 and December 31, 2007</u>	3
	<u>Condensed Consolidated Statements of Operations - Three Months and Nine Months Ended September 30, 2008 and 2007</u>	4
	<u>Condensed Consolidated Statements of Cash Flows - Nine Months Ended September 30, 2008 and 2007</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>	11
Item 3.	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	23
Item 4.	<u>Controls and Procedures</u>	23

Part II. Other Information

Item 1A.	<u>Risk Factors</u>	24
Item 6.	<u>Exhibits</u>	36

	<u>SIGNATURES</u>	37
--	--------------------------	----

	<u>EXHIBITS</u>	38
--	------------------------	----

Exhibit 31.1

Exhibit 31.2

Exhibit 32.1

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

(in thousands)

	September 30, 2008 (unaudited)	December 31, 2007 ⁽¹⁾
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 64,230	\$ 135,457
Marketable securities	26,159	105,153
Investments held by Symphony Evolution, Inc.	18,473	30,935
Other receivables	1,820	6,087
Prepaid expenses and other current assets	6,760	6,151
Total current assets	117,442	283,783
Restricted cash and investments	4,854	7,238
Long-term marketable securities	21,434	20,747
Property and equipment, net	38,683	34,664
Goodwill	63,684	63,684
Other assets	8,666	2,004
Total assets	\$ 254,763	\$ 412,120
LIABILITIES, NONCONTROLLING INTEREST AND STOCKHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 7,342	\$ 9,288
Accrued clinical trial liabilities	26,674	21,651
Other accrued expenses	4,827	7,594
Accrued compensation and benefits	17,828	14,480
Current portion of notes payable and bank obligations	16,945	15,767
Deferred revenue	45,266	64,105
Total current liabilities	118,882	132,885
Notes payable and bank obligations	21,433	20,747
Convertible loans	85,000	85,000
Other long-term liabilities	27,338	24,924
Deferred revenue	25,556	63,053
Total liabilities	278,211	326,609
Noncontrolling interest in Symphony Evolution, Inc.	3,510	13,430
Commitments		
Stockholders' equity (deficit):		
Common stock	106	105
Additional paid-in-capital	889,313	863,127

Edgar Filing: EXELIXIS INC - Form 10-Q

Accumulated other comprehensive income	178	499
Accumulated deficit	(916,555)	(791,650)
Total stockholders' equity (deficit)	(26,958)	72,081
Total liabilities, noncontrolling interest and stockholders' equity (deficit)	\$ 254,763	\$ 412,120

(1) The condensed consolidated balance sheet at December 31, 2007 has been derived from the audited consolidated financial statements at that date but does not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements.

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Revenues:				
Contract	\$ 16,665	\$ 17,496	\$ 52,047	\$ 49,040
License	13,267	9,329	36,240	35,180
Total revenues	29,932	26,825	88,287	84,220
Operating expenses:				
Research and development	65,670	58,643	200,512	165,159
General and administrative	8,867	10,757	27,786	33,151
Amortization of intangible assets		51		195
Total operating expenses	74,537	69,451	228,298	198,505
Loss from operations	(44,605)	(42,626)	(140,011)	(114,285)
Other income (expense):				
Interest income and other, net	1,090	2,908	5,072	9,786
Interest expense	(2,171)	(970)	(4,386)	(3,001)
Gain on sale of business	4,500	18,808	4,500	18,808
Total other income	3,419	20,746	5,186	25,593
Loss before noncontrolling interest in Symphony Evolution, Inc.	(41,186)	(21,880)	(134,825)	(88,692)
Loss attributed to noncontrolling interest in Symphony Evolution, Inc.	2,680	8,184	9,920	22,233
Net loss	\$ (38,506)	\$ (13,696)	\$ (124,905)	\$ (66,459)
Net loss per share, basic and diluted	\$ (0.36)	\$ (0.14)	\$ (1.19)	\$ (0.68)
Shares used in computing basic and diluted loss per share amounts	105,548	98,551	105,294	97,313

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)**

	Nine Months Ended	
	September 30,	
	2008	2007
Cash flows from operating activities:		
Net loss	\$ (124,905)	\$ (66,459)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	9,822	7,988
Loss attributed to noncontrolling interest	(9,920)	(22,233)
Stock-based compensation expense	17,081	14,950
Amortization of intangibles		195
Gain on sale of business	(4,500)	(18,808)
Other	1,009	559
Changes in assets and liabilities:		
Other receivables	(233)	18,441
Prepaid expenses and other current assets	(609)	(3,673)
Other assets	(3,191)	(602)
Accounts payable and other accrued expenses	5,790	18,003
Other long-term liabilities	2,414	3,928
Deferred revenue	(56,336)	3,886
Net cash used in operating activities	(163,578)	(43,825)
Cash flows from investing activities:		
Purchases of investments held by Symphony Evolution, Inc.	(601)	(1,836)
Proceeds on sale of investments held by Symphony Evolution, Inc.	13,063	18,192
Purchases of property and equipment	(13,925)	(14,150)
Proceeds on sale of business	9,000	18,000
Changes in restricted cash and investments	2,384	1,557
Proceeds from maturities of marketable securities	51,172	141,187
Proceeds from sale of marketable securities	32,571	
Purchases of marketable securities	(5,619)	(173,091)
Net cash provided by (used in) investing activities	88,045	(10,141)
Cash flows from financing activities:		
Proceeds from sale of stock, net of offering costs		71,897
Proceeds from exercise of stock options and warrants	299	7,821
Proceeds from employee stock purchase plans	2,142	1,742
Proceeds from notes payable and bank obligations	13,619	
Principal payments on notes payable and bank obligations	(11,754)	(9,285)
Net cash provided by financing activities	4,306	72,175
Effect of foreign exchange rate changes on cash and cash equivalents		(252)

Edgar Filing: EXELIXIS INC - Form 10-Q

Net (decrease) increase in cash and cash equivalents	(71,227)	17,957
Cash and cash equivalents, at beginning of period	135,457	123,369
Cash and cash equivalents, at end of period	\$ 64,230	\$ 141,326
Non-cash investing and financing activities:		
Warrants issued in conjunction with Deerfield financing agreement	3,438	

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

Table of Contents

EXELIXIS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2008

(unaudited)

NOTE 1. Organization and Summary of Significant Accounting Policies

Organization

Exelixis, Inc. (Exelixis, we, our or us) is committed to developing innovative therapies for cancer and other serious diseases. Through our drug discovery and development activities, we are building a portfolio of novel compounds that we believe have the potential to be high-quality, differentiated pharmaceutical products. Our most advanced pharmaceutical programs focus on drug discovery and development of small molecules in cancer.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and pursuant to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission (SEC). Accordingly, they do not include all of the information and footnotes required by U.S. generally accepted accounting principles (GAAP) for complete financial statements. In our opinion, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the results of operations and cash flows for the period presented have been included. Operating results for the three- and nine-month periods ended September 30, 2008 are not necessarily indicative of the results that may be expected for the 2008 fiscal year or for any future period. These financial statements and notes should be read in conjunction with the consolidated financial statements and notes thereto for the fiscal year ended December 31, 2007 included in our Annual Report on Form 10-K filed with the SEC on February 25, 2008.

In 2006, we adopted a 52- or 53-week fiscal year that ends on the Friday closest to December 31st. Fiscal year 2006, a 52-week year, ended on December 29, 2006, fiscal year 2007, a 52-week year, ended on December 28, 2007 and fiscal year 2008, a 53-week year, will end on January 2, 2009. For convenience, references in these Condensed Consolidated Financial Statements and Notes as of and for the fiscal year ended December 28, 2007 are indicated on a calendar year basis as ending December 31, 2007, and as of and for the three- and nine-month periods ended September 28, 2007 and September 26, 2008 are indicated as ending September 30, 2007 and 2008, respectively.

Basis of Consolidation

The consolidated financial statements include the accounts of Exelixis and those of our wholly owned subsidiaries as well as one variable interest entity, Symphony Evolution, Inc., (SEI), 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.

Cash and Investments

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

All marketable securities are classified as available-for-sale and are carried at fair value. We view our available-for-sale portfolio as available for use in current operations. Accordingly, we have classified certain investments as short-term marketable securities, even though the stated maturity date may be one year or more beyond the current balance sheet date. Available-for-sale securities are stated at fair value based upon quoted market prices of the securities. We have classified certain investments as cash and cash equivalents or marketable securities that collateralize loan balances, however they are not restricted to withdrawal. Unrealized gains and losses on available-for-sale investments are reported as a separate component of stockholders' equity. Realized gains and losses, net, on available-for-sale securities are included in interest income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

Edgar Filing: EXELIXIS INC - Form 10-Q

As of September 30, 2008, unrealized losses were primarily due to the current economic crisis in addition to changes in interest rates. Based on the scheduled maturities of our marketable securities we concluded that some of the unrealized losses in our investment securities are other-than-temporary. Accordingly, we recorded an impairment charge of \$0.2 million in interest income and other, net, during the quarter ended September 30, 2008 in order to write down the carrying value of these securities to estimated fair value.

Fair Value Measurements

As of January 1, 2008, we adopted FASB Statement of Financial Accounting Standards No. 157, *Fair Value Measurements* (SFAS 157). SFAS 157 established a framework for measuring fair value in GAAP and clarified the definition of fair value within that framework. SFAS 157 does not require any new fair value measurements in GAAP. SFAS 157 introduced, or reiterated, a number

Table of Contents

of key concepts which form the foundation of the fair value measurement approach to be utilized for financial reporting purposes. The fair value of our financial instruments reflect the amounts that would be received upon sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price). SFAS 157 also established a fair value hierarchy that prioritizes the use of inputs used in valuation techniques into the following three levels:

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

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

Level 3 unobservable inputs.

The adoption of SFAS 157 did not have a material effect on our financial condition and results of operations, but SFAS 157 introduced new disclosures about how we value certain assets and liabilities. Much of the disclosure requirement is focused on the inputs used to measure fair value, particularly in instances where the measurement uses significant unobservable (Level 3) inputs. Our financial instruments are valued using quoted prices in active markets or based upon other observable inputs. The following table sets forth the fair value of our financial assets that were measured on a recurring basis as of September 30, 2008 (in thousands):

	Level 1	Level 2	Level 3	Total
Marketable securities	\$ 63,282	\$ 55,497	\$	\$ 118,779
Investments held by Symphony Evolution, Inc.	18,473			18,473
Total	\$ 81,755	\$ 55,497	\$	\$ 137,252

Recent Accounting Pronouncements

Effective January 1, 2008, we adopted Emerging Issues Task Force (EITF) 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities (EITF 07-3). EITF 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed. The adoption did not have a material impact on our consolidated results or operations or financial condition.

In December 2007, the FASB issued SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements an amendment of Accounting Research Bulletin No. 51 (SFAS 160). SFAS 160 establishes accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income attributable to the parent and to the noncontrolling interest, changes in a parent s ownership interest and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. SFAS 160 also establishes disclosure requirements that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS 160 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and will be adopted by us in the first quarter of fiscal 2009. We are currently evaluating the potential impact of the adoption of SFAS 160 on our consolidated results of operations and financial condition. SFAS 160 could change our accounting for the noncontrolling interest in SEI, a variable interest entity which we consolidate. Under current accounting standards, we do not allocate losses to the noncontrolling interest in SEI such that the carrying value of the noncontrolling interest is reduced below zero. Under SFAS 160, we would allocate losses to the noncontrolling interest in SEI such that the noncontrolling interest could have a negative carrying value.

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 September 30,	Nine Months Ended September 30,
---	--

Edgar Filing: EXELIXIS INC - Form 10-Q

	2008	2007	2008	2007
Net loss	\$ (38,506)	\$ (13,696)	\$ (124,905)	\$ (66,459)
Net (decrease) increase in unrecognized gains on available-for-sale securities	(424)	36	(321)	62
Decrease in foreign cumulative translation adjustment		(121)		(190)
Comprehensive loss	\$ (38,930)	\$ (13,781)	\$ (125,226)	\$ (66,587)

Table of Contents**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 September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Research and development expense	\$ 3,773	\$ 3,021	\$ 10,985	\$ 8,461
General and administrative expense	1,990	1,869	6,021	5,431
Total employee stock-based compensation expense	\$ 5,763	\$ 4,890	\$ 17,006	\$ 13,892

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 Three Months Ended September 30,		ESPP Three Months Ended September 30,	
	2008	2007	2008	2007
Weighted average fair value of awards	\$ 3.48	\$ 6.12	\$ 2.42	\$ 3.25
Risk-free interest rate	3.25%	4.71%	1.73%	5.01%
Dividend yield	0%	0%	0%	0%
Volatility	61%	59%	59%	52%
Expected life	5.2 years	4.9 years	0.5 years	0.5 years

	Stock Options Nine Months Ended September 30,		ESPP Nine Months Ended September 30,	
	2008	2007	2008	2007
Weighted average fair value of awards	\$ 4.53	\$ 5.26	\$ 2.83	\$ 3.02
Risk-free interest rate	3.20%	4.69%	2.72%	5.06%
Dividend yield	0%	0%	0%	0%
Volatility	61%	60%	56%	52%
Expected life	5.2 years	4.9 years	0.5 years	0.5 years

A summary of all stock option activity for the nine month period ended September 30, 2008 is presented below:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Options outstanding at December 31, 2007	20,718,661	\$ 10.32		
Granted	3,384,382	8.20		
Exercised	(47,074)	6.35		
Cancelled	(1,359,082)	9.99		
Options outstanding at September 30, 2008	22,696,887	\$ 10.03	6.8 years	\$ 503,880
Exercisable at September 30, 2008	13,342,484	\$ 10.69	5.5 years	\$ 247,519

Edgar Filing: EXELIXIS INC - Form 10-Q

As of September 30, 2008, \$37.1 million of total unrecognized compensation expense related to employee stock options was expected to be recognized over a weighted-average period of 2.52 years.

NOTE 4. Research and Collaboration Agreements

Bristol-Myers Squibb

LXR Collaboration. In December 2005, we entered into a collaboration agreement with Bristol-Myers Squibb Company (Bristol-Myers Squibb), for the discovery, development and commercialization of novel therapies targeted against LXR, a nuclear hormone receptor implicated in a variety of cardiovascular and metabolic disorders. This agreement became effective in January 2006, at which time we granted Bristol-Myers Squibb an exclusive, worldwide license with respect to certain intellectual property primarily relating to compounds that modulate LXR. During the research term, we expect to jointly identify drug candidates with Bristol-Myers Squibb that are ready for investigational new drug (IND) -enabling studies. After the selection of an Exelixis drug candidate for

Table of Contents

further clinical development by Bristol-Myers Squibb, Bristol-Myers Squibb has agreed to be solely responsible for further preclinical development as well as clinical development, regulatory, manufacturing and sales/marketing activities for the selected drug candidate. After Bristol-Myers Squibb's selection, except in certain termination scenarios described below, we would not have rights to reacquire the selected drug candidate.

Under the collaboration agreement, Bristol-Myers Squibb paid us a nonrefundable upfront payment in the amount of \$17.5 million and was obligated to provide research and development funding of \$10.0 million per year for an initial research period of two years. In August 2007, the collaboration was extended at Bristol-Myers Squibb's request through January 2009, for which they paid us additional research funding of \$7.5 million. In addition, the collaboration agreement was amended to grant Bristol-Myers Squibb an option to extend the research period for an additional one-year term, through January 2010.

2007 Cancer Collaboration. In December 2006, we entered into a worldwide collaboration with Bristol-Myers Squibb, 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 of our future 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 payment from Bristol-Myers Squibb. Once selected, Bristol-Myers Squibb will lead the further development and commercialization of the selected IND candidates. In addition, we have the right to opt in to co-develop and co-promote the selected IND candidates, in which case we will equally share all development costs and profits in the United States. If we opt-in, we will be responsible for 35% of all development costs related to clinical trials intended to support regulatory approval in both the United States and the rest of the world, with the remaining 65% to be paid by Bristol-Myers Squibb. If we do not opt in to co-promote the selected IND candidates, we could be entitled to receive milestones and royalties in lieu of profits from sales in the United States. Outside of the United States, Bristol-Myers Squibb will have primary responsibility for development activities and we will be entitled to receive royalties on product sales. Once we opt in to co-develop and co-promote an IND candidate, we have the right thereafter to opt out after any clinical trial of the IND candidate. 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.

In January 2008, Bristol-Myers Squibb exercised its option to develop and commercialize compound XL139, which entitled us to a selection milestone payment of \$20.0 million that we received in February 2008. In addition, we exercised our option under the collaboration agreement to co-develop and co-commercialize XL139 in the United States and share expenses and profits. We will be entitled to receive double-digit royalties on product sales of co-developed and co-commercialized products associated with XL139 outside of the United States.

Genentech

In December 2006, we entered into a worldwide co-development agreement with Genentech, Inc. (Genentech), for the development and commercialization of XL518, a small-molecule inhibitor of MEK. Genentech paid us upfront and milestone payments of \$25.0 million in December 2006 and \$15.0 million in January 2007 upon signing of the agreement and with the submission of an IND for XL518. We expect to recognize the upfront and milestone payments as revenue over the estimated research term of 33 months.

In March 2008, Genentech exercised its option to further develop and commercialize compound XL518, entitling us to a milestone payment of \$3.0 million. We will continue to be responsible for the phase 1 clinical trial until the point that a maximum tolerated dose (MTD) is determined. After MTD is achieved, Genentech will be responsible for completing the phase 1 clinical trial and subsequent clinical development. We are entitled to an additional \$7.0 million milestone payment when a phase 2 program is initiated by Genentech. In addition, we have the option to co-promote in the United States and will be entitled to receive an initial equal share in profits within the United States, which will decrease as sales increase. We will receive royalties on any sales of the product that may be commercialized outside of the United States.

GlaxoSmithKline

In October 2002, we established a collaboration with SmithKlineBeecham Corporation, which does business as GlaxoSmithKline, to discover and develop novel therapeutics in the areas of vascular biology, inflammatory disease and oncology. The collaboration involved three agreements: (i) a Product Development and Commercialization Agreement (PDA), (ii) a Stock Purchase and Stock Issuance Agreement and (iii) a Loan and Security Agreement (LSA).

Edgar Filing: EXELIXIS INC - Form 10-Q

Under the LSA, we borrowed \$85.0 million for use in our efforts under the collaboration. The loan bears interest at a rate of 4.0% per annum and is secured by the intellectual property, technology and equipment created or utilized pursuant to the collaboration. Principal and accrued interest becomes due in three annual installments, beginning on October 27, 2009. Repayment of all or any of the amounts advanced to us under this agreement may, at our election, be in the form of our common stock at fair market value, subject to certain conditions.

Table of Contents

In June 2008, we were informed by GlaxoSmithKline that the development term under the existing PDA would not be extended. Accordingly, the original development term concluded on October 27, 2008, as scheduled. GlaxoSmithKline previously selected XL880 and had the right to choose one additional compound from among XL184, XL281, XL228, XL820 and XL844. For periods prior to the quarter ended June 30, 2008, revenues from upfront payments, premiums paid on equity purchases and milestones had been recognized assuming that the development term would be extended through the longest contractual period of October 27, 2010. However, as a result of the development term concluding on the earliest scheduled end date under the PDA, the remaining deferred revenues will be recognized through October 27, 2008. The change in the estimated development term increased our total revenues by \$8.6 million and \$17.3 million for the three and nine month periods ended September 30, 2008, respectively.

In July 2008, we achieved proof-of-concept for XL184 and submitted the corresponding data report to GlaxoSmithKline. On October 22, 2008, GlaxoSmithKline notified us in writing that it decided not to select XL184 for further development and commercialization and that it waived its right to select XL281, XL228, XL820 and XL844 for further development and commercialization. As a result of the conclusion of the six-year collaboration, our exclusivity obligations are limited to XL880. Going forward, we have the right to develop and commercialize all compounds in the collaboration not selected by GlaxoSmithKline, either alone or in collaboration with partners, subject to a 3% royalty payment to GlaxoSmithKline on sales of any products incorporating XL184, or XL647 in the event we exercise our option to reacquire rights to the compound.

NOTE 5. Deerfield Credit Facility

On June 4, 2008, we entered into a Facility Agreement with Deerfield Private Design Fund, L.P., Deerfield Private Design International, L.P., Deerfield Partners, L.P. and Deerfield International Limited (collectively, the Deerfield Entities), pursuant to which the Deerfield Entities agreed to loan to us up to \$150.0 million. We may draw down on the loan facility in \$15.0 million increments through December 4, 2009, with any amounts drawn being due on June 4, 2013. We are under no obligation to draw down on the loan facility and at any time prior to any draw downs, we may terminate the loan facility without penalty. Pursuant to the Facility Agreement, we paid the Deerfield Entities a one time transaction fee of \$3.8 million, or 2.5% of the loan facility. In addition, we are obligated to pay an annual commitment fee of \$3.4 million, or 2.25% of the loan facility, that is payable quarterly and will be recognized as interest expense as incurred. Any outstanding balances under the loan facility will accrue interest at a rate of 6.75% per annum compounded annually and can be repaid at any time with shares of our common stock, subject to certain restrictions, or in cash. If our cash and cash equivalents and marketable securities on the last day of any calendar quarter are less than \$75.0 million, then we would be in default under the Facility Agreement with the Deerfield Entities, and the Deerfield Entities would have the right, among other remedies, to cancel our right to request disbursements and declare immediately due and payable any amounts accrued or payable under the Facility Agreement.

Pursuant to the Facility Agreement, we issued six-year warrants to the Deerfield Entities to purchase an aggregate of 1,000,000 shares of our common stock at an exercise price of \$7.40 per share. In addition, upon drawing on the loan facility, we must issue additional warrants as follows: (a) for each of the first through fifth disbursements, warrants to purchase an aggregate of 400,000 shares of our common stock at an exercise price equal to \$7.40 per share and (b) for each disbursement, warrants to purchase an aggregate of 800,000 shares of our common stock at an exercise price equal to 120% of the average of the Volume Weighted Average Price (as defined in the Facility Agreement) of our common stock for each of the 15 trading days beginning with the trading day following receipt by the Deerfield Entities of a disbursement request. If we were to draw the entire loan facility, we would be required to grant warrants to purchase an aggregate of 11,000,000 shares of our common stock.

The warrants issued upon signing of the Facility Agreement were assigned a value of \$3.4 million using the Black-Scholes option pricing model. The related assumptions were as follows: risk-free interest rate of 3.41%, expected life of six years, volatility of 62% and expected dividend yield of 0%. The value of the warrants and the one time transaction fee of \$3.8 million have been included as deferred charges under Other assets on the accompanying consolidated balance sheet and will be expensed as interest expense over the five year term of the loan facility.

As of September 30, 2008, we had not drawn down under the Facility Agreement.

NOTE 6. Equipment Line of Credit

In June 2008, we drew down \$13.6 million under our Loan and Security Agreement with Silicon Valley Bank, dated May 22, 2002, as amended. This amended agreement provides for an additional equipment line of credit in the amount of up to \$30.0 million with a draw down period of approximately 2 years. Each advance must be repaid in 48 equal, monthly installments of principal, plus accrued interest, at an annual rate of 0.75%. The loan facility requires security in the form of a non-interest bearing certificate of deposit account with the bank. The collateral balance of \$13.6 million was recorded in the accompanying consolidated balance sheet as Cash and cash equivalents and Marketable securities as the deposit is not restricted to withdrawal.

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

On September 4, 2007, we sold to Agrigenetics, Inc. (Agrigenetics), a wholly-owned subsidiary of The Dow Chemical Company, assets used for crop trait discovery and granted to Agrigenetics licenses to certain other related assets and intellectual property. As consideration for these assets and licenses, Agrigenetics paid us \$18.0 million upon execution and \$4.5 million in September 2008, for an aggregate of \$22.5 million. Under the agreement, we have agreed to indemnify Agrigenetics and its affiliates up to a specified amount if they incur damages due to any infringement or alleged infringement of certain patents.

The transaction was accounted for as a sale of our plant trait business and we initially recognized a gain of \$18.8 million, net of \$0.2 million in transaction costs. The gain primarily consisted of a purchase price of \$22.5 million, less a net book value of \$0.3 million of property and equipment, \$2.1 million of intangible assets (acquired patents) and the derecognition of \$1.4 million of goodwill. We allocated goodwill to the disposed business based on the relative fair value of our plant trait business to Exelixis (excluding the value of the Artemis Pharmaceuticals reporting unit) on September 4, 2007, the closing date for the transaction.

In addition to the \$22.5 million consideration above, in September 2008, we received \$4.5 million from Agrigenetics as contingent consideration. We recognized this payment as an additional gain on sale of the business.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis contains forward-looking statements. These statements are based on our current expectations, assumptions, estimates and projections about our business and our industry, and involve known and unknown risks, uncertainties and other factors that may cause our or our industry's results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied in, or contemplated by, the forward-looking statements. Words such as believe, anticipate, expect, intend, plan, will, determine, may, could, would, estimate, predict, potential, continue or the negative of such terms or other similar expressions identify forward-looking statements. Our actual results and the timing of events may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such a difference include those discussed in Part II, Item 1A of this Form 10-Q, as well as those discussed elsewhere in this report.

This discussion and analysis should be read in conjunction with our financial statements and accompanying notes included in this report and the financial statements and accompanying notes thereto included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007, filed with the Securities and Exchange Commission, or SEC, on February 25, 2008. Operating results are not necessarily indicative of results that may occur in future periods. We undertake no obligation to update any forward-looking statement to reflect events after the date of this report.

Overview

We are committed to developing innovative therapies for cancer and other serious diseases. Through our integrated drug discovery and development activities, we are building a portfolio of novel compounds that we believe have the potential to be high-quality, differentiated pharmaceutical products. Our most advanced pharmaceutical programs focus on discovery and development of small molecule drugs for cancer.

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

To date, we have filed 15 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.

Our development portfolio being developed internally includes the following compounds in clinical development:

Edgar Filing: EXELIXIS INC - Form 10-Q

Compound	Principal Targets	Indication	Stage of Development
XL184	MET, VEGFR2, RET	Cancer	Phase 3
XL647*	EGFR, HER2, VEGFR2	Cancer	Phase 2
XL820	KIT, VEGFR2, PDGFR	Cancer	Phase 2
XL281	RAF	Cancer	Phase 1
XL019	JAK2	Cancer	Phase 1
XL844	CHK1, CHK2	Cancer	Phase 1
XL228	IGF1R , ABL, SRC	Cancer	Phase 1
XL147	PI3K	Cancer	Phase 1
XL765	PI3K, mTOR	Cancer	Phase 1
XL888	HSP90	Cancer	Phase 1**

* Out-licensed to Symphony Evolution, Inc., or SEI, and subject to a repurchase option as more fully described below under the heading Certain Factors that May Affect Our Business.

Table of Contents

** We anticipate that the Phase 1 trial will begin in early November 2008.

Though not represented in the table above, we also have compounds in preclinical development that we are developing internally.

Based on the strength of our expertise in biology, drug discovery and development, we have established collaborations with major pharmaceutical and biotechnology companies 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 Bristol-Myers Squibb Company, or Bristol-Myers Squibb, and Genentech, Inc., or Genentech. We expect to continue to use corporate partnering as a strategic tool to cultivate our assets, help fund our operations and expand the therapeutic and commercial potential of our pipeline.

Our development portfolio supported primarily by our collaboration partners includes the following compounds in preclinical and clinical development:

Compound	Partner	Principal Targets	Indication	Stage of Development
XL880	GlaxoSmithKline	MET, VEGFR2	Cancer	Phase 2
XL518*	Genentech	MEK	Cancer	Phase 1
XL652	Bristol-Myers Squibb	LXR	Metabolic and cardiovascular diseases	Phase 1
XL139	Bristol-Myers Squibb	Hedgehog	Cancer	Phase 1
XL550	Daiichi-Sankyo	MR	Metabolic and cardiovascular diseases	Preclinical
FXR	Wyeth Pharmaceuticals	FXR	Metabolic and liver disorders	Preclinical

* We will continue to be responsible for the phase 1 clinical trial until the point that a maximum tolerated dose, or MTD, is determined. After MTD is achieved, Genentech will be responsible for completing the phase 1 clinical trial and subsequent clinical development.

Recent Developments***Conclusion of Six-Year Collaboration with GlaxoSmithKline***

On October 27, 2008, the development term under our six-year collaboration with SmithKlineBeecham Corporation (which does business as GlaxoSmithKline) to discover and develop novel therapeutics in the areas of vascular biology, inflammatory disease and oncology, concluded as scheduled. Under the terms of the collaboration, GlaxoSmithKline had the right to select up to two of the compounds in the collaboration for further development and commercialization. GlaxoSmithKline previously selected XL880 and had the right to choose one additional compound from among XL184, XL281, XL228, XL820, and XL844.

In July 2008, we achieved proof-of-concept for XL184 and submitted the corresponding data report to GlaxoSmithKline. On October 22, 2008, GlaxoSmithKline notified us in writing that it decided not to select XL184 for further development and commercialization and that it waived its right to select XL281, XL228, XL820 and XL844 for further development and commercialization. As a result of the conclusion of the six-year collaboration, our exclusivity obligations are limited to XL880. Going forward, we have the right to develop and commercialize all compounds in the collaboration not selected by GlaxoSmithKline, either alone or in collaboration with partners, subject to a 3% royalty payment to GlaxoSmithKline on sales of any products incorporating XL184. The foregoing royalty obligations will also apply to XL647 in the event we reacquire rights to the compound by exercising our purchase option to acquire all of the equity of SEI, as more fully described below under the heading -Certain Factors that May Affect Our Business.

Strategy Update

As a result of the current turmoil in the capital markets and world economy, we plan to implement a strategy that will bring our net cash usage in line with our cash, with the goal of allowing us to operate independently of the capital markets for a substantial period of time. We are seeking new collaborations for the development and ultimate commercialization of some of our clinical assets, particularly those product candidates for which we believe that the capabilities and bandwidth of a large partner can accelerate development and commercialization more quickly. We also intend to significantly reduce our total costs while maintaining resources consistent with the terms of any new collaborations. Furthermore, we intend to focus our internal later stage clinical development efforts on a limited number of programs. We believe that the most attractive compounds to develop ourselves have a lower-cost, lower-risk route to the market, usually for a niche indication, with the possibility of

Edgar Filing: EXELIXIS INC - Form 10-Q

substantially expanding the market into major indications. We expect to further define and implement these plans during the remainder of 2008 and in early 2009.

XL413 Update

In October 2008, under our collaboration agreement with Bristol-Myers Squibb, we submitted a data report for IND candidate XL413 to Bristol-Myers Squibb. Under the terms of the collaboration, Bristol-Myers Squibb has 30 days to review the data package and determine if it will select the compound for further clinical development and commercialization. If Bristol-Myers Squibb selects XL413, we will be entitled to a \$20 million milestone payment as well as the right to opt in to co-develop and co-promote XL413, in which case we will equally share all development costs and profits in the United States. If we opt-in, we would be responsible for

Table of Contents

35% of all development costs related to XL413 clinical trials intended to support regulatory approval in both the United States and the rest of the world, with the remaining 65% to be paid by Bristol-Myers Squibb. If we do not opt in to co-promote XL413, we could be entitled to receive milestones and royalties in lieu of profits from sales in the United States. Outside of the United States, Bristol-Myers Squibb would have primary responsibility for XL413 development activities and we would be entitled to receive royalties on product sales.

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.

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 factors outside of our control. The future development path of each of our compounds depends upon the results of each stage of clinical development and our analysis of each compound's clinical and commercial potential. 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 September 30, 2008, we had \$135.2 million in cash and cash equivalents and short-term and long-term marketable securities, which included investments held by SEI, of \$18.5 million and restricted cash and investments of \$4.9 million. We anticipate that our current cash and cash equivalents, short-term and long-term marketable securities, investments held by SEI, funds available under the Facility Agreement with the Deerfield Entities and other funding that we expect to receive from collaborators, which assumes a significant 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 our plans for the aggressive development of our broad clinical and preclinical pipelines, whether we generate funds from existing or new collaborations for the development of any of our compounds and whether we repay amounts outstanding under our loan and security agreement with GlaxoSmithKline in cash or shares of our common stock. 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 (the amount by which our current assets exceed our current liabilities as defined by the agreement, which excludes restricted cash and deferred revenue, but includes amounts available for borrowing under the Facility Agreement with the Deerfield Entities) of at least \$25.0 million and cash and investments (total cash, cash equivalents and investments as defined by the agreement, which excludes restricted cash) of at least \$50.0 million. We are also required to maintain certain cash balances in order to access the Facility Agreement with the Deerfield Entities. 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 existing or new collaboration agreements with partners. Milestones under these agreements may be tied to factors that are outside of our control, such as significant clinical or regulatory events with respect to compounds that have been licensed to our partners.

Table of Contents

GlaxoSmithKline Loan Repayment Obligations. In October 2002, we entered into a collaboration with GlaxoSmithKline, to discover and develop novel therapeutics in the areas of vascular biology, inflammatory disease and oncology. As part of the collaboration, we entered into a loan and security agreement with GlaxoSmithKline, pursuant to which we borrowed \$85.0 million for use in our efforts under the collaboration. The loan bears interest at a rate of 4.0% per annum and is secured by certain intellectual property, technology and equipment created or utilized pursuant to the collaboration. Principal and accrued interest under the loan becomes due in three annual installments, beginning on October 27, 2009. Repayment of all or any of the amounts advanced to us under this agreement may, at our election, be in the form of our common stock at fair market value, subject to certain conditions. As of September 30, 2008, the aggregate principal and interest outstanding under our GlaxoSmithKline loan was \$101.1 million. Following the conclusion on October 27, 2008 of the development term under our collaboration with GlaxoSmithKline, we are no longer eligible to receive selection milestone payments from GlaxoSmithKline to credit against outstanding loan amounts, and unstable market conditions may adversely impact our ability to repay the loan in shares of our common stock or result in significantly dilutive impact from any repayment of the loan in shares of our common stock. As a result, we may need to obtain additional funding, including from funds available under the Facility Agreement with the Deerfield Entities, to satisfy our repayment obligations. There can be no assurance that we will have sufficient funds to repay amounts outstanding under the loan when due or that we will satisfy the conditions to our ability to repay the loan in shares of our common stock.

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

Symphony Evolution, Inc. In 2005, we licensed three of our compounds, XL647, XL784 and XL999, to SEI in return for an \$80.0 million investment for the clinical development of these compounds. We have an exclusive purchase option to acquire all of the equity of SEI, thereby allowing us to reacquire XL647, XL784 and XL999 at our sole discretion. We do not have the right to repurchase a single product candidate without also repurchasing the other two product candidates. The purchase option price, which may be paid in cash and/or shares of our common stock, at our sole discretion, would be equal to the sum of (1) the total amount of capital invested in SEI by its investors (\$80.0 million) and (2) an amount equal to 25% per year on such funded capital, compounded from the time of funding. As a result, the purchase option price for the compounds licensed to SEI increases over time. In 2007 we discontinued the development of XL999 and completed the phase 2 trial for XL784; the phase 2 clinical development program for XL647 is ongoing. We are in discussions with SEI regarding the future clinical development of XL647 and XL784 and related funding. We do not intend to further develop XL647 or XL784 on our own. In light of the foregoing, in the absence of a partner, we do not anticipate using our own funds or common stock to exercise the purchase option.

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.

Table of Contents

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. Except as noted below, there have been no changes during the nine months ended September 30, 2008 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 31, 2007.

Fair Value Measurements

As of January 1, 2008, we adopted FASB Statement No. 157, *Fair Value Measurements* or SFAS 157. SFAS 157 established a framework for measuring fair value in GAAP and clarified the definition of fair value within that framework. SFAS 157 does not require any new fair value measurements in GAAP. SFAS 157 introduced, or reiterated, a number of key concepts which form the foundation of the fair value measurement approach to be utilized for financial reporting purposes. The fair value of our financial instruments reflect the amounts that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price). SFAS 157 also established a fair value hierarchy that prioritizes the use of inputs used in valuation techniques into the following three levels:

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

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

Level 3 unobservable inputs.

The adoption of SFAS 157 did not have a material effect on our financial condition and results of operations, but SFAS 157 introduced new disclosures about how we value certain assets and liabilities. Much of the disclosure requirement is focused on the inputs used to measure fair value, particularly in instances where the measurement uses significant unobservable (Level 3) inputs. Our financial instruments are valued using quoted prices in active markets or based upon other observable inputs. The following table sets forth the fair-value of our financial assets that were measured on a recurring basis as of September 30, 2008 (in thousands).

	Level 1	Level 2	Level 3	Total
Marketable securities	\$ 63,282	\$ 55,497	\$	\$ 118,779
Investments held by Symphony Evolution, Inc.	18,473			18,473
Total	\$ 81,755	\$ 55,497	\$	\$ 137,252

The fair value of the Level 2 assets is estimated using pricing models using current observable market information for similar securities. There is a small degree of variation in the pricing sources for these securities; however the potential differences in the estimate of fair value for our available-for-sale securities are immaterial. Due to the current economic crisis, the fair value of our securities could be impacted and if we conclude that these unrealized losses are other than temporary, we will record an impairment charge in other income. For the quarter ending September 30, 2008, we recorded an impairment charge of \$0.2 million to write down the carrying value of our securities to estimated fair value.

Fiscal Year Convention

In 2006, we adopted a 52- or 53-week fiscal year that ends on the Friday closest to December 31st. Fiscal year 2006, a 52-week year, ended on December 29, 2006, fiscal year 2007, a 52-week year, ended on December 28, 2007 and fiscal year 2008, a 53-week year, will end on January 2, 2009. For convenience, references in this report as of and for the fiscal year ended December 28, 2007 are indicated on a calendar year basis, as ending December 31, 2007, and as of and for the three- and nine-month periods ended September 28, 2007 and September 26, 2008 are indicated as ending September 30, 2007 and 2008, respectively.

Table of Contents**Results of Operations****Revenues**

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Contract revenue:				
Research and development funding	\$ 6.3	\$ 13.7	\$ 21.6	\$ 39.7
Milestones	10.3	3.8	30.5	9.3
License revenue:				
Amortization of upfront payments, including premiums paid on equity purchases	13.3	9.3	36.2	35.2
Total revenues	\$ 29.9	\$ 26.8	\$ 88.3	\$ 84.2
Dollar increase	\$ 3.1		\$ 4.1	
Percentage increase	12%		5%	

The decrease in research and development funding revenue for the three months ended September 30, 2008, as compared to the comparable period for the prior year, was primarily due to the exclusion of \$3.5 million of revenues associated with our former subsidiary Artemis Pharmaceuticals GmbH (Artemis), which is no longer consolidated as a result of the sale of 80.1% of our ownership in 2007. In addition, various collaboration agreements with Genentech, Inc. (Genentech), Daiichi-Sankyo Company Limited, (Daiichi-Sankyo) and Agrigenetics, Inc. (Agrigenetics), a wholly-owned subsidiary of The Dow Chemical Company, ended in 2007 and early 2008, resulting in a combined decrease of \$2.5 million. We also had a decrease of \$1.1 million in funding under two of our agreements with Bristol-Myers Squibb in accordance with contractual terms.

The decrease in research and development funding revenue for the nine months ended September 30, 2008, as compared to the comparable period for the prior year, was primarily due to the exclusion of \$9.0 million of revenues associated with Artemis. In addition, various collaboration agreements with Genentech, Daiichi-Sankyo, and Agrigenetics, ended in 2007 and early 2008, resulting in a combined decrease of \$5.8 million. We also had a decrease of \$2.9 million in funding under two of our agreements with Bristol-Myers Squibb, in accordance with contractual terms.

The increase in milestone revenues for the three months ended September 30, 2008, as compared to the comparable period for the prior year, was primarily due to the acceleration of \$4.4 million in deferred revenues under our collaboration with GlaxoSmithKline, for which the development term concluded on October 27, 2008. In periods prior to the quarter ended June 30, 2008, revenues from upfront payments, premiums paid on equity purchases and milestones had been recognized assuming that the development term would be extended through the longest contractual period of October 27, 2010. However, as a result of the development term concluding on the earliest scheduled end date under the collaboration, the remaining deferred revenues will be recognized through October 27, 2008. In addition, we recognized \$1.3 million in revenues associated with the \$20.0 million milestone achieved under collaboration with Bristol-Myers Squibb for various oncology programs and an additional \$0.5 million in revenues associated with the \$3.0 million milestone achieved under our co-development collaboration with Genentech.

The increase in milestone revenues for the nine months ended September 30, 2008, as compared to the comparable period for the prior year, was primarily due to the acceleration of \$8.8 million in deferred revenues under our collaboration with GlaxoSmithKline, for which the development term concluded on October 27, 2008. In addition, we recognized \$8.6 million in revenues associated with the \$20.0 million milestone achieved under collaboration with Bristol-Myers Squibb for various oncology programs and recognized an additional \$2.4 million in revenues achieved under our co-development collaboration with Genentech.

The increase in the amortization of upfront payments for the three months ended September 30, 2008, as compared to the comparable period in the prior year, was primarily due to the acceleration of \$4.2 million in deferred revenues under our collaboration with GlaxoSmithKline. This increase is partially offset by a decrease in revenues of \$0.6 million relating to the conclusion of the amortization of the upfront payments from Genentech related to our collaboration to discover and develop therapeutics directed against certain targets in the Notch signaling pathway, which ended in May 2008.

Edgar Filing: EXELIXIS INC - Form 10-Q

The increase in the amortization of upfront payments for the nine months ended September 30, 2008, as compared to the comparable period for the prior year, including amortization of premiums paid for equity purchases, was primarily due to the acceleration of \$8.4 million in deferred revenues under our collaboration with GlaxoSmithKline. This increase was offset by a decrease in revenues of \$7.7 million relating to the conclusion of the amortization of the upfront payments from Daiichi-Sankyo in December 2007.

Table of Contents**Research and Development Expenses**

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

	Three Months Ended		Nine Months Ended	
	September 30, 2008	September 30, 2007	September 30, 2008	September 30, 2007
Research and development expenses	\$ 65.7	\$ 58.6	\$ 200.5	\$ 165.2
Dollar increase	\$ 7.1		\$ 35.3	
Percentage increase	12%		21%	

Research and development expenses consist primarily of personnel expenses, stock-based compensation, clinical trials, consulting, laboratory supplies and general corporate costs.

The increase for the three month period ended September 30, 2008, as compared to the comparable period in 2007, resulted primarily from the following:

Clinical Trials Clinical trial expenses, which include services performed by third-party contract research organizations and other vendors, increased by \$4.0 million, or 26%, primarily due to start-up activities for a phase 3 clinical trial for XL184, phase 2 clinical trial activity for XL184 and XL647, additional phase 1 clinical trial activity for XL019, XL147, XL228 and XL765, and preclinical studies for XL413 and XL888. These increases were partially offset by a decline in expense associated with XL999 and XL784 phase 2 clinical trial activities, a decline in expense associated with XL443 for non-clinical toxicology studies performed in 2007, and a decline in expenses related to XL880 due to the transfer of XL880 to GlaxoSmithKline in March 2008.

General Corporate Costs There was an increase of \$3.4 million, or 41%, in the allocation of general corporate costs (such as facilities costs, property taxes and insurance) to research and development, which primarily reflected the relative growth of the research and development function compared to the general and administrative function.

Personnel Personnel expense, which includes salaries, bonuses, related fringe benefits, temporaries, recruiting and relocation costs, increased by \$1.5 million, or 8%, primarily due to the expanded workforce supporting drug development operations to advance our clinical and preclinical development programs.

Laboratory Supplies Laboratory supplies expense decreased by \$1.4 million, or 24%, primarily due to cost savings measures implemented during 2008.

The increase for the nine month period ended September 30, 2008, as compared to the comparable period in 2007, resulted primarily from the following:

Clinical Trials Clinical trial expenses increased by \$22.5 million, or 56%, primarily due to start-up activities for a phase 3 clinical trial for XL184, phase 2 clinical trial activity for XL184 and XL647, additional phase 1 clinical trial activity for XL147, XL228, XL281 and XL765, and preclinical studies for XL413 and XL888. The increase was also due in part to start-up activities for a phase 3 clinical trial for XL647 that we subsequently determined not to initiate. These increases were partially offset by a decline in expense associated with XL999 and XL784 phase 2 clinical trial activities, a decline in expense associated with XL443 for non-clinical toxicology studies performed in 2007, and a decline in expenses related to XL880 due to the transfer of XL880 to GlaxoSmithKline in March 2008.

Edgar Filing: EXELIXIS INC - Form 10-Q

Personnel Personnel expense increased by \$8.6 million, or 16%, primarily due to the expanded workforce supporting drug development operations.

General Corporate Costs There was an increase of \$7.3 million, or 29%, in the allocation of general corporate costs (such as facilities costs, property taxes and insurance) to research and development, which primarily reflected the relative growth of the research and development function compared to the general and administrative function.

Cost Reimbursement As a result of our contract research agreement with Agrigenetics, we received research and development funding of \$3.7 million that was recognized as a reduction to research and development expense.

Laboratory Supplies Laboratory supplies expense decreased by \$3.2 million, or 18%, primarily due to cost savings measures implemented during 2008.

Stock-Based Compensation Stock-based compensation expense increased by \$2.4 million, or 28%, primarily due to the expanded workforce supporting drug development operations to advance our clinical and preclinical development programs.

Table of Contents

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

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

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2008	2007	2008	2007
Drug discovery	\$ 25.6	\$ 25.8	\$ 78.3	\$ 76.8
Development	35.6	27.2	109.8	71.1
Other	4.5	5.6	12.4	17.3
Total research and development expense	\$ 65.7	\$ 58.6	\$ 200.5	\$ 165.2

For the nine month period ended September 30, 2008, the programs representing the greatest portion of our research and development expenses (in approximate order of magnitude), based on estimates of the allocation of our research and development efforts and expenses among specific programs, were XL647, X184, XL147, XL765 and XL019. The expenses for these programs are included in the development category of our research and development expenses.

We currently do not have reliable estimates regarding the timing of our clinical trials. We currently estimate that typical phase 1 clinical trials last approximately one year, phase 2 clinical trials last approximately one to two years and phase 3 clinical trials last approximately two to four years. However, the length of time may vary substantially according to factors relating to the particular clinical trial, such as the type and intended use of the drug candidate, the clinical trial design and the ability to enroll suitable patients.

We also currently do not have reliable estimates of total costs for a particular drug candidate to reach the market, as there is great variability in the costs necessary to develop a drug candidate. Our potential therapeutic products are subject to a lengthy and uncertain regulatory process that may involve unanticipated additional clinical trials and may not result in receipt of the necessary regulatory approvals. Failure to receive the necessary regulatory approvals would prevent us from commercializing the drug 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. Our development costs for a particular drug candidate may also be impacted by scope and timing of enrollment in clinical trials for the drug candidate, future decisions to study new indications for the drug candidate and whether in the future we decide to pursue development of the drug candidate with a partner or independently. Similarly, we do not have a reasonable basis to predict when or if material net cash inflows from the commercialization and sale of our drug candidates will occur. To date, we have not commercialized any of our drug candidates and in fact may never do so. For a discussion of the risks and uncertainties associated with the timing and costs of completing the development of the Company's drug candidates, see Part II, Item 1A, Risk Factors.

Table of Contents**General and Administrative Expenses**

Total general and administrative expenses, as compared to the prior year periods, were as follows (dollar amounts are presented in millions):

	Three Months Ended		Nine Months Ended	
	September 30, 2008	September 30, 2007	September 30, 2008	September 30, 2007
General and administrative expenses	\$ 8.9	\$ 10.8	\$ 27.8	\$ 33.2
Dollar decrease	\$ (1.9)		\$ (5.4)	
Percentage decrease	18%		16%	

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 decreases in expenses for the three- and nine-month periods ended September 30, 2008, as compared to the comparable periods in 2007, were primarily due to an increase of \$3.4 million and \$7.3 million, respectively, in the allocation of general corporate costs (such as facilities costs, property taxes and insurance) to research and development, which primarily reflected the relative growth of the research and development function compared to the general and administrative function.

Total Other Income

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

	Three Months Ended		Nine Months Ended	
	September 30, 2008	September 30, 2007	September 30, 2008	September 30, 2007
Total other income	\$ 3.4	\$ 20.7	\$ 5.2	\$ 25.6
Dollar decrease	\$ (17.3)		\$ (20.4)	
Percentage decrease	84%		80%	

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, convertible loans and the Facility Agreement with the Deerfield Entities. The decreases in total other income for the three- and nine-month periods ended September 30, 2008, as compared to the comparable periods in 2007, were primarily due to the inclusion in 2007 of the \$18.8 million gain on the sale of assets recognized in conjunction with our transaction with Agrigenetics, which was accounted for as a sale of our plant trait business, in addition to lower average cash and investment balances and lower average interest rates. In September 2008, we received \$4.5 million from Agrigenetics as contingent consideration and we recognized this payment in total other income, as an additional gain on sale of the business.

In June 2008, we entered into the \$150.0 million Facility Agreement with the Deerfield Entities for which we paid a one time transaction fee of \$3.8 million and issued warrants with a fair value of \$3.4 million. The transaction fee and the value of the warrants are being expensed as interest expense over the five year term of the loan facility. In addition, we are required to pay an annual commitment fee of \$3.4 million that will be recognized as interest expense as incurred.

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. The noncontrolling interest holders' ownership in the consolidated balance sheet was \$3.5 million as of September 30, 2008. 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 through the end of 2008. For the three-month period ended September 30, 2008, the loss attributed to the noncontrolling interest holders was \$2.7 million, as compared to \$8.2 million for the comparable period in 2007, and for the nine month period ended September 30, 2008, the loss attributed to the noncontrolling interest holders was \$9.9 million, as compared to \$22.2 million for the comparable period in 2007. The decreases in the losses attributed to the noncontrolling interest holders for the three- and nine-month periods ended September 30, 2008, as compared to the comparable periods in 2007, were primarily due to decreased development expenses associated with XL784 and XL999.

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

The following table summarizes our cash flow activities for the nine months ended September 30, 2008 and 2007, respectively (in thousands):

	Nine Months Ended	
	September 30,	
	2008	2007
Net loss	\$ (124,905)	\$ (66,459)
Adjustments to reconcile net loss to net cash used in operating activities	13,492	(17,349)
Changes in operating assets and liabilities	(52,165)	39,983
Net cash used in operating activities	(163,578)	(43,825)
Net cash provided by (used in) investing activities	88,045	(10,141)
Net cash provided by financing activities	4,306	72,175
Effect of foreign exchange rate changes on cash and cash equivalents		(252)
Net (decrease) increase in cash and cash equivalents	(71,227)	17,957
Cash and cash equivalents, at beginning of period	135,457	123,369
Cash and cash equivalents, at end of period	\$ 64,230	\$ 141,326

To date, we have financed our operations primarily through the sale of equity, payments and loans from collaborators, equipment financing facilities and interest income. We have also financed certain of our research and development activities under our agreements with SEI. As of September 30, 2008, we had \$135.2 million in cash and cash equivalents and short-term and long-term marketable securities, which included investments held by SEI of \$18.5 million and restricted cash and investments of \$4.9 million. In addition, as of September 30, 2008, approximately \$39.3 million of cash and cash equivalents and marketable securities served as collateral for bank lines of credit.

Operating Activities

Our operating activities used cash of \$163.6 million for the nine months ended September 30, 2008, compared to \$43.8 million for the comparable period in 2007. Cash used by operating activities for the 2008 period related primarily to our net loss of \$124.9 million, losses attributed to noncontrolling interest and to a decrease in cash received from collaborators, which caused a decrease in deferred revenues of \$56.3 million. In addition to the decrease in cash received in 2008, the decline in deferred revenues also reflects the acceleration of \$17.3 million in previously deferred revenue relating to the conclusion of our collaboration with GlaxoSmithKline, the development term for which concluded on October 27, 2008. These uses of cash by operating activities were partially offset by non-cash charges of stock-based compensation expense and depreciation and amortization expense. Cash used in operating activities for the 2007 period primarily related to our net loss of \$66.5 million, losses attributed to noncontrolling interest, and a gain on the sale of our plant trait business, which were partially offset by changes in other receivables, accounts payable and other accrued expenses and non-cash charges such as stock compensation expense, amortization and depreciation.

Cash used in our operating activities increased by \$119.8 million for the nine months ended September 30, 2008, as compared to the comparable period in 2007. This increase was primarily driven by the increase in our net loss and a decrease in deferred revenues and other assets. The increase in our net loss of \$58.4 million was primarily driven by the continued advancement and expansion of our clinical trial activity in addition to the inclusion in 2007 of the \$18.8 million gain on the sale of assets recognized in conjunction with our transaction with Agrigenetics, which was accounted for as a sale of our plant trait business. The decrease in deferred revenues of \$60.2 million year over year primarily relates to a decline in cash received from collaborators in 2008, in addition to the acceleration of revenues under our collaboration with GlaxoSmithKline. As of September 30, 2008, we had received cash payments from collaborators leading to most of our \$45.3 million in deferred revenues that we expect to recognize as revenue of the next 12-month period.

Investing Activities

Edgar Filing: EXELIXIS INC - Form 10-Q

Our investing activities provided cash of \$88.0 million for the nine months ended September 30, 2008, compared to cash used of \$10.1 million for the comparable period in 2007. Cash provided by investing activities for the 2008 period was primarily driven by proceeds of \$83.7 million from the sale and maturities of our marketable securities and the sale of \$13.1 million of investments held by SEI. In addition, in September 2008 we received the \$4.5 million anniversary payment plus an additional \$4.5 million of contingent consideration in association with our transaction with Agrigenetics. This cash inflow was partially offset by purchases of property and equipment of \$13.9 million and marketable securities purchases of \$5.6 million. The proceeds provided by maturities or sale of our marketable securities and the sale of investments by SEI were used to fund our operations. We expect to continue to make moderate investments in property and equipment to support our expanding operations.

Table of Contents

Cash used in investing activities for the 2007 period was primarily driven by purchases of marketable securities of \$173.1 million and purchases of property and equipment of \$14.2 million. These uses of cash were partially offset by proceeds of \$141.2 million from the maturities of marketable securities, \$18.2 million from the sales of investments held by SEI, and \$18.0 million in proceeds associated with the gain on the sale of assets recognized in conjunction with our transaction with Agrigenetics.

Financing Activities

Our financing activities provided cash of \$4.3 million for the nine months ended September 30, 2008, compared to \$72.2 million for the comparable period in 2007. Cash provided by our financing activities for the 2008 period was primarily due to proceeds of \$13.6 million from our notes payable and bank obligations and \$2.4 million from the exercise of stock options and the issuance of stock under the employee stock purchase plan. These increases were partially offset by principal payments on notes payable and bank obligations of \$11.8 million. Cash provided by our financing activities for the 2007 period was primarily from net proceeds of \$71.9 million from the sale of seven million shares of our common stock in September 2007 and proceeds of \$7.8 million from the exercise of stock options, which was partially offset by \$9.3 million of principal payments on notes payable and bank obligations.

We finance property and equipment purchases through equipment financing facilities, such as notes and bank obligations. Proceeds from collaboration loans and common stock issuances are used for general working capital purposes, such as research and development activities and other general corporate purposes. Over the next several years, we are required to make certain payments on notes, bank obligations and our loan from GlaxoSmithKline. In June 2008, we entered into the Facility Agreement with the Deerfield Entities for which the Deerfield Entities agreed to loan to us up to \$150.0 million, subject to certain conditions. We may draw down on the facility in \$15.0 million increments at any time until December 2009. The outstanding principal and interest under the loan, if any, is due by June 4, 2013, and, at our option, can be repaid at any time with shares of our common stock, subject to certain restrictions, or in cash.

Cash Requirements

We have incurred net losses since inception, including a net loss of \$38.5 million for the three-month period ended September 30, 2008 and \$124.9 million for the nine-month period ended September 30, 2008, and we expect to incur substantial losses for at least the next several years as we continue our research and development activities, including manufacturing and development expenses for compounds in preclinical and clinical studies. As of September 30, 2008, we had \$135.2 million in cash and cash equivalents and short-term and long-term marketable securities, compared to \$299.5 million for the period ended December 31, 2007. We anticipate that our current cash and cash equivalents, short-term and long-term marketable securities, investments held by SEI, funds available under the Facility Agreement with the Deerfield Entities and other funding that we expect to receive from collaborators, which assumes a significant level of business development activity, will enable us to maintain our operations for a period of at least 12 months following the filing date of this report. However, our future capital requirements will be substantial and will depend on many factors that may require us to use available capital resources significantly sooner than we currently anticipate. These factors include:

repayment of our loan from GlaxoSmithKline In October 2002, we entered into a collaboration with GlaxoSmithKline, to discover and develop novel therapeutics in the areas of vascular biology, inflammatory disease and oncology. As part of the collaboration, we entered into a loan and security agreement with GlaxoSmithKline, pursuant to which we borrowed \$85.0 million for use in our efforts under the collaboration. The loan bears interest at a rate of 4.0% per annum and is secured by certain intellectual property, technology and equipment created or utilized pursuant to the collaboration. Principal and accrued interest under the loan becomes due in three annual installments, beginning on October 27, 2009. Repayment of all or any of the amounts advanced to us under this agreement may, at our election, be in the form of our common stock at fair market value, subject to certain conditions. As of September 30, 2008, the aggregate principal and interest outstanding under our GlaxoSmithKline loan was \$101.1 million. Following the conclusion on October 27, 2008 of the development term under our collaboration with GlaxoSmithKline, we are no longer eligible to receive selection milestone payments from GlaxoSmithKline to credit against outstanding loan amounts, and unstable market conditions may adversely impact our ability to repay the loan in shares of our common stock or result in a significantly dilutive impact from any repayment of the loan in shares of our common stock. As a result, we may need to obtain additional funding, including from funds available under the Facility Agreement with the Deerfield Entities, to satisfy our repayment obligations. There can be no assurance that we will have sufficient funds to repay amounts outstanding under the loan when due or that we will satisfy the conditions to our ability to repay the loan in shares of our common stock.

Table of Contents

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

the continued clinical development of our product candidates XL647 and XL784, which are out-licensed to SEI In 2007 we discontinued the development of XL999 and completed the phase 2 trial for XL784; the phase 2 clinical development program for XL647 is ongoing. We are in discussions with SEI regarding the future clinical development of XL647 and XL784 and related funding. We do not intend to further develop XL647 or XL784 on our own. In order to retain rights to XL647 and/or XL784 after the expiration of the purchase option period, our agreements with SEI require us to reacquire XL647, XL784 and XL999 from SEI's investors through the exercise of our exclusive purchase option, which is described elsewhere in this report. We do not have the right to repurchase a single product candidate without also repurchasing the other two product candidates. The purchase option price, which may be paid in cash and/or shares of our common stock, at our sole discretion, would be equal to the sum of (1) the total amount of capital invested in SEI by its investors (\$80.0 million) and (2) an amount equal to 25% per year on such funded capital, compounded from the time of funding. As a result, the purchase option price for the compounds licensed to SEI increases over time. In light of the foregoing, we do not anticipate using our own funds or common stock to exercise the purchase option;

our ability to meaningfully reduce costs;

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

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.

In addition, we will have to obtain additional funding in order to stay in compliance with financial covenants under our loan and security agreement with GlaxoSmithKline dated October 28, 2002, as amended. The loan and security agreement 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. We are also required to maintain certain cash balances in order to access the Deerfield Facility.

If our capital resources are insufficient to meet future capital requirements, we will have to raise additional funds. We may seek to raise funds through the sale of equity or debt securities or through external borrowings. In addition, we may enter into strategic partnerships for the development and commercialization of our compounds. However, we may be unable to raise sufficient additional capital when we need it, on favorable terms or at all. The sale of equity or convertible debt securities in the future may be dilutive to our stockholders, and debt-financing arrangements may require us to pledge certain assets and enter into covenants that would restrict

Table of Contents

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 September 30, 2008 (in thousands):

Contractual Obligations (1)	Total	Payments Due by Period			
		Less than 1 year	1-3 years	4-5 years	More than 5 years
Licensing agreements	\$ 546	\$ 546	\$	\$	\$
Notes payable and bank obligations	38,379	16,945	18,601	2,833	
Convertible loans (2)	101,133		67,422	33,711	
Operating leases	167,748	19,543	37,741	38,572	71,892
Total contractual cash obligations	\$ 307,806	\$ 37,034	\$ 123,764	\$ 75,116	\$ 71,892

- (1) In June 2008, we entered into the Facility Agreement pursuant to which the Deerfield Entities agreed to loan to us up to \$150.0 million. We are obligated to pay an annual commitment fee of \$3.4 million or 2.25% of the loan facility, payable quarterly. We are under no obligation to draw down on the loan facility and at any time prior to any draw downs, we may terminate the loan facility without penalty. As a result, such amounts are not included in this table.
- (2) Includes interest payable on convertible loans of \$16.1 million as of September 30, 2008. Additional interest may accrue at 4% per annum. The debt and interest payable can be repaid in cash or common stock at our election. The development term under our collaboration with GlaxoSmithKline concluded on October 27, 2008, as scheduled. As a result of the development term ending as scheduled, the first payment of principal \$28.3 million plus accrued interest will be due in October 2009.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our market risks at September 30, 2008 have not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2007 filed with the SEC. Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio and our long-term debt. We have estimated the effects on our interest rate sensitive assets and liabilities based on a one percentage point hypothetical adverse change in interest rates as of September 30, 2008 and December 31, 2007, respectively. As of September 30, 2008 and December 31, 2007, a decrease in the interest rates of one percentage point would have had a net adverse change in the fair value of interest rate sensitive assets and liabilities of \$1.6 million and \$1.4 million, respectively.

ITEM 4. CONTROLS AND PROCEDURES

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

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

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 for the fiscal year ended December 31, 2007 filed with the Securities and Exchange Commission on February 25, 2008.*

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

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

We will need to raise additional capital to:

fund our operations and clinical trials;

continue our research and development efforts; and

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

As of September 30, 2008, we had \$135.2 million in cash and cash equivalents and short-term and long-term marketable securities, which included investments held by SEI of \$18.5 million and restricted cash and investments of \$4.9 million. We anticipate that our current cash and cash equivalents, short-term and long-term marketable securities, investments held by SEI, funds available under the Facility Agreement with the Deerfield Entities, and other funding that we expect to receive from collaborators, which assumes a significant level of business development activity, will enable us to maintain our operations for a period of at least 12 months following the filing date of this report. However, our future capital requirements will be substantial and will depend on many factors that may require us to use available capital resources significantly earlier than we currently anticipate. These factors include:

repayment of our loan from GlaxoSmithKline In October 2002, we entered into a collaboration with GlaxoSmithKline, to discover and develop novel therapeutics in the areas of vascular biology, inflammatory disease and oncology. As part of the collaboration, we entered into a loan and security agreement with GlaxoSmithKline, pursuant to which we borrowed \$85.0 million for use in our efforts under the collaboration. The loan bears interest at a rate of 4.0% per annum and is secured by certain intellectual property, technology and equipment created or utilized pursuant to the collaboration. Principal and accrued interest under the loan becomes due in three annual installments, beginning on October 27, 2009. Repayment of all or any of the amounts advanced to us under this agreement may, at our election, be in the form of our common stock at fair market value, subject to certain conditions. As of September 30, 2008, the aggregate principal and interest outstanding under our GlaxoSmithKline loan was \$101.1 million. Following the conclusion on October 27, 2008 of the development term under our collaboration with GlaxoSmithKline, we are no longer eligible to receive selection milestone payments from GlaxoSmithKline to credit against outstanding loan amounts, and unstable market conditions may adversely impact our ability to repay the loan in shares of our common stock or result in a significantly dilutive impact from any repayment of the loan in shares of our common stock. As a result, we may need to obtain additional funding, including from funds available under the Facility Agreement with the Deerfield Entities, to satisfy our repayment obligations. There can be no assurance that we will have sufficient funds to repay amounts outstanding under the loan when due or

that we will satisfy the conditions to our ability to repay the loan in shares of our common stock.

whether and when we draw funds under our Facility Agreement with the Deerfield Entities In June 2008, we entered into the Facility Agreement with the Deerfield Entities pursuant to which the Deerfield Entities agreed to loan to us up to \$150.0 million, subject to certain conditions. We may draw down on the facility in \$15.0 million increments at any time until December 2009. The outstanding principal and interest under the loan, if any, is due by June 4, 2013, and, at our option, can be repaid at any time with shares of our common stock, subject to certain restrictions, or in cash. Interest under the loan does not accrue until we draw down on the facility, at which time interest will begin to accrue at a rate of 6.75% per annum compounded annually on the outstanding principal amount of the facility. The Deerfield Entities also have limited rights to accelerate repayment of the loan upon certain changes of control of Exelixis or an event of default. Pursuant to the Facility Agreement, we paid the Deerfield Entities a one time transaction fee of \$3.8 million, or 2.5% of the loan facility, and we are obligated to pay an annual commitment fee of \$3.4 million, or 2.25% of the loan facility, payable quarterly. If we draw down under the Facility Agreement, we would be required to issue to the Deerfield Entities additional warrants to purchase shares of our common stock. If we draw down under the Facility Agreement, there is no

Table of Contents

assurance that the conditions to our ability to repay the loan in shares of our common stock would be satisfied at the time that any outstanding principal and interest under the loan is due, in which case we would be obligated to repay the loan in cash, or that events permitting acceleration of the loan will not occur, in which event we would be required to repay any outstanding principal and interest sooner than anticipated;

the continued clinical development of our product candidates XL647 and XL784, which are out-licensed to SEI. In 2007 we discontinued the development of XL999 and completed the phase 2 trial for XL784; the phase 2 clinical development program for XL647 is ongoing. We are in discussions with SEI regarding the future clinical development of XL647 and XL784 and related funding. We do not intend to further develop XL647 or XL784 on our own. In order to retain rights to XL647 and/or XL784 after the expiration of the purchase option period, our agreements with SEI require us to reacquire XL647, XL784 and XL999 from SEI's investors through the exercise of our exclusive purchase option, which is described elsewhere in this report. We do not have the right to repurchase a single product candidate without also repurchasing the other two product candidates. The purchase option price, which may be paid in cash and/or shares of our common stock, at our sole discretion, would be equal to the sum of (1) the total amount of capital invested in SEI by its investors (\$80.0 million) and (2) an amount equal to 25% per year on such funded capital, compounded from the time of funding. As a result, the purchase option price for the compounds licensed to SEI increases over time. In light of the foregoing, we do not anticipate using our own funds or common stock to exercise the purchase option;

our ability to meaningfully reduce costs;

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

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;

Edgar Filing: EXELIXIS INC - Form 10-Q

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

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

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

One or more of these factors or changes to our current operating plan may require us to use available capital resources significantly earlier than we anticipate. If our capital resources are insufficient to meet future capital requirements, we will have to raise additional funds. We may 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 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 the loan and security agreement, which, as amended, contains financial covenants pursuant to which our working capital (the amount by which our current assets exceed our current liabilities as defined by the agreement, which excludes restricted cash and deferred revenue, but includes amounts available for borrowing under the Facility Agreement) must not be less than \$25.0 million and our cash and investments (total cash, cash equivalents and investments as defined by the agreement, which excludes restricted cash) must not be less than \$50.0 million. As of September 30, 2008, our working capital was \$193.8 million (including \$150.0 million available for borrowing under the Facility Agreement) and our cash and investments were \$135.2 million. If we were to default on the financial

Table of Contents

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 \$101.1 million at September 30, 2008. Principal and accrued interest under the loan becomes due in three annual installments beginning on October 27, 2009. In addition, if our cash and cash equivalents and marketable securities on the last day of any calendar quarter are less than \$75.0 million, then we would be in default under the Facility Agreement with the Deerfield Entities, and the Deerfield Entities would have the right, among other remedies, to cancel our right to request disbursements and declare immediately due and payable any amounts accrued or payable under the Facility Agreement.

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

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

We have incurred net losses since inception, including a net loss of \$38.5 million for the three-month period ended September 30, 2008 and \$124.9 million for the nine-month period ended September 30, 2008. As of that date, we had an accumulated deficit of \$916.6 million. We expect our losses in 2008 to increase as compared to 2007 and anticipate negative operating cash flow for the foreseeable future. We have not yet completed the development, including obtaining regulatory approval, of any of our pharmaceutical product candidates and, consequently, have not generated revenues from the sale of pharmaceutical products. Except for revenues associated with the transgenic mouse business of our former German subsidiary, Artemis Pharmaceuticals, GmbH, or Artemis, our only revenues to date are license revenues and revenues under contracts with our partners. In December 2007, we sold 80.1% of our ownership interest in Artemis, and will not recognize revenue associated with Artemis in future periods. The amount of our net losses will depend, in part, on the rate of growth, if any, in our license and contract revenues and on the level of our expenses. These losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Our research and development expenditures and general and administrative expenses have exceeded our revenues to date, and we expect to spend significant additional amounts to fund research and development in order to enhance our technologies and undertake product development. We currently have numerous product candidates in various stages of clinical development and we anticipate filing additional IND applications for additional product candidates within the next 12 months. As a result, we expect to continue to incur substantial operating expenses, and, consequently, we will need to generate significant additional revenues to achieve profitability. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do increase our revenues and achieve profitability, we may not be able to maintain or increase profitability.

We have licensed the intellectual property, including commercialization rights, to our product candidates XL647, XL784 and XL999 to SEI and will not be able to pursue further development of or enter into partnering arrangements with respect to these product candidates unless we exercise our option to acquire these product candidates or otherwise reach agreement with SEI on terms that would allow us to reacquire some or all of these product candidates.*

We have licensed to SEI our intellectual property rights, including commercialization rights, to our product candidates XL647, XL784 and XL999 in exchange for SEI's investment of \$80.0 million to advance the clinical development of XL647, XL784 and XL999. 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. Under our amended purchase option agreement with SEI, we cannot repurchase a single product candidate without also repurchasing the other two product candidates. We may, at our sole discretion, exercise our purchase option at any time until the earlier of June 9, 2009 or the 90th day after the date on which SEI provides us with financial statements showing cash and cash equivalents of less than \$5.0 million. The purchase option exercise price, which may be paid in cash and/or shares of our common stock, at our sole discretion, is equal to the sum of: (1) the total amount of capital invested in SEI by its investors and (2) an amount equal to 25% per year on such funded capital, compounded from the time of funding. 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. 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, XL784 and XL999 will terminate, and we will no longer have any rights to these compounds. In 2007 we discontinued the development of XL999 and completed the phase 2 trial for XL784; the phase 2 clinical development program for XL647 is ongoing. We are in discussions with SEI regarding the future clinical development of XL647 and XL784 and related funding. We do not intend to further develop XL647 or XL784 on our own. In light of the foregoing, we do not anticipate using our own funds or common stock to exercise the purchase option, and we may not be able to reach agreement with SEI and potential partner(s) on financial terms that would permit the continued development or partnering of XL647 or XL784.

Table of Contents

Risks Related to Development of Product Candidates

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

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

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

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

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

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

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

If any of these events were to occur and, as a result, we were to have significant delays in or termination of our clinical testing, our expenses could increase or our ability to generate revenue from the affected product candidates could be impaired, either of which could adversely impact our financial results. For example, in December 2007 we discontinued our development program for XL999 following observation of cardiac adverse events in the clinical program.

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.

Risks Related to Our Relationships with Third Parties

Disagreements between SEI and us regarding the development of our product candidates XL647 and XL784 may impair our ability to find a partner for and cause significant delays 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, XL784 and XL999, in exchange for SEI's investment of \$80.0 million to advance the clinical development of these three compounds. We are responsible for development 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 impair our ability to find a partner to develop XL647 and XL784 and consequently cause significant delays in the development and commercialization of the compounds. Such disagreements may also 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 and XL784. In December 2007, we discontinued our development program for XL999 following observation of cardiac adverse events in the clinical program.

Table of Contents

We are dependent upon our collaborations with major companies. If we are unable to achieve milestones, develop products or renew or enter into new collaborations, our revenues may decrease and our activities may fail to lead to commercialized products.

We have derived substantially all of our revenues to date from collaborative research and development agreements. Revenues from research and development collaborations depend upon continuation of the collaborations, the achievement of milestones and royalties we earn from any future products developed from the collaborative research. If we are unable to successfully achieve milestones or our collaborators fail to develop successful products, we will not earn the revenues contemplated under such collaborative agreements. In addition, some of our collaborations are exclusive and preclude us from entering into additional collaboration arrangements with other parties in the area or field of exclusivity. Future collaborations may require us to relinquish some important rights, such as marketing and distribution rights.

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

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

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

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

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

Table of Contents

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 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

Table of Contents

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.

*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

Edgar Filing: EXELIXIS INC - Form 10-Q

payors do not provide coverage or reimbursement for any products that we may develop, our revenues and prospects for profitability will suffer. In addition, even if third-party payors provide some coverage or reimbursement for our products, the availability of such coverage or reimbursement for prescription drugs under private health insurance and managed care plans often varies based on the type of contract or plan purchased.

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

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

Table of Contents

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

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

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

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

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

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

Risks Related to Our Intellectual Property

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

Our success will depend in part upon our ability to obtain patents and maintain adequate protection of the intellectual property related to our technologies and products. The patent positions of biotechnology companies, including our patent position, are generally uncertain and involve complex legal and factual questions. We will be able to protect our intellectual property rights from unauthorized use by third parties only to the extent that our technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. We will continue to apply for patents covering our technologies and products as and when we deem appropriate. However, these applications may be challenged or may fail to result in issued patents. In addition, because patent applications can take many years to issue, there may be currently pending

Edgar Filing: EXELIXIS INC - Form 10-Q

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

Table of Contents

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. Regardless of their merit, such claims could require us to incur substantial costs, including the diversion of management and technical personnel, in defending ourselves against any such claims or enforcing our patents. In the event that a successful claim of infringement is brought against us, we may be required to pay damages and obtain one or more licenses from third parties. We may not be able to obtain these licenses at a reasonable cost, or at all. Defense of any lawsuit or failure to obtain any of these licenses could adversely affect our ability to develop and commercialize products.

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

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

Risks Related to Employees, Growth and Location

The loss of key personnel or the inability to 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

Table of Contents

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.

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

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

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

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

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

expensive, and current or future environmental regulations may impair our research, development and production efforts.

Table of Contents

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;

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 securities analysts and investors, which could result in a decline in the price of our common stock.

Table of Contents

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;

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

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

These factors, as well as general economic, political and market conditions, may materially adversely affect the market price of our common stock. As with the stock of many other public companies, the market price of our common stock has been particularly volatile during the recent period of upheaval in the capital markets and world economy. This excessive volatility may continue for an extended period of time following the filing date of this report.

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

We are exposed to risks associated with acquisitions.

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

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

diversion of management's attention from other operational matters;

the potential loss of key employees;

the potential loss of key collaborators;

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

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

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

Table of Contents

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;

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

limitations on the removal of directors; and

advance notice requirements for director nominations and stockholder proposals.

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

ITEM 6. EXHIBITS

(a) Exhibits

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

Table of Contents

SIGNATURES

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

Date: October 27, 2008

EXELIXIS, INC.

/s/ Frank Karbe

Frank Karbe

Executive Vice President and Chief Financial Officer

(Principal Financial and Accounting Officer)

Table of Contents**EXHIBIT INDEX**

Number	Exhibit Description
3.1	Amended and Restated Certificate of Incorporation of Exelixis, Inc. (1)
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Exelixis, Inc. (2)
3.3	Amended and Restated Bylaws of Exelixis, Inc. (3)
4.1	Specimen Common Stock Certificate. (1)
4.2	Form of Warrant, dated June 9, 2005, to purchase 750,000 shares of Exelixis, Inc. common stock in favor of Symphony Evolution Holdings LLC. (4)
4.3	Form of Warrant, dated June 13, 2006, to purchase 750,000 shares of Exelixis, Inc. common stock in favor of Symphony Evolution Holdings LLC. (5)
4.4	Warrant Purchase Agreement, dated June 9, 2005, between Exelixis, Inc. and Symphony Evolution Holdings LLC. (4)
4.5	Form Warrant to Purchase Common Stock of Exelixis, Inc. issued or issuable to Deerfield Private Design Fund, L.P., Deerfield Private Design International, L.P., Deerfield Partners, L.P. and Deerfield International Limited (6)
4.6	Fourth Amended and Restated Registration Rights Agreement, dated February 26, 1999, among Exelixis, Inc. and certain Stockholders of Exelixis, Inc. (1)
4.7	Registration Rights Agreement, dated October 18, 2004, by and among Exelixis, Inc., X-Ceptor Therapeutics, Inc., and certain holders of capital stock of X-Ceptor Therapeutics, Inc. listed in Annex I thereto. (7)
4.8	Registration Rights Agreement, dated October 18, 2004, by and among Exelixis, Inc., X-Ceptor Therapeutics, Inc., and certain holders of capital stock of X-Ceptor Therapeutics, Inc. listed in Annex I thereto. (7)
4.9	Registration Rights Agreement, dated June 9, 2005, between Exelixis, Inc. and Symphony Evolution Holdings LLC. (4)
4.10	Registration Rights Agreement between Exelixis, Inc. and Deerfield Private Design Fund, L.P., Deerfield Private Design International, L.P., Deerfield Partners, L.P. and Deerfield International Limited dated June 4, 2008 (6)
10.1*	Fourth Amendment to the Loan and Security Agreement, dated as of July 10, 2008, by and between SmithKlineBeecham Corporation d/b/a GlaxoSmithKline and Exelixis, Inc. (8)
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 granted for certain portions of this exhibit

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

Table of Contents

- (1) Filed as an Exhibit to Exelixis, Inc. s Registration Statement on Form S-1 (File No. 333-96335), as filed with the Securities and Exchange Commission on February 7, 2000, as amended, and incorporated herein by reference.
- (2) Filed as an Exhibit to Exelixis, Inc. s Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, filed with the Securities and Exchange Commission on August 5, 2004 and incorporated herein by reference.
- (3) Filed as an Exhibit to Exelixis, Inc. s Current Report on Form 8-K, as filed with the Securities and Exchange Commission on October 4, 2007 and incorporated herein by reference.
- (4) Filed as an Exhibit to Exelixis, Inc. s Quarterly Report on Form 10-Q for the quarter ended June 30, 2005, filed with the Securities and Exchange Commission on August 9, 2005 and incorporated herein by reference.
- (5) Filed as an Exhibit to Exelixis, Inc. s Current Report on Form 8-K, as filed with the Securities and Exchange Commission on June 15, 2006 and incorporated herein by reference.
- (6) Filed as an Exhibit to Exelixis, Inc. s Current Report on Form 8-K, as filed with the Securities and Exchange Commission on June 9, 2008 and incorporated herein by reference.
- (7) Filed as an Exhibit to Exelixis, Inc. s Current Report on Form 8-K, as filed with the Securities and Exchange Commission on October 21, 2004 and incorporated herein by reference.
- (8) Filed as an Exhibit to Exelixis, Inc. s Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, filed with the Securities and Exchange Commission on August 5, 2008 and incorporated herein by reference.