

EXELIXIS INC  
Form 10-Q  
November 06, 2006  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

\_\_\_\_\_  
**FORM 10-Q**  
\_\_\_\_\_

**x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the quarterly period ended September 30, 2006

Or

**.. TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 0-30235

\_\_\_\_\_  
**Exelixis, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**04-3257395**  
(I.R.S. Employer

Identification No.)

**170 Harbor Way**

**P.O. Box 511**

**South San Francisco, CA 94083**

(Address of principal executive offices, including zip code)

**(650) 837-7000**

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(Registrant's telephone number, including area code)

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

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

Large accelerated filer  Accelerated filer  Non-accelerated filer

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

On October 27, 2006 there were 95,775,300 shares of common stock, par value \$.001 per share, of Exelixis, Inc. outstanding.

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**EXELIXIS, INC.**

**QUARTERLY REPORT ON FORM 10-Q**

**FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2006**

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

	<b>September 30, 2006 (unaudited)</b>	<b>December 31, 2005 <sup>(1)</sup></b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 55,700	\$ 81,328
Marketable securities	15,965	67,307
Investments held by Symphony Evolution, Inc.	59,740	34,039
Other receivables	3,511	7,102
Prepaid expenses and other current assets	7,502	5,442
Total current assets	142,418	195,218
Restricted cash and investments	11,221	12,682
Long-term marketable securities	11,768	15,143
Property and equipment, net	33,344	35,577
Goodwill	67,364	67,364
Other intangibles, net	2,704	3,425
Other assets	1,838	3,303
Total assets	\$ 270,657	\$ 332,712
<b>LIABILITIES, NONCONTROLLING INTEREST AND STOCKHOLDERS EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 2,755	\$ 1,689
Other accrued expenses	13,613	13,774
Accrued compensation and benefits	10,781	7,817
Current portion of capital lease obligations		98
Current portion of notes payable and bank obligations	11,527	11,893
Convertible promissory note		30,000
Deferred revenue	43,655	43,484
Total current liabilities	82,331	108,755
Notes payable and bank obligations	15,965	21,858
Convertible promissory loans	85,000	85,000
Other long-term liabilities	19,180	14,475
Deferred revenue	42,845	45,329
Total liabilities	245,321	275,417
Noncontrolling interest in Symphony Evolution, Inc.	44,934	23,752
Commitments		
Stockholders' equity (deficit):		
Common stock	84	84
Additional paid-in-capital	659,198	636,263
Accumulated other comprehensive income	1,207	973
Accumulated deficit	(680,087)	(603,777)

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Total stockholders' equity (deficit)	(19,598)	33,543
Total liabilities, noncontrolling interest and stockholders' equity (deficit)	\$ 270,657	\$ 332,712

<sup>(1)</sup> The condensed consolidated balance sheet at December 31, 2005 has been derived from the audited consolidated financial statements at that date but does not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements.

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

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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
<b>Revenues:</b>				
Contract	\$ 13,347	\$ 10,279	\$ 42,609	\$ 45,323
License	10,193	4,121	26,290	16,261
<b>Total revenues</b>	<b>23,540</b>	<b>14,400</b>	<b>68,899</b>	<b>61,584</b>
<b>Operating expenses:</b>				
Research and development	46,048	35,202	133,344	105,091
General and administrative	8,843	6,819	27,834	20,173
Amortization of intangibles	210	271	722	815
<b>Total operating expenses</b>	<b>55,101</b>	<b>42,292</b>	<b>161,900</b>	<b>126,079</b>
Loss from operations	(31,561)	(27,892)	(93,001)	(64,495)
<b>Other income (expense):</b>				
Interest income	1,892	1,581	5,829	3,555
Interest expense	(1,071)	(1,550)	(3,943)	(4,647)
Other income (expense), net	(3)		(29)	190
<b>Total other income (expense)</b>	<b>818</b>	<b>31</b>	<b>1,857</b>	<b>(902)</b>
Loss before noncontrolling interest	(30,743)	(27,861)	(91,144)	(65,397)
Loss attributed to noncontrolling interest	5,546	5,086	14,834	5,515
<b>Net loss</b>	<b>\$ (25,197)</b>	<b>\$ (22,775)</b>	<b>\$ (76,310)</b>	<b>\$ (59,882)</b>
<b>Net loss per share, basic and diluted</b>	<b>\$ (0.30)</b>	<b>\$ (0.29)</b>	<b>\$ (0.91)</b>	<b>\$ (0.77)</b>
Shares used in computing basic and diluted net loss per share	84,178	79,540	83,972	77,288

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

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

	<b>Nine Months Ended September 30,</b>	
	<b>2006</b>	<b>2005</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (76,310)	\$ (59,882)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation and amortization	12,566	12,554
Loss attributed to noncontrolling interest	(14,834)	(5,515)
Stock-based compensation expense	13,155	35
Amortization of intangibles	722	815
Loss (gain) on the sale of equipment	35	(138)
Other	552	446
<b>Changes in assets and liabilities:</b>		
Other receivables	3,584	(2,347)
Prepaid expenses and other current assets	(2,063)	(2,843)
Other assets	674	(966)
Accounts payable and other accrued expenses	4,064	(2,238)
Other long-term liabilities	4,705	4,754
Deferred revenue	(2,313)	15,141
<b>Net cash used in operating activities</b>	<b>(55,463)</b>	<b>(40,184)</b>
<b>Cash flows from investing activities:</b>		
Purchases of investments held by Symphony Evolution, Inc.	(41,593)	(40,330)
Proceeds from sale of investments held by Symphony Evolution, Inc.	15,892	2,788
Purchases of property and equipment	(8,337)	(11,119)
Proceeds from sale of equipment	4	153
Change in restricted cash and investments	1,462	2,518
Proceeds from maturities of marketable securities	91,508	86,221
Purchases of marketable securities	(36,599)	(84,591)
<b>Net cash provided by (used in) investing activities</b>	<b>22,337</b>	<b>(44,360)</b>
<b>Cash flows from financing activities:</b>		
Proceeds from the issuance of common stock, net of offering costs		58,468
Proceeds from exercise of stock options and warrants	2,519	1,089
Proceeds from employee stock purchase plan	1,267	1,116
Payments on capital lease obligations	(98)	(1,682)
Proceeds from notes payable and bank obligations	2,424	6,618
Principal payments on notes and bank obligations	(38,683)	(7,581)
Proceeds from purchase of noncontrolling interest by preferred shareholders in Symphony Evolution, Inc., net of fees	40,000	37,000
<b>Net cash provided by financing activities</b>	<b>7,429</b>	<b>95,028</b>
Effect of foreign exchange rate changes on cash and cash equivalents	69	(132)

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Net increase (decrease) in cash and cash equivalents	(25,628)	10,352
Cash and cash equivalents, at beginning of period	81,328	67,541
Cash and cash equivalents, at end of period	\$ 55,700	\$ 77,893

### Supplemental cash flow disclosure:

Warrants issued in conjunction with the Symphony Evolution, Inc. transaction	\$ 3,984	\$ 2,842
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The accompanying notes are an integral part of these condensed consolidated financial statements.



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**EXELIXIS, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**SEPTEMBER 30, 2006**

**(unaudited)**

**NOTE 1 Organization and Summary of Significant Accounting Policies**

**Organization**

Exelixis, Inc. ( Exelixis, we, our or us ) is a biotechnology company committed to using its discovery and development capabilities to develop high-quality, differentiated pharmaceutical products for the treatment of cancer and other serious diseases. The majority of our pharmaceutical programs focus on drug discovery and development of small molecules in cancer. We believe that our proprietary technologies and drug discovery engine are also valuable to other industries whose products can be enhanced by an understanding of DNA or proteins, including the agrochemical and agricultural industries. We also maintain operations in Germany, which are engaged in activities dedicated towards the provision of transgenic mouse generation services, tools and related licenses to the industrial and academic community.

**Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and pursuant to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission ( SEC ). Accordingly, they do not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements. In our opinion, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the results of operations and cash flows for the periods presented have been included. Operating results for the three- and nine-month periods ended September 30, 2006 are not necessarily indicative of the results that may be expected for the year ending December 31, 2006 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 year ended December 31, 2005 included in our Annual Report on Form 10-K filed with the SEC on March 9, 2006.

Exelixis adopted a 52- or 53-week fiscal year that ends on the last Friday in December. Fiscal year 2006, a 52-week year, will end on December 30, 2006.

**Basis of Consolidation**

The consolidated financial statements include the accounts of Exelixis and our wholly owned subsidiaries as well as one variable interest entity, Symphony Evolution, Inc., for which we are the primary beneficiary as defined by Financial Accounting Standards Board ( FASB ) Interpretation No. 46 (revised 2003), *Consolidation of Variable Interest Entities* ( FIN 46R ). All significant intercompany balances and transactions have been eliminated. We have determined that our subsidiary located in Germany, Artemis Pharmaceuticals, is an operating segment and it has been aggregated into one reportable segment with Exelixis.

**Net Loss Per Share**

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

**Stock-Based Compensation**

We adopted Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment*, ( SFAS 123R ) effective January 1, 2006, which requires the recognition of stock-based compensation at fair value in our consolidated statements of operations. We adopted SFAS 123R under the modified prospective method and therefore we have not restated results for prior periods. Under the modified prospective method, we recorded compensation expense for all awards granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair

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value estimated in accordance with the original provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, ( SFAS 123 ). Stock-based compensation expense for all stock-based compensation awards granted after January 1, 2006 is based on the grant date fair value estimated using the Black-Scholes option pricing model. We recognize compensation expense on a straight-line basis over the requisite service period. Prior to the adoption of SFAS 123R, we recognized stock-based compensation expense in

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accordance with Accounting Principles Board ( APB ) Opinion No. 25, Accounting for Stock Issued to Employees ( APB 25 ). See Note 3 to the Condensed Consolidated Financial Statements for a further discussion on stock-based compensation.

**Reclassification**

Certain prior period amounts have been reclassified to conform to the current period presentation. We reclassified certain amounts from cash and cash equivalents to long-term marketable securities.

**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		Nine Months Ended	
	September 30, 2006	September 30, 2005	September 30, 2006	September 30, 2005
Net loss	\$ (25,197)	\$ (22,775)	\$ (76,310)	\$ (59,882)
Increase (decrease) in unrealized gains on available-for-sale securities	156	(37)	320	(66)
Reclassification for losses on marketable securities recognized in earnings	43		43	
Increase (decrease) in foreign currency translation adjustment	(20)	5	(129)	254
Comprehensive loss	\$ (25,018)	\$ (22,807)	\$ (76,076)	\$ (59,694)

**NOTE 3 Stock-Based Compensation***Stock Option Plans*

We have several stock option plans under which we have granted incentive stock options and non-qualified stock options to employees, directors and consultants. The Board of Directors or a designated Committee of the Board is responsible for administration of our employee stock option plans and determines the term, exercise price and vesting terms of each option. In general, our options have a four-year vesting term, an exercise price equal to the fair market value on the date of grant, and a ten year life from the date of grant. As of September 30, 2006, a total of 7.8 million shares were available for grant under our stock option plans.

*Stock Purchase Plan*

In January 2000, we adopted the 2000 Employee Stock Purchase Plan (the ESPP). The ESPP allows for qualified employees (as defined in the ESPP) to purchase shares of our common stock at a price equal to the lower of 85% of the closing price at the beginning of the offering period or 85% of the closing price at the end of each six month purchase period. As of September 30, 2006, we had 1.4 million shares available for grant under our ESPP.

*Adoption of SFAS 123R*

SFAS 123R requires the recognition of stock-based compensation at fair value in our consolidated statements of operations. We recognize stock-based compensation expense net of estimated forfeitures in order to only recognize the expense for the shares expected to vest on a straight-line basis over the requisite service period of the award, which is generally the option vesting term of four years. We estimated the forfeiture rate for the nine-month period ended September 30, 2006, based on our historical experience, at an annual rate of 3.9%.

As a result of adopting SFAS 123R, we recorded employee stock-based compensation expense of \$4.0 million and \$13.0 million for the three- and nine-month periods ended September 30, 2006, respectively. The impact on both basic and diluted net loss per share for the three- and nine-month periods ended September 30, 2006 were \$0.05 and \$0.16, respectively. For the three- and nine-month periods ended September 30, 2006, employee stock-based compensation expenses under SFAS 123R were allocated as follows (in thousands):

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	<b>Three Months</b>	<b>Nine Months</b>
	<b>Ended September 30, 2006</b>	<b>Ended September 30, 2006</b>
Research and development expense	\$ 2,520	\$ 8,515
General and administrative expense	1,525	4,513
<b>Total employee stock-based compensation expense</b>	<b>\$ 4,045</b>	<b>\$ 13,028</b>

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Prior to January 1, 2006, we provided pro forma disclosure amounts in accordance with SFAS 123, as if we recorded stock based compensation using the fair value method defined by SFAS 123. The following table illustrates the effect on net loss and loss per share for the three- and nine-month periods ended September 30, 2005, had we applied the fair value recognition provisions of SFAS 123 (in thousands, except per share amounts):

	Three Months Ended September 30, 2005	Nine Months Ended September 30, 2005
Net loss:		
As reported	\$ (22,775)	\$ (59,882)
Add: Stock-based employee compensation reversal included in reported net loss		(16)
Deduct: Total stock-based employee compensation expense determined under fair value method for all awards	(2,667)	(9,450)
Pro forma net loss	\$ (25,442)	\$ (69,348)
Net loss per share (basic and diluted):		
As reported	\$ (0.29)	\$ (0.77)
Pro forma	\$ (0.32)	\$ (0.90)

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,	
	2006	2005	2006	2005
Weighted average grant date fair value of grants	\$ 5.67	\$ 3.97	\$ 2.99	\$ 2.72
Risk-free interest rate	4.84%	3.81%	4.90%	2.20%
Dividend yield	0%	0%	0%	0%
Volatility	68%	65%	53%	63%
Expected life	4.7 years	4.0 years	0.5 years	0.5 years

	Stock Options Nine Months Ended September 30,		ESPP Nine Months Ended September 30,	
	2006	2005	2006	2005
Weighted average grant date fair value of grants	\$ 5.37	\$ 4.78	\$ 2.62	\$ 2.72
Risk-free interest rate	4.38%	3.59%	4.53%	2.20%
Dividend yield	0%	0%	0%	0%
Volatility	64%	71%	54%	63%
Expected life	4.7 years	4.0 years	0.5 years	0.5 years

A summary of all stock option activity for the nine months ended September 30, 2006 is presented below:

Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
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Options outstanding at December 31, 2005	13,157,431	\$	10.73		
Granted	4,117,805		9.53		
Exercised	(333,852)		7.30		
Cancelled	(745,451)		12.42		
Options outstanding at September 30, 2006	16,195,933	\$	10.42	7.4 years	\$ 7,379,665
Exercisable at September 30, 2006	8,647,418	\$	11.49	6.0 years	\$ 6,953,723

The aggregate intrinsic value in the table above represents the total intrinsic value (the difference between our closing stock price on the last trading day of the third quarter of fiscal 2006 and the exercise prices, multiplied by the number of

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in-the-money options) that would have been received by the option holders had all option holders exercised their options on September 30, 2006. Total intrinsic value of options exercised for the three- and nine-month periods ended September 30, 2006 was \$0.1 million and \$1.1 million, respectively. Total fair value of options vested during the three- and nine-month periods ended September 30, 2006 was \$3.8 million and \$12.4 million, respectively. Compensation expense related to our ESPP for the three- and nine-month periods ended September 30, 2006 was \$0.2 million and \$0.6 million, respectively.

As of September 30, 2006, \$38.8 million of total unrecognized compensation expense related to stock options is expected to be recognized over a weighted-average period of 3.0 years. Cash received from option exercises for the three- and nine-month periods ended September 30, 2006 was \$0.1 million and \$2.4 million, respectively.

**NOTE 4 Bristol-Myers Squibb**

In December 2005, Exelixis and Bristol-Myers Squibb ( BMS ) entered into a collaboration agreement for the discovery, development and commercialization of novel therapies targeted against the Liver X Receptor ( LXR ), a nuclear hormone receptor implicated in a variety of cardiovascular and metabolic disorders. This agreement became effective in January 2006, at which time Exelixis granted BMS an exclusive, worldwide license with respect to certain intellectual property primarily relating to compounds that modulate LXR. During the research term, Exelixis and BMS expect to jointly identify drug candidates that are ready for IND-enabling studies. After the selection of a drug candidate for further clinical development by BMS, BMS will be solely responsible for further preclinical development as well as clinical development, regulatory, manufacturing and sales/marketing activities for the selected drug candidate and we do not have rights to reacquire such drug candidates.

Under the LXR collaboration agreement, BMS paid Exelixis a nonrefundable upfront payment in the amount of \$17.5 million and is obligated to provide research and development funding of \$10.0 million per year for an initial research period of two years. BMS has the option to extend the research period for an additional one-year term. The upfront payment and the research and development funding will be recognized as revenue over the research period. Under the agreement, BMS is required to pay us development and regulatory milestones of up to \$140.0 million per product for up to two products from the collaboration. In addition, we are also entitled to receive sales milestones and royalties on any sales of products commercialized under the agreement.

**NOTE 5 Sankyo Company**

In March 2006, Exelixis and Sankyo Company, a wholly owned subsidiary of Daiichi Sankyo Company, Limited ( Sankyo ), entered into a collaboration agreement for the discovery, development and commercialization of novel therapies targeted against the mineralocorticoid receptor ( MR ), a nuclear hormone receptor implicated in a variety of cardiovascular and metabolic diseases. Under the terms of the agreement, we granted to Sankyo an exclusive, worldwide license with respect to certain intellectual property primarily relating to compounds that modulate MR. After completion of the research term, Sankyo will be responsible for all further preclinical and clinical development, regulatory, manufacturing and commercialization activities for the compounds and we do not have rights to reacquire such compounds.

Sankyo paid us a nonrefundable upfront payment in the amount of \$20.0 million and is obligated to provide research and development funding of \$3.8 million over a 15-month research term. Exelixis and Sankyo may mutually agree to extend the research term for an additional two years. The upfront payment and research and development funding will be recognized as revenue over the research term, which commenced on April 1, 2006. For each product from the collaboration, Exelixis is also entitled to receive payments upon attainment of pre-specified development, regulatory and commercialization milestones. In addition, Exelixis is also entitled to receive royalties on sales of certain products commercialized under the collaboration. Sankyo may terminate the agreement upon 90 days written notice in which case Sankyo's payment obligations will cease, its license relating to compounds that modulate MR will terminate and revert to us, and we will receive, subject to certain terms and conditions, licenses from Sankyo to research, develop and commercialize compounds that were discovered under the agreement.

**NOTE 6 Helsinn Healthcare**

In June 2005, Exelixis and Helsinn Healthcare S.A. ( Helsinn ) entered into a license agreement for the development and commercialization of XL119 (becatecarin). Helsinn paid us a nonrefundable upfront payment in the amount of \$4.0 million and is obligated to pay additional development and commercialization milestones, as well as royalties on worldwide sales. The upfront payment was recognized as revenue during 2005. Helsinn assumed all costs incurred for the ongoing multi-national Phase 3 clinical trial for XL119 after the execution of the license agreement.

In May 2006, we supplied Helsinn with certain clinical trial materials in order for Helsinn to maintain the current enrollment in the ongoing Phase 3 clinical trial for XL119. Helsinn's acceptance of the clinical trial materials triggered a \$4.0





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million milestone payment, which was received and recognized as revenue in June 2006. We are eligible to receive further milestones of up to \$17.0 million.

**NOTE 7 PDL BioPharma**

Pursuant to the original terms of the 2001 agreement with PDL BioPharma, Inc. (formerly Protein Design Labs), Exelixis repaid in full the \$30.0 million convertible promissory note in May 2006.

**NOTE 8 Symphony Evolution**

On June 9, 2005, we entered into a series of related agreements providing for the financing of the clinical development of XL784, XL647 and XL999 (the Programs). Pursuant to the agreements, Symphony Evolution, Inc. (SEI) and its investors have invested \$80.0 million to fund the clinical development of these Programs and we licensed to SEI our intellectual property rights related to these Programs. SEI is a wholly owned subsidiary of Symphony Evolution Holdings LLC (Holdings), which provided the first \$40.0 million in funding to SEI in June 2005 and an additional \$40.0 million on June 9, 2006. We continue to be primarily responsible for the development of the Programs in accordance with specified development plans and related development budgets.

We issued to Holdings warrants to purchase an aggregate of 1.5 million shares of our common stock at \$8.90 per share. The initial warrants for 750,000 shares of common stock were issued in June 2005 in connection with the initial \$40.0 million in funding and were assigned a value of \$2.8 million. The subsequent warrants for 750,000 shares of common stock were issued in connection with the additional \$40.0 million in funding in June 2006 and were assigned a value of \$4.0 million. We valued the warrants in accordance with the Black-Scholes option valuation methodology and recorded such values as a reduction to the noncontrolling interest in SEI. The warrants have a five-year contractual term.

**NOTE 9 Subsequent Event**

In October 2006, we completed a public offering of 11.5 million shares of our common stock under an effective registration statement, at a price of \$8.40 per share, for gross proceeds of \$96.6 million. We received approximately \$90.5 million in net proceeds after deducting underwriting fees of \$5.8 million and estimated offering expenses of approximately \$0.3 million.

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

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

*This discussion and analysis should be read in conjunction with our financial statements and accompanying notes included in this report and the 2005 audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2005, filed with the Securities and Exchange Commission on March 9, 2006. 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 a biotechnology company focused on the discovery and development of novel small molecule therapeutics for cancer and other serious diseases. Utilizing our library of more than four million compounds, we integrate high-throughput processes, medicinal chemistry, bioinformatics, structural biology and early *in vivo* testing in parallel to characterize thousands of compounds. This approach enables us to identify and select from this large pool of compounds those highly qualified drug candidates that meet our stringent list of development criteria. Our broad pipeline consists of product candidates in various stages of development that target cancer, renal disease and various metabolic and cardiovascular disorders. Most of these product candidates are orally administered small molecules and we believe that they offer advantages over currently available therapies.

We currently have a total of 18 compounds in clinical and preclinical development. We believe the breadth and quality of our pipeline represents a key strategic asset that diversifies the risk associated with product development and demonstrates the productivity of our drug discovery and development platform.

Our business strategy is to become a fully integrated biotechnology company by leveraging our broad pipeline of diverse compounds with first-in-class or best-in-class potential that fulfill unmet medical needs in the treatment of cancer and other serious diseases. To execute our strategy, we intend to continue to establish strategic alliances with world-class pharmaceutical and biotechnology companies that generate near-term revenues, diversify our risk of product failure and allow us to retain meaningful long-term value.

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

**Pipeline Update**

Our current pipeline includes the following compounds:

<b>Compound</b>	<b>Target(s)</b>	<b>Indication</b>	<b>Stage of Development</b>
XL119*	Topoisomerase 2	Biliary Tract Cancer	Phase 3
XL999**	VEGFR2, PDGFR, FGFR, FLT3	Renal Cell Carcinoma, Colon, Ovarian, Non-Small Cell Lung Cancer, Acute Myelogenous Leukemia, Multiple Myeloma	Phase 2
XL784**	ADAM10, MMP-2	Diabetic Nephropathy	Phase 2



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XL880	c-MET, VEGFR2	Papillary Renal Cell Carcinoma	Phase 2
XL647**	VEGFR2, EGFR, HER2	Non-Small Cell Lung Cancer	Phase 2
XL820	c-KIT, VEGFR2, PDGFR	Solid Tumors	Phase 1
XL844	CHK1, CHK2	Solid Tumors and Hematologic Malignancies	Phase 1
XL184	c-MET, VEGFR2	Solid Tumors	Phase 1
XL228	ABL, IGF1R, SRC	Solid Tumors and Hematologic Malignancies	IND Filed
XL281	RAF	Solid Tumors	IND Filed
XL418	AKT, S6K	Solid Tumors	Preclinical
XL518	MEK	Solid Tumors	Preclinical
XL147	PI-3K	Solid Tumors	Preclinical
XL765	PI-3K, mTOR	Solid Tumors	Preclinical
XL019	JAK2	Hematologic Malignancies	Preclinical
XL550*	MR	Hypertension	Preclinical
XL335*	FXR	Atherosclerosis	Preclinical
EXEL2255*	LXR	Atherosclerosis	Preclinical

\* XL119, XL550, XL335 and EXEL2255 are out-licensed to Helsinn, Sankyo, Wyeth and Bristol-Myers Squibb, respectively.

\*\* Out-licensed to Symphony Evolution, Inc. and subject to exclusive repurchase options as described in this report. Pursuant to a product development and commercialization agreement between Exelixis and GlaxoSmithKline, GlaxoSmithKline has the option, after completion of clinical proof-of-concept by Exelixis, to elect to develop up to three compounds in Exelixis' product pipeline, which may include XL784 and any of the cancer compounds identified in the table above (other than XL119, XL518, XL147, XL765 and XL019).

We currently have 10 compounds in clinical development. XL119, which has been exclusively licensed to Helsinn Healthcare S.A. of Switzerland, is in a multi-national Phase 3 clinical trial for the treatment of bile duct tumors. XL999 is being evaluated in Phase 2 clinical trials in patients with renal cell, colorectal, ovarian, and non-small cell lung cancer as well as acute myelogenous leukemia (AML) and multiple myeloma. In November 2006, we suspended enrollment of new patients into the XL999 clinical trial program until further data have been collected and analyzed. We suspended enrollment after a preliminary review of patient data relating to adverse events for the month of October showed an apparent increase in the rate of serious adverse cardiovascular events compared to the period prior to October. We commenced a Phase 2 clinical trial for XL784 in March 2006 to test its efficacy in patients with renal failure. In June 2006, we initiated a Phase 2 clinical trial for XL880 in papillary renal cell carcinoma and we expect to initiate three additional Phase 2 clinical trials for XL880 in the first quarter of 2007 (one in head and neck cancer and two in gastric cancer). In August 2006, we initiated a Phase 2 clinical trial for XL647 in patients with non-small cell lung cancer and we expect to initiate three additional Phase 2 clinical trials for XL647 in the first quarter 2007 (two in non-small cell lung cancer and one metastatic breast cancer). In addition, we have Phase 1 clinical trials ongoing for XL820, XL844 and XL184. These compounds are being tested in patients with various solid tumors for which there is no other treatment option with the exception of XL844, which is being tested in patients with chronic lymphocytic leukemia (CLL).

All of our compounds, with the exception of XL119 (which was in-licensed from Bristol-Myers Squibb), were generated through our internal drug discovery efforts. The oncology program currently is comprised of 14 compounds—nine in clinical development and five in preclinical development. In October 2006, we filed an IND for XL281 and we intend to file an IND for XL518 by the end of 2006. We are also continuing our preclinical work on XL418, XL147, XL765 and XL019, all of which are potential IND candidates in 2007.

We have licensed to Symphony Evolution, Inc. (SEI) our intellectual property rights, including commercialization rights, to XL647, XL999 and XL784 in exchange for SEI's investment of \$80.0 million to advance the clinical development of these compounds. We have retained exclusive options to reacquire the compounds, including intellectual property rights and commercialization rights at specified prices. We continue to be primarily responsible for the development of these product candidates in accordance with a specified development plan and related development budget.



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### **Recent Developments**

#### **Bristol-Myers Squibb**

In December 2005, Exelixis and Bristol-Myers Squibb entered into a collaboration agreement for the discovery, development and commercialization of novel therapies targeted against the Liver X Receptor (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, Exelixis and Bristol-Myers Squibb expect to jointly identify drug candidates that are ready for IND-enabling studies. After the selection of a drug candidate for further clinical development by Bristol-Myers Squibb, Bristol-Myers Squibb will be solely responsible for further preclinical development as well as clinical development, regulatory, manufacturing and commercialization activities for the selected drug candidate and we do not have rights to reacquire such drug candidates.

Under the LXR collaboration agreement, Bristol-Myers Squibb paid us a nonrefundable upfront payment in the amount of \$17.5 million and is obligated to provide research and development funding of \$10.0 million per year for an initial research period of two years. Bristol-Myers Squibb has the option to extend the research period for an additional one-year term. The upfront payment and the research and development funding will be recognized as revenue over the research period. Under the agreement, Bristol-Myers Squibb is required to pay us development and regulatory milestones of up to \$140.0 million per product for up to two products from the collaboration. In addition, we are also entitled to receive sales milestones and royalties on any sales of products commercialized under the collaboration. Bristol-Myers Squibb has the option to terminate the collaboration agreement starting in January 2008, in which case Bristol-Myers Squibb's payment obligations will cease, its license relating to compounds that modulate LXR will terminate and revert to us, and we will receive, subject to certain terms and conditions, licenses from Bristol-Myers Squibb to research, develop and commercialize certain collaboration compounds that were discovered under the agreement.

#### **Sankyo Company**

In March 2006, Exelixis and Sankyo Company, a wholly owned subsidiary of Daiichi Sankyo Company, Limited (Sankyo), entered into a collaboration agreement for the discovery, development and commercialization of novel therapies targeted against the mineralocorticoid receptor (MR), a nuclear hormone receptor implicated in a variety of cardiovascular and metabolic diseases. Under the terms of the agreement, we granted to Sankyo an exclusive, worldwide license to certain intellectual property primarily relating to compounds that modulate MR. After completion of the research term, Sankyo will be responsible for all further preclinical and clinical development, regulatory, manufacturing and commercialization activities for the compounds and we do not have rights to reacquire such compounds.

Sankyo paid us a nonrefundable upfront payment in the amount of \$20.0 million and is obligated to provide research and development funding of \$3.8 million over a 15-month research term. Exelixis and Sankyo may mutually agree to extend the research term for an additional two years. The upfront payment and research and development funding will be recognized as revenue over the initial research term, which commenced on April 1, 2006. For each product from the collaboration, we are also entitled to receive payments upon attainment of pre-specified development, regulatory and commercialization milestones. In addition, we are also entitled to receive royalties on any sales of certain products commercialized under the collaboration. Sankyo may terminate the agreement upon 90 days' written notice in which case Sankyo's payment obligations will cease, its license relating to compounds that modulate MR will terminate and revert to us, and we will receive, subject to certain terms and conditions, licenses from Sankyo to research, develop and commercialize compounds that were discovered under the agreement.

#### **Helsinn Healthcare**

In June 2005, Exelixis and Helsinn Healthcare S.A. (Helsinn) entered into a license agreement for the development and commercialization of XL119 (becatecarin). Helsinn paid us a nonrefundable upfront payment in the amount of \$4.0 million and is obligated to pay development and commercialization milestones, as well as royalties on worldwide sales. The upfront payment was recognized as revenue during 2005. Helsinn assumed all costs incurred for the ongoing multi-national Phase 3 clinical trial for XL119 after the execution of the license agreement.

In May 2006, we supplied Helsinn with certain clinical trial materials in order for Helsinn to maintain the current enrollment in the ongoing Phase 3 clinical trial for XL119. Helsinn's acceptance of the clinical trial materials triggered a \$4.0 million milestone payment, which was received and recognized as revenue in June 2006. We are eligible to receive further milestones of up to \$17.0 million.

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Beginning in June 2006, if Helsinn determines, based on reasonable business judgment from scientific or economic evidence, that it is unable to carry out further development or marketing of XL119, it may terminate the license agreement upon six months' prior written notice.

### **PDL BioPharma**

Pursuant to the original terms of the 2001 agreement with PDL BioPharma, Inc. (formerly Protein Design Labs), Exelixis repaid in full the \$30.0 million convertible promissory note in May 2006.

### **Symphony Evolution**

On June 9, 2005, we closed a transaction involving a series of related agreements providing for the financing of the clinical development of XL784, XL647 and XL999. Pursuant to the agreements, SEI and its investors have invested \$80.0 million to fund the clinical development of our product candidates XL784, XL647 and XL999, and we have licensed to SEI our intellectual property rights related to these product candidates. SEI is a wholly owned subsidiary of Symphony Evolution Holdings LLC (Holdings), which provided \$40.0 million in funding to SEI at closing and an additional \$40.0 million on June 9, 2006. We continue to be primarily responsible for the development of XL784, XL647 and XL999 in accordance with specified development plans and related development budgets.

### **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 testing and expect to continue to advance more compounds into clinical development. Our compounds may fail to show safety or efficacy in clinical testing. Furthermore, predicting the timing of the completion or initiation 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. 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, 2006, we had \$154.4 million in cash and cash equivalents and short-term and long-term marketable securities, which included investments held by SEI of \$59.7 million and restricted cash and investments of \$11.2 million. In October 2006, we received net proceeds, after underwriting fees and estimated offering expenses, of approximately \$90.5 million from the sale of 11.5 million shares of our common stock under an effective shelf registration statement. We anticipate that our current cash and cash equivalents, short-term and long-term marketable securities, investments held by SEI and other funding that we expect to receive from collaborators, which assumes a moderate level of business development activity, will enable us to maintain our operations for a period of at least 12 months following the filing date of this report. However, our future capital requirements will be substantial and depend on many factors, including the timing of key events in our agreements with GlaxoSmithKline and SEI that may require us to consume available capital resources significantly sooner than we currently anticipate. We will have to obtain additional funding in order to support our plans for the aggressive development of our broad clinical and preclinical pipelines. Our minimum liquidity needs are also determined by certain financial covenants contained in our loan and security agreement with GlaxoSmithKline, which require us to maintain working capital of at least \$25.0 million and cash and investments of at least \$50.0 million. Our ability to raise additional funds may be severely impaired if any of our product candidates fails to show safety or efficacy in clinical testing.

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*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 revenues, such as milestone and royalty revenues, will be generated from collaboration agreements with our partners. Milestones under these agreements may be tied to factors that are outside of our control, such as significant clinical or regulatory events with respect to compounds that have been licensed to our partners.



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*GlaxoSmithKline Compound Selection.* Pursuant to our product development and commercialization agreement with GlaxoSmithKline, GlaxoSmithKline has the option, after completion of clinical proof-of-concept by us, to elect to develop up to three compounds in our product pipeline, which may include XL784, XL647, XL999, XL880, XL184, XL820, XL844, XL281, XL418, XL228 and two earlier stage oncology programs. XL784, XL647 and XL999 have been licensed to SEI, as described below. A compound selection by GlaxoSmithKline could potentially trigger significant milestone payments to be received by Exelixis. The size of these milestone payments depends largely on how quickly we can advance compounds to proof-of-concept. Delays in obtaining clinical proof-of-concept for compounds subject to GlaxoSmithKline's election rights may decrease the size of any GlaxoSmithKline milestones and negatively affect our financial position.

*Symphony Evolution.* In 2005, we licensed three of our lead compounds (XL784, XL647 and XL999) to SEI in return for \$80.0 million in investment for the clinical development of these compounds. We continue to be primarily responsible for the development of these compounds in accordance with specified development plans and related development budgets. We have retained exclusive options to reacquire the compounds from SEI at specified purchase prices. The repurchase prices for the compounds licensed to SEI increase over the length of the option period. If GlaxoSmithKline elects any of the compounds licensed to SEI for further development, we would be required to repurchase such compound or compounds from SEI. If selection milestones received under our GlaxoSmithKline collaboration are insufficient to cover the repurchase price, or if we repurchase one or all of the compounds in anticipation of one or more milestones from GlaxoSmithKline that are not ultimately received in the anticipated time frame or at all, we may have to raise additional funds to cover the repurchase price.

**Critical Accounting Estimates**

Our consolidated financial statements and related notes are prepared in accordance with U.S. generally accepted accounting principles (GAAP), which requires us to make judgments, estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses and related disclosure of contingent assets and liabilities. We have based our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our senior management has discussed the development, selection and disclosure of these estimates with the Audit Committee of our Board of Directors. Actual results may differ from these estimates under different assumptions or conditions.

An accounting policy is considered to be critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, and if different estimates that reasonably could have been used, or changes in the accounting estimates that are reasonably likely to occur periodically, could materially impact the financial statements. There have been no changes during the nine months ended September 30, 2006 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, 2005.

**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		Nine Months	
	Ended		Ended	
	September 30, 2006	September 30, 2005	September 30, 2006	September 30, 2005
Contract revenue:				
Research and development funding	\$ 11.5	\$ 8.7	\$ 34.0	\$ 38.2
Milestones	1.8	1.6	8.6	7.1
License revenue:				
Amortization of upfront payments, including premiums paid on equity purchases	10.2	4.1	26.3	16.3
Total revenues	\$ 23.5	\$ 14.4	\$ 68.9	\$ 61.6

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Dollar increase	\$ 9.1	\$ 7.3
Percentage increase	63%	12%
The increase of \$2.8 million in research and development funding for the three months ended September 30, 2006, as compared to the comparable prior year period, was primarily a result of increases in funding from new collaborations,		

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notably \$2.5 million from Bristol-Myers Squibb and \$0.8 million from Sankyo. This was partially offset by a decrease in funding of \$0.4 million related to the conclusion of our development activities under the Helsinn license agreement. The decrease of \$4.2 million in research and development funding for the nine months ended September 30, 2006, as compared to the comparable prior year period, was primarily a result of the conclusion of our Genoptera collaboration in June 2005, which included a one-time termination fee related to research and development funding of \$13.4 million. This decrease was partially offset by increases in funding of \$7.2 million from Bristol-Myers Squibb, \$1.3 million from Sankyo and \$1.2 million from Genentech.

The increase of \$1.5 million in milestone revenues for the nine months ended September 30, 2006, as compared to the comparable prior year period, was primarily associated with a \$4.0 million milestone achieved under our collaboration with Helsinn. This increase was partially offset by a decrease of \$2.7 million in accelerated milestone revenues related to the conclusion of our Genoptera collaboration in June 2005.

The increase of \$6.1 million in the amortization of upfront payments, including premiums paid on equity purchases for the three months ended September 30, 2006, as compared to the comparable prior year period, was primarily due to additional revenues from upfront payments of \$4.1 million from Sankyo, \$2.5 million from Wyeth Pharmaceuticals and \$1.5 million from Bristol-Myers Squibb. This increase was partially offset by a decrease of \$2.0 million related to the conclusion of our collaboration with Helsinn. The increase of \$10.0 million in the amortization of upfront payments, including premiums paid on equity purchases, for the nine months ended September 30, 2006, as compared to the comparable prior year period, was primarily due to additional revenues from upfront payments of \$8.2 million from Sankyo, \$7.5 million from Wyeth and \$4.2 million from Bristol-Myers Squibb. This increase was partially offset by a decrease of \$7.8 million related to the conclusion of our Genoptera collaboration in June 2005, which included acceleration of upfront payments, and by a decrease of \$2.4 million related to the conclusion of our collaboration with Helsinn.

**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		Nine Months	
	Ended		Ended	
	September 30, 2006	2005	September 30, 2006	2005
Research and development expenses	\$ 46.0	\$ 35.2	\$ 133.3	\$ 105.1
Dollar increase	\$ 10.8		\$ 28.3	
Percentage increase	31%		27%	

Research and development expenses consist primarily of personnel expenses, employee stock-based compensation expenses, laboratory supplies, consulting and facilities costs. The increase for the three months ended September 30, 2006, as compared to the comparable period in 2005, resulted primarily from the following:

**Consulting and Professional** Consulting and professional expense, which includes services performed by third-party contract research organizations and other vendors, increased by \$5.1 million, or 91%, primarily due to an increase in activities associated with advancing our clinical and preclinical development programs. These activities included Phase 2 clinical trial activity for XL999, XL784, XL880 and XL647 and Phase 1 clinical trial activity for XL844, XL820 and XL184 as well as pre-clinical activity for XL228, XL281, XL418, XL518, XL147, XL765 and XL019.

**Personnel** Personnel expense, which includes salaries, bonuses, related fringe benefits, recruiting and relocation costs, increased by \$3.1 million, or 26%, primarily due to the expanded workforce supporting drug development operations to advance our clinical and preclinical development programs.

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**Employee Stock-Based Compensation** Employee stock-based compensation expense increased by \$2.5 million due to our adoption of SFAS 123R effective January 1, 2006.

The increase for the nine months ended September 30, 2006, as compared to the comparable period in 2005, resulted primarily from the following:

**Consulting and Professional** Consulting and professional expense, which includes services performed by third-party contract research organizations and other vendors, increased by \$13.0 million, or 89%, primarily due to an increase in activities associated with the advancing of our clinical and preclinical development programs, as described above.

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**Employee Stock-Based Compensation** Employee stock-based compensation expense increased by \$8.5 million due to our adoption of SFAS 123R effective January 1, 2006.

**Personnel** Personnel expense, which includes salaries, bonuses, related fringe benefits, recruiting and relocation costs, increased by \$6.2 million, or 17%, primarily due to the expanded workforce supporting drug development operations to advance our clinical and preclinical development programs.

We currently estimate that typical Phase 1 clinical trials last approximately one year, Phase 2 clinical trials last approximately one to two years and Phase 3 clinical trials last approximately two to four years. However, the length of time may vary substantially according to factors relating to the particular clinical trial, such as the type and intended use of the product candidate, the clinical trial design and the ability to enroll suitable patients. We expect that research and development expenses will continue to increase as we advance our compounds through development.

We currently do not have estimates of total costs for a particular drug candidate to reach the market. Our potential therapeutic products are subject to a lengthy and uncertain regulatory process that may involve unanticipated additional clinical trials and may not result in the necessary regulatory approvals. Failure to receive the necessary regulatory approvals would prevent us from commercializing the product candidates affected. In addition, clinical trials of our potential products may fail to demonstrate safety and efficacy, which could prevent or significantly delay regulatory approval.

**General and Administrative Expenses**

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

	Three Months		Nine Months	
	Ended		Ended	
	September 30, 2006	2005	September 30, 2006	2005
General and administrative expenses	\$ 8.8	\$ 6.8	\$ 27.8	\$ 20.2
Dollar increase	\$ 2.0		\$ 7.7	
Percentage increase	30%		38%	

General and administrative expenses consist primarily of personnel expenses, employee stock-based compensation expense, facility costs and consulting and professional expenses, such as legal and accounting fees. The increase in expenses for the three months ended September 30, 2006, as compared to the comparable period in 2005, and for the nine months ended September 30, 2006, as compared to the comparable period in 2005, resulted primarily from increases of \$1.5 million and \$4.5 million, respectively, in employee stock-based compensation expense due to our adoption of SFAS 123R as well as increases in consulting and personnel expenses to support our general operating activities.

**Amortization of Intangibles**

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

	Three Months		Nine Months	
	Ended		Ended	
	September 30, 2006	2005	September 30, 2006	2005
Amortization of intangible assets	\$ 0.2	\$ 0.3	\$ 0.7	\$ 0.8
Dollar decrease	\$ 0.1		\$ 0.1	
Percentage decrease	23%		11%	

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Intangible assets result from our acquisitions of X-Ceptor, Genomica, Artemis and Agritope (renamed Exelixis Plant Sciences). The decrease in amortization of intangibles expense for the three months ended September 30, 2006, as compared to the comparable period in 2005, and for the nine months ended September 30, 2006, as compared to the comparable period in 2005, were due to decreases in amortization expenses related to fully amortized expenses for the developed technology related to our acquisition of Artemis in 2001.

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

	Three Months		Nine Months	
	Ended		Ended	
	September 30, 2006	2005	September 30, 2006	2005
Total other income (expense)	\$ 0.8	\$	\$ 1.9	\$ (0.9)
Dollar increase	\$ 0.8		\$ 2.8	

Total other income (expense) consists primarily of interest income earned on cash and cash equivalents, short-term and long-term marketable securities and investments held by SEI, partially offset by interest expense incurred on our notes payable, bank obligations, capital lease obligations and convertible notes and loans. The increase in total other income (expense) for the three months ended September 30, 2006, as compared to the comparable period in 2005, and for the nine months ended September 30, 2006, as compared to the comparable period in 2005, was primarily due to increases in interest income as a result of higher cash and investment balances and higher average interest rates. Such increase was also affected by a decrease in interest expense due to the repayment of our PDL Biopharma convertible promissory note in May 2006.

**Noncontrolling Interest in Symphony Evolution, Inc.**

We have consolidated SEI's financial condition and results of operations in accordance with Financial Accounting Standards Board (FASB) Interpretation No. 46 (revised 2003), *Consolidation of Variable Interest Entities* (FIN 46R), commencing June 9, 2005. While we have consolidated SEI's financial condition and results of operations in accordance with FIN 46R, SEI is wholly owned by the noncontrolling interest holders. Therefore, we have deducted the losses attributed to the noncontrolling interest (SEI's losses) from our net loss in the condensed consolidated statement of operations and we have also reduced the noncontrolling interest holders' ownership interest in SEI in the condensed consolidated balance sheet by SEI's losses. For the three- and nine-month periods ended September 30, 2006, the losses attributed to the noncontrolling interest holders were \$5.5 million and \$14.8 million, respectively, as compared to \$5.1 million and \$5.5 million, respectively, for the comparable periods in 2005.

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

The following table summarizes our cash flow activities for the nine-month periods ended September 30, 2006 and 2005 (dollar amounts are presented in thousands), respectively:

	Nine Months Ended	
	September 30, 2006	2005
Net loss	\$ (76,310)	\$ (59,882)
Adjustments to reconcile net loss to net cash used in operating activities	12,196	8,197
Changes in operating assets and liabilities	8,651	11,501
Net cash used in operating activities	(55,463)	(40,184)
Net cash provided by (used in) investing activities	22,337	(44,360)
Net cash provided by financing activities	7,429	95,028
Effect of foreign exchange rate changes on cash and cash equivalents	69	(132)

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Net increase (decrease) in cash and cash equivalents	(25,628)	10,352
Cash and cash equivalents, at beginning of year	81,328	67,541
 Cash and cash equivalents, at end of period	 \$ 55,700	 \$ 77,893

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, 2006, we had \$154.4 million in cash and cash equivalents and short-term and long-term marketable securities, which includes investments held by SEI of \$59.7 million and restricted cash and investments of \$11.2 million.

### *Operating Activities*

Our operating activities used cash of \$55.5 million and \$40.2 million for the nine months ended September 30, 2006 and 2005, respectively. Cash used in operating activities for the 2006 period related primarily to funding net losses and losses attributed to the noncontrolling interest, partially offset by changes in non-cash charges related to stock-based compensation expense recognized due to our adoption of SFAS 123R and non-cash charges related to depreciation and amortization. Cash



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used in operating activities for the 2005 period related primarily to funding net losses, partially offset by changes in deferred revenues from collaborators and non-cash charges related to depreciation and amortization.

The increase of \$15.3 million in cash used in our operating activities for the 2006 period, as compared to the 2005 period, was primarily driven by a \$16.4 million increase in our net loss. While cash used in operating activities is primarily driven by our net loss, operating cash flows differ from our net loss as a result of differences in the timing of cash receipts and earnings recognition, expenses related to the noncontrolling interest and non-cash charges. For example, deferred revenue decreased by \$2.3 million during the 2006 period, which represents an excess in revenues recognized in the 2006 period over cash received. In addition, losses attributed to the noncontrolling interest in SEI of \$14.8 million and \$5.5 million for the nine-month periods ended September 30, 2006 and 2005, respectively, were included in operating activities but excluded from net loss. We expect to use cash for operating activities for the next several years as we continue to incur net losses associated with our research and development activities, including manufacturing and development expenses for compounds in preclinical and clinical studies.

*Investing Activities*

Our investing activities provided cash of \$22.3 million and used cash of \$44.4 million for the nine months ended September 30, 2006 and 2005, respectively. Cash provided by investing activities for the 2006 period and cash used in investing activities for the 2005 period, were primarily due to purchases and proceeds from maturities of marketable securities, purchases and proceeds from sale of investments held by SEI and purchases of property and equipment.

The increase of \$66.7 million in cash provided by investing activities for the 2006 period, as compared to the 2005 period, was primarily due to a decrease in purchases of marketable securities of \$48.0 million, an increase of \$13.1 million from proceeds from sale of investments held by SEI and an increase of \$5.3 million in proceeds from maturities of marketable securities. In the nine months ended September 30, 2006 and 2005, respectively, we made purchases of \$8.3 million and \$11.1 million, respectively, of property and equipment. We expect to continue to make significant investments in research and development and our administrative infrastructure, including purchases of property and equipment to support our expanding preclinical and clinical development operations.

*Financing Activities*

Our financing activities provided cash of \$7.4 million and \$95.0 million for the nine months ended September 30, 2006 and 2005, respectively. Cash provided by our financing activities for the 2006 period was primarily due to proceeds of \$40.0 million from the purchase of noncontrolling interest by preferred shareholders in SEI. The cash provided by SEI's preferred shareholders was partially offset by principal payments on notes and bank obligations of \$38.7 million, which included the repayment of a \$30.0 million convertible promissory note to PDL BioPharma. Cash provided by our financing activities for the 2005 period was primarily due to net proceeds of \$37.0 million from the purchase of the noncontrolling interest by preferred shareholders in SEI and net proceeds of \$49.6 million received through the sale of our common stock. In addition, we received \$11.1 million from the purchase of 1.0 million shares of our common stock by GlaxoSmithKline, which included a \$2.2 million premium.

We finance property and equipment purchases through equipment financing facilities, such as capital leases, notes and bank obligations. Proceeds from collaboration loans and common stock issuances are used for general working capital purposes, such as research and development activities and other general corporate purposes. Over the next several years, we are required to make certain payments on notes, bank obligations and loans from collaborators.

**Cash Requirements**

We have incurred net losses since inception, including a net loss of \$76.3 million for the nine-month period ended September 30, 2006, and expect to incur substantial losses for at least the next several years as we continue our research and development activities, including manufacturing and development expenses for compounds in preclinical and clinical studies. In October 2006, we received net proceeds, after underwriting fees and estimated offering expenses, of approximately \$90.5 million from the sale of 11.5 million shares of our common stock under an effective shelf registration statement. We anticipate that our current cash and cash equivalents, short-term and long-term marketable securities, investments held by SEI and other funding that we expect to receive from collaborators, which assumes a moderate level of business development activity, will enable us to maintain our operations for a period of at least 12 months following the filing date of this report. However, our future capital requirements will be substantial and will depend on many factors that may require us to consume available capital resources significantly sooner than we currently anticipate. These factors include:

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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 providing for funding;

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

the timing and progress of the clinical development of our out-licensed product candidates XL647, XL999 and XL784, which will determine if and when we exercise our program and/or purchase options to reacquire these product candidates from SEI;

whether and when GlaxoSmithKline selects at proof-of-concept for further development one or more of the product candidates licensed to SEI, which would require us to repurchase the selected candidate or candidates through the exercise of our purchase option or program option, and the amount of any selection milestones received from GlaxoSmithKline compared to the amount we are required to pay or previously paid to exercise the purchase option or program option;

the relative timing of the exercise of our options to repurchase candidates from SEI and GlaxoSmithKline's selection, or decision not to select, product candidates for further development and the possibility that we repurchase one or all of the compounds in anticipation of one or more milestones from GlaxoSmithKline that are ultimately not received in the anticipated time frame or at all;

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

future clinical trial results;

our plans 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 contained in our collaboration with GlaxoSmithKline. Under a loan and security agreement, 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.

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If our capital resources are insufficient to meet future capital requirements, we will have to raise additional funds. We currently have a shelf registration statement on file with the SEC that allows us to offer for sale from time to time common stock, preferred stock, debt securities and warrants, either individually or in units. However, we may be unable to raise sufficient additional capital when we need it, on favorable terms or at all. The sale of equity or convertible debt securities in the future may be dilutive to our stockholders, and debt-financing arrangements may require us to pledge certain assets and enter into covenants that would restrict certain business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our stockholders or us. If we are unable to obtain adequate funds on reasonable terms, we may be required to curtail operations significantly or obtain funds by entering into financing, supply or collaboration agreements on unattractive terms or we may be required to relinquish rights to technology or product candidates or to grant licenses on terms that are unfavorable to us.

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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, 2006 (in thousands):

	Total	Payments Due by Period			
		Less than 1 year	1-3 years	4-5 years	More than 5 years
Contractual Obligations					
Notes payable and bank obligations	\$ 27,491	\$ 11,527	\$ 14,197	\$ 1,767	\$
Licensing agreements	1,949	1,311	618	20	
Convertible promissory loans	94,333		31,130	63,203	
Operating leases	152,854	15,440	28,406	27,564	81,444
<b>Total contractual cash obligations</b>	<b>\$ 276,627</b>	<b>\$ 28,278</b>	<b>\$ 74,351</b>	<b>\$ 92,554</b>	<b>\$ 81,444</b>

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

Our market risks at September 30, 2006 have not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2005 on file with the Securities and Exchange Commission. Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio and our long-term debt. 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, 2006 and December 31, 2005, respectively. As of September 30, 2006 and December 31, 2005, 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 \$2.4 million and \$3.3 million, respectively.

**ITEM 4. CONTROLS AND PROCEDURES**

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

**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.

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**PART II. OTHER INFORMATION**

**ITEM 1A. RISK FACTORS**

*An updated description of the risk factors associated with our business is set forth below. This description includes any material changes to the risk factors associated with our business previously disclosed in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2005.*

**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, 2006, we had \$154.4 million in cash and cash equivalents and short-term and long-term marketable securities, which included investments held by SEI of \$59.7 million and restricted cash and investments of \$11.2 million. In October 2006, we received net proceeds, after underwriting fees and estimated offering expenses, of \$90.5 million from the sale of 11.5 million shares of our common stock under our shelf registration statement. We anticipate that our current cash and cash equivalents, short-term and long-term marketable securities, investments held by SEI and other funding that we expect to receive from collaborators, which assumes a moderate level of business development activity, will enable us to maintain our operations for a period of at least 12 months following the filing date of this report. However, our future capital requirements will be substantial and will depend on many factors that may require us to consume available capital resources significantly sooner than we currently anticipate. These factors include:

the 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 for additional payments;

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

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

the timing and progress of the clinical development of our out-licensed product candidates XL647, XL999 and XL784, which will determine if and when we exercise our program and/or purchase options to reacquire these product candidates from SEI;

whether and when GlaxoSmithKline selects at proof-of-concept for further development one or more of the product candidates licensed to SEI, which would require us to repurchase the selected candidate or candidates through the exercise of our purchase option

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or program option, and the amount of any selection milestones received from GlaxoSmithKline compared to the amount we are required to pay to exercise the purchase option or program option;

the relative timing of the exercise of our options to repurchase candidates from SEI and GlaxoSmithKline's selection, or decision not to select, product candidates for further development and the possibility that we repurchase one or all of the compounds in anticipation of one or more milestones from GlaxoSmithKline that are ultimately not received in the anticipated time frame or at all;

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;

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

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

One or more of these factors or changes to our current operating plan may require us to consume available capital resources significantly sooner than we expect. 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 a loan and security agreement, dated October 28, 2002, which, as amended, contains financial covenants pursuant to which our working capital (the amount by which our current assets exceed our current liabilities as defined by the agreement) must not be less than \$25.0 million and our cash and investments (total cash, cash equivalents and investments as defined by the agreement, which excludes restricted cash) must not be less than \$50.0 million. As of September 30, 2006, our working capital was \$60.1 million and our cash and investments were \$143.2 million. If we were to default on the financial covenants under the loan and security agreement, GlaxoSmithKline may, among other remedies, declare immediately due and payable all obligations under the loan and security agreement. Outstanding borrowings and accrued interest under the loan and security agreement totaled \$94.3 million at September 30, 2006.

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 each year since our inception, including a net loss of \$76.3 million for the nine-month period ended September 30, 2006. As of that date, we had an accumulated deficit of \$680.1 million. We expect these losses to continue and anticipate negative operating cash flow for the foreseeable future. We have not yet completed the development, including obtaining regulatory approval, of any of our pharmaceutical product candidates and, consequently, have not generated revenues from the sale of pharmaceutical products. Except for revenues associated with the transgenic mouse business of our German subsidiary, Artemis, our only revenues to date are license revenues and revenues under contracts with our partners. The size of our net losses will depend, in part, on the rate of growth, if any, in our license and contract revenues and on the level of our expenses. These losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Our research and development expenditures and general and administrative expenses have exceeded our revenues to date, and we expect to spend significant additional amounts to fund research and development in order to enhance our technologies and undertake product development. We currently have numerous product candidates in various stages of clinical development and we anticipate filing additional IND applications for additional product candidates within the next 12 months. As a result, we expect that our operations will continue to increase, and, consequently, we will need to generate significant additional revenues to achieve profitability. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do increase our revenues and achieve profitability, we may not be able to maintain or increase profitability.

***We have licensed the intellectual property, including commercialization rights, to our product candidates XL647, XL999 and XL784 to SEI and will not receive any future royalties or revenues with respect to these product candidates unless we exercise our options to acquire one or all of these product candidates in the future. We may not have the financial resources to exercise these options or sufficient clinical data in order to determine whether we should exercise these options.***

We have licensed to SEI our intellectual property rights, including commercialization rights, to our product candidates XL647, XL999 and XL784 in exchange for SEI's investment of \$80.0 million to advance the clinical development of XL647, XL999 and XL784. In exchange for this investment and for five-year warrants to purchase shares of our common stock, we received an exclusive purchase option to acquire all of the equity of SEI, thereby allowing us to reacquire the product





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candidates, including any associated intellectual property rights and commercialization rights. We may, at our sole discretion, exercise this purchase option at any time until the earlier of June 9, 2009 or the 90th day after the date that SEI provides us with financial statements showing cash and cash equivalents of less than \$5.0 million. The purchase option exercise price is equal to the sum of: (i) the total amount of capital invested in SEI by its investors and (ii) an amount equal to 25% per year on such funded capital, subject to specified adjustments. The exercise price will also be subject to a premium if we exercise the purchase option before December 11, 2006. The option exercise price may be paid in cash or a combination of cash and our common stock, at our sole discretion, provided that the common stock portion may not exceed 33% of the purchase option exercise price.

We have also received an exclusive program option from SEI allowing us under certain conditions to separately reacquire from SEI one of the three product candidates licensed to SEI. The program option is exercisable at any time, at our sole discretion, until December 9, 2006 at an exercise price equal to that portion of the funded capital expended on the development of the applicable product candidate being repurchased, plus a specified premium. The program option exercise price may be paid in cash only.

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

In addition, under our collaboration with GlaxoSmithKline, GlaxoSmithKline may continue to select at proof-of-concept for further development one or more of the product candidates licensed to SEI, in which case we would have to repurchase the selected candidate or candidates through the exercise of our purchase option or program option. If, after receiving any selection milestones from GlaxoSmithKline, we do not have sufficient resources to exercise the purchase option or program option following a product candidate selection by GlaxoSmithKline, we could be in breach of our collaboration agreement with GlaxoSmithKline. In the event of such breach, GlaxoSmithKline could terminate the collaboration and, among other remedies, declare all amounts under our loan facility with GlaxoSmithKline immediately due and payable, which would harm our business.

### **Risks Related to Development of Product Candidates**

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

Clinical trials are inherently risky and may reveal that our product candidates are ineffective or have unacceptable toxicity or other side effects that may significantly decrease the likelihood of regulatory approval. The results of preliminary studies do not necessarily predict clinical or commercial success, and later-stage clinical trials may fail to confirm the results 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

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

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

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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.

***Serious adverse cardiovascular events observed in the XL999 program may result in significant delays or termination of clinical testing, which could cause our stock price to decline.***

In November 2006, we suspended enrollment of new patients into the XL999 program after a preliminary review of patient data relating to adverse events for the month of October showed an apparent increase in the rate of serious cardiovascular events compared to the period prior to October. We may experience a number of events that could further delay or prevent development of XL999, including:

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

additional serious adverse events in the XL999 program;

failure to resume enrollment in the XL999 program in a timely manner or at all;

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

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

In addition, because the size of acceptance milestones is reduced over time under our agreement with GlaxoSmithKline, delays in the clinical development of XL999 may result in reduced acceptance milestone payments if GlaxoSmithKline selects XL999 for further clinical development. The occurrence of any of the foregoing events could negatively affect our stock price.

## **Risks Related to Our Relationships with Third Parties**

***We depend on our exclusive licensee, Helsinn, for the completion of the XL119 clinical program and the commercialization of XL119.***

Under an exclusive license agreement with us, Helsinn is responsible for all aspects of clinical development of XL119. If XL119 receives regulatory approval, Helsinn will be responsible for the marketing and sale of the commercial product worldwide unless we reacquire the commercialization rights for North America. Because Helsinn is responsible for these functions, we have no control over the development schedule or, if XL119 receives regulatory approval, the marketing plan for XL119. If the clinical trials for XL119 are not successful, XL119 will not be commercialized. Moreover, Helsinn may relinquish all rights and the license granted to it under the license agreement and thereby terminate the license agreement on at least six months' prior written notice, if in Helsinn's reasonable business judgment based on scientific or economic evidence, it is impossible for Helsinn to carry out further development or marketing of XL119. If the rights to develop and market XL119 revert to us, we will have to fund the clinical programs for XL119 on our own, seek a strategic partner to fund the further development, which may not be available on favorable terms, or at all, or out-license or abandon XL119.

Our reliance on Helsinn poses a number of risks, including the following:

potential disputes regarding milestone payments may arise in the future, which may postpone or disrupt payments under the license agreement;

if Helsinn fails to successfully advance XL119 in clinical development or fails to obtain regulatory approvals for XL119, we will not be able to generate revenues from milestones or the commercialization of XL119;

we cannot control whether Helsinn will devote sufficient resources to the clinical program and, if XL119 is approved by the FDA or other regulatory agencies, the marketing plan for the commercialization of the drug product in countries where we do not hold commercialization rights;

although we have no history of royalty payment disputes, even if XL119 is approved and commercialized, disputes may arise in the future with respect to the calculation of royalty payments based on net sales related to XL119; and

if Helsinn perceives that the market opportunity for XL119 or its profit margin from the sale of XL119 is too small to justify commercialization, the interests and motivations of Helsinn may not be, or may not remain, aligned with ours.

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

We have licensed to SEI our intellectual property rights, including commercialization rights, to our product candidates XL647, XL999 and XL784 in exchange for SEI's investment of \$80.0 million to advance the clinical development of XL647, XL999 and XL784. We are responsible for developing XL647, XL999 and XL784 in accordance with a specified development plan and related development budget. Our development activities will be supervised by SEI's development committee, which is comprised of an equal number of representatives from Exelixis and SEI. If the development committee

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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 Exelixis regarding a development decision may cause significant delays in the development and commercialization of our product candidates XL647, XL999 and XL784 as well as lead to development decisions that do not reflect our interests. Any such delays or development decisions not in our interest could negatively affect the value of XL647, XL999 and XL784.

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

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

If these agreements or agreements with other partners are not renewed or are terminated early, whether unilaterally or by mutual agreement, or if we are unable to enter into new collaboration agreements on commercially acceptable terms, our revenues and product development efforts could suffer. For example, our agreement with Pharmacia Corporation terminated by mutual agreement in February 2002, which eliminated the opportunity for us to earn approximately \$9.0 million in research revenue in 2002 and 2003. Similarly, our collaboration with GlaxoSmithKline is scheduled to expire in October 2008 but became subject to earlier termination at the discretion of GlaxoSmithKline starting in 2005. Our agreements with Bristol-Myers Squibb and Wyeth also contain early termination provisions. In addition, from time to time we review and assess certain aspects of our collaborations, partnerships and agreements and may amend or terminate, either by mutual agreement or pursuant to any applicable early termination provisions, such collaborations, partnerships or agreements if we deem them to be no longer in our economic or strategic interests. For example, in March 2005, we agreed with Bayer CropScience LP to terminate the research term under our collaboration with Bayer CropScience in order to allow us to focus on our core business. We may not be able to enter into new collaboration agreements on similar or superior financial terms to offset the loss of revenue from the termination or expiration of any of our existing arrangements, and the timing of new collaboration agreements may have a material adverse effect on our ability to continue to successfully meet our objectives.

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

We are conducting proprietary research programs in specific disease, therapeutic modality and agricultural product areas that are not covered by our collaboration agreements. Our pursuit of opportunities in pharmaceutical and agricultural markets could result in conflicts with our collaborators in the event that any of our collaborators takes the position that our internal activities overlap with those areas that are exclusive to our collaboration agreements, and we should be precluded from such internal activities. Moreover, disagreements with our collaborators could develop over rights to our intellectual property. In addition, our collaboration agreements may have provisions that give rise to disputes regarding the respective rights and obligations of the parties, including the rights of collaborators with respect to our internal programs and disease area research. Any conflict with or among our collaborators could lead to the termination of our collaborative agreements, delay collaborative activities, impair our ability to renew agreements or obtain future collaboration agreements or result in litigation or arbitration and would negatively impact our relationship with existing collaborators. If our collaborators fail to 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.

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

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

***We lack the capability to manufacture compounds for clinical trials and rely on third parties to manufacture our product candidates, and we may be unable to obtain required material in a timely manner, at an acceptable cost or at a quality level required to receive regulatory approval.***

We currently do not have the manufacturing capabilities or experience necessary to enable us to produce materials for our clinical trials. We rely on collaborators and third-party contractors to produce our compounds for preclinical and clinical testing. These suppliers must comply with applicable regulatory requirements, including the FDA's current Good Manufacturing Practices, or GMP. Our current and anticipated future dependence upon these third-party manufacturers may adversely affect our future profit margins and our ability to develop and commercialize product candidates on a timely and competitive basis. These manufacturers may not be able to produce material on a timely basis or manufacture material at the quality level or in the quantity required to meet our development timelines and applicable regulatory requirements. We may not be able to maintain or renew our existing third-party manufacturing arrangements, or enter into new arrangements, on acceptable terms, or at all. Our third-party manufacturers could terminate or decline to renew our manufacturing arrangements based on their own business priorities, at a time that is costly or inconvenient for us. If we are unable to contract for the production of materials in sufficient quantity and of sufficient quality on acceptable terms, our clinical trials may be delayed. Delays in preclinical or clinical testing could delay the filing of our INDs and the initiation of clinical trials.

Our third-party manufacturers may not be able to comply with the GMP regulations, other applicable FDA regulatory requirements or similar regulations applicable outside of the United States. Additionally, if we are required to enter into new supply arrangements, we may not be able to obtain approval from the FDA of any alternate supplier in a timely manner, or at all, which could delay or prevent the clinical development and commercialization of any related product candidates. Failure of our third-party manufacturers or us to obtain approval from the FDA or to comply with applicable regulations could result in sanctions being imposed on us, including fines, civil penalties, delays in or failure to grant marketing approval of our product candidates, injunctions, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products and compounds, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect 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





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in other countries. Failure to obtain regulatory approval for a product candidate would prevent us from commercializing that product candidate. We have not received regulatory approval to market any of our product candidates in any jurisdiction and have only limited experience in preparing and filing the applications necessary to gain regulatory approvals. The process of obtaining regulatory approvals is expensive, and often takes many years, if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidates involved. Before a new drug application can be filed with the FDA, the product candidate must undergo extensive clinical trials, which can take many years and may require substantial expenditures. Any clinical trial may fail to produce results satisfactory to the FDA. For example, the FDA could determine that the design of a clinical trial is inadequate to produce reliable results. The regulatory process also requires preclinical testing, and data obtained from preclinical and clinical activities are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. In addition, delays or rejections may be encountered based upon changes in regulatory policy for product approval during the period of product development and regulatory agency review. Changes in regulatory approval policy, regulations or statutes or the process for regulatory review during the development or approval periods of our product candidates may cause delays in the approval or rejection of an application. Even if the FDA or a comparable authority in another country approves a product candidate, the approval may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, marketing and/or production of such product and may impose ongoing requirements for post-approval studies, including additional research and development and clinical trials. These agencies also may impose various civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval.

### **Risks Related to Commercialization of Products**

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

Our ability to commercialize any products that we may develop will be highly dependent upon the extent to which these products gain market acceptance among physicians, patients, health care payors, such as Medicare and Medicaid, private health insurers, including managed care organizations and group purchasing organizations, and the medical community. If these products do not achieve an adequate level of acceptance, we may not generate adequate product revenues, and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend upon a number of factors, including:

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

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

potential advantages over alternative treatments;

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

relative convenience and ease of administration;

the strength of marketing and distribution support; and

sufficient third-party coverage or reimbursement.

*If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate product revenues.*

We have no experience as a company in the sales, marketing and distribution of pharmaceutical products and do not currently have a sales and marketing organization. Developing a sales and marketing force would be expensive and time-consuming, could delay any product launch, and

we may never be able to develop this capacity. To the extent that we enter into arrangements with third parties to provide sales, marketing and distribution services, our product revenues are likely to be lower than if we market and sell any products that we develop ourselves. If we are unable to establish adequate sales, marketing and distribution capabilities, independently or with others, we may not be able to generate product revenues.

***If we are unable to obtain adequate coverage and reimbursement from third-party payors for any products that we may develop, our revenues and prospects for profitability will suffer.***

Our ability to commercialize any products that we may develop will be highly dependent on the extent to which coverage and reimbursement for our products will be available from third-party payors, including governmental payors, such as Medicare and Medicaid, and private health insurers, including managed care organizations and group purchasing organizations. Many patients will not be capable of paying themselves for some or all of the products that we may develop and will rely on third-party payors to pay for, or subsidize, their medical needs. If third-party payors do not provide coverage or reimbursement for any products that we may develop, our revenues and prospects for profitability will suffer. In addition, even if third-party payors provide some coverage or reimbursement for our products, the availability of such coverage or

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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, the President signed into law legislation creating a prescription drug benefit program for Medicare recipients. The new prescription drug program may have the effect of reducing the prices that we are able to charge for products we develop and sell through plans under the program. The new prescription drug program may also cause third-party payors other than the federal government, including the States under the Medicaid program, to discontinue coverage for products we develop or to lower the price that they will pay.

Proponents of drug reimportation may attempt to pass legislation, which would allow direct reimportation under certain circumstances. If legislation or regulations were passed allowing the reimportation of drugs, it could decrease the price we receive for any products that we may develop, thereby negatively affecting our revenues and prospects for profitability.

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

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

The biotechnology industry is highly fragmented and is characterized by rapid technological change. In particular, the area of kinase-targeted therapies is a rapidly evolving and competitive field. We face, and will continue to face, intense competition from large 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.

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**Table of Contents****Risks Related to Our Intellectual Property**

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

Our success will depend in part upon our ability to obtain patents and maintain adequate protection of the intellectual property related to our technologies and products. The patent positions of biotechnology companies, including our patent position, are generally uncertain and involve complex legal and factual questions. We will be able to protect our intellectual property rights from unauthorized use by third parties only to the extent that our technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. We will continue to apply for patents covering our technologies and products as and when we deem appropriate. However, these applications may be challenged or may fail to result in issued patents. In addition, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that cover the production, manufacture, commercialization or use of our product candidates. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Furthermore, others may independently develop similar or alternative technologies or design around our patents. In addition, our patents may be challenged or invalidated or may fail to provide us with any competitive advantages, if, for example, others were the first to invent or to file patent applications for these inventions.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties (for example, the patent owner has failed to work the invention in that country or the third party has patented improvements). In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. Compulsory licensing of life-saving drugs is also becoming increasingly popular in developing countries either through direct legislation or international initiatives. Such compulsory licenses could be extended to include some of our product candidates, which could limit our potential revenue opportunities. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patent and other intellectual property protection, which makes it difficult to stop infringement. We rely on trade secret protection for our confidential and proprietary information. We have taken security measures to protect our proprietary information and trade secrets, but these measures may not provide adequate protection. While we seek to protect our proprietary information by entering into confidentiality agreements with employees, collaborators and consultants, we cannot assure you that our proprietary information will not be disclosed, or that we can meaningfully protect our trade secrets. In addition, our competitors may independently develop substantially equivalent proprietary information or may otherwise gain access to our trade secrets.

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

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

Third parties may accuse us of employing their proprietary technology without authorization. In addition, third parties may obtain patents that relate to our technologies and claim that use of such technologies infringes on their patents. 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



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employees, independent contractors or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying money claims, we may lose valuable intellectual property rights or personnel. A loss of key research personnel and/or their work product could hamper or prevent our ability to commercialize certain product candidates, which could severely harm our business.

### **Risks Related to Employees, Growth and Location**

#### ***The loss of key personnel or the inability to attract and retain additional personnel could impair our ability to expand our operations.***

We are highly dependent upon the principal members of our management and scientific staff, the loss of whose services might adversely impact the achievement of our objectives and the continuation of existing collaborations. Also, we do not currently have sufficient technical personnel to fully execute our business plan. Recruiting and retaining qualified scientific and clinical 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 technical personnel, and we may be unable to retain or recruit scientists 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 they 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 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, 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, SEC rules and regulations have increased the internal control and regulatory requirements under which we operate. We may not be able to successfully implement improvements to our management information and control systems in an efficient or timely manner to meet future requirements.

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

Given our headquarters location in South San Francisco, California, our facilities are vulnerable to damage from earthquakes. We currently do not carry earthquake insurance. We are also vulnerable to damage from other types of disasters, including fire, floods, power loss, communications failures, terrorism and similar events since any insurance we may 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



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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 be sued for any injury or contamination that results from our use or the use by third parties of these materials, and our liability may exceed our insurance coverage and our total assets. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development and production efforts.

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

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

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

### **Risks Related to Genetic Engineering of Agricultural Products**

*Social issues may limit the public acceptance of genetically engineered products, which could reduce demand for our products.*

Although our technology is not dependent upon genetic engineering, genetic engineering plays a prominent role in our approach to product development. For example, research efforts focusing on plant traits may involve either selective breeding or modification of existing genes in the plant under study. Public attitudes may be influenced by claims that genetically engineered products are unsafe for consumption or pose a danger to the environment. The commercial success of our future products will depend, in part, upon public acceptance of the use of genetically engineered products, including drugs and plant and animal products.

The subject of genetically modified organisms has received negative publicity, which has aroused public debate. For example, certain countries in Europe require labeling of products that contain genetic modifications or are genetically modified. In addition, the European Union has implemented rules that regulate the placing on the market of food and feed products containing or consisting of genetically modified organisms. These rules also provide for the labeling of such products to the final consumer. Adverse publicity has resulted in greater regulation internationally and trade restrictions on imports of genetically altered products. If similar action is taken in the United States or other countries, genetic research and genetically engineered products could be subject to greater domestic regulation, including stricter labeling requirements. To date, our business has not been hampered by these activities. However, such publicity in the future may prevent any products resulting from our research from gaining market acceptance and reduce demand for our products, which are developed using genetic engineering.





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*Laws and regulations may reduce our ability to sell genetically engineered products that we or our collaborators develop in the future.*

We or our collaborators may develop genetically engineered agricultural and animal products. The field-testing, production and marketing of genetically engineered products are subject to regulation by federal, state, local and foreign governments. Regulatory agencies administering existing or future regulations or legislation may prevent us from producing and marketing genetically engineered products in a timely manner or under technically or commercially feasible conditions. In addition, regulatory action or private litigation could result in expenses, delays or other impediments to our product development programs and the commercialization of products. The FDA has released a policy statement stating that it will apply the same regulatory standards to foods developed through genetic engineering as it applies to foods developed through traditional plant breeding. Genetically engineered food products will be subject to premarket review, however, if these products raise safety questions or are deemed to be food additives. Our product candidates may be subject to lengthy FDA reviews and unfavorable FDA determinations if they raise questions regarding safety or if our products are deemed to be food additives.

To date, the FDA has not required genetically engineered agricultural products to be labeled as such, provided that these products are as safe and have the same nutritional characteristics as conventionally developed products. The FDA may reconsider or change its policies, and local or state authorities may enact labeling requirements, either of which could have a material adverse effect on our ability or the ability of our collaborators to develop and market products resulting from our efforts.

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

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*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;

litigation, including intellectual property infringement 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.

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

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

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

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

diversion of management's attention from other operational matters;

the potential loss of key employees;

the potential loss of key collaborators;

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

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

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

***Future sales of our common stock may depress our stock price.***

If our stockholders sell substantial amounts of our common stock (including shares issued upon the exercise of options and warrants) in the public market, the market price of our common stock could fall. These sales also might make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate. For example, following an acquisition, a significant number of shares of our common stock held by new stockholders may

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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

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

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

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**SIGNATURES**

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

Date: November 6, 2006

EXELIXIS, INC.

/s/ Frank Karbe

Frank Karbe

Senior Vice President, Chief Financial Officer

*(Principal Financial and Accounting Officer)*



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**EXHIBIT INDEX**

<b>Number</b>	<b>Exhibit Description</b>
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).

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\* 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.