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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D. C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2005

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	**04-3257395**
(State or other jurisdiction of incorporation or organization)	**(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
(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes ☒ No ☐

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 31, 2005, there were 83,131,424 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, 2005

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ITEM 1. FINANCIAL STATEMENTS

EXELIXIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	September 30, 2005 (unaudited)	December 31, 2004 [1]
ASSETS		
Current assets:		
Cash and cash equivalents	$ 90,010	$ 78,105
Short-term investments	72,929	77,078
Investments held by Symphony Evolution, Inc.	37,542	—
Other receivables	6,671	4,424
Prepaid expense and other current assets	7,141	4,350
Total current assets	214,293	163,957
Restricted cash and investments	13,522	16,040
Property and equipment, net	36,144	35,463
Related-party receivables	7	51
Goodwill	67,364	67,364
Other intangibles, net	3,697	4,512
Other assets	3,679	3,953
Total assets	$ 338,706	$ 291,340
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,065	$ 5,931
Other accrued expenses	11,419	12,012
Accrued compensation and benefits	7,236	6,297
Current portion of capital lease obligations	347	1,931
Current portion of notes payable and bank obligations	9,691	8,928
Convertible promissory note	30,000	—
Deferred revenue	27,935	28,697
Total current liabilities	88,693	63,796
Capital lease obligations	—	98
Notes payable and bank obligations	19,672	21,398
Convertible promissory loans	85,000	115,000
Other long-term liabilities	12,750	7,995
Deferred revenue	48,043	32,382
Total liabilities	254,158	240,669
Noncontrolling interest in Symphony Evolution, Inc.	28,643	—
Commitments		
Stockholders' equity:		
Common stock	84	75
Additional paid-in-capital	634,264	569,345
Accumulated other comprehensive income	812	624
Accumulated deficit	(579,255)	(519,373)
Total stockholders' equity	55,905	50,671
Total liabilities and stockholders' equity	$ 338,706	$ 291,340

[1] The condensed consolidated balance sheet at December 31, 2004 has been derived from the audited financial statement 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Revenues:				
Contract	$ 10,279	$ 10,617	$ 45,323	$ 28,812
License	4,121	2,045	16,261	8,301
Total revenues	14,400	12,662	61,584	37,113
Operating expenses:				
Research and development	35,202	34,054	105,091	102,694
General and administrative	6,819	5,078	20,173	15,356
Amortization of intangibles	271	168	815	501
Restructuring charge	—	—	—	2,275
Acquired in-process research and development	—	—	—	395
Total operating expenses	42,292	39,300	126,079	121,221
Loss from operations	(27,892)	(26,638)	(64,495)	(84,108)
Other income (expense):				
Interest income	1,581	728	3,555	2,426
Interest expense	(1,550)	(1,285)	(4,647)	(3,739)
Other income, net	—	6	190	98
Total other income (expense)	31	(551)	(902)	(1,215)
Loss before noncontrolling interest in Symphony Evolution, Inc.	(27,861)	(27,189)	(65,397)	(85,323)
Loss attributed to noncontrolling interest in Symphony Evolution, Inc.	5,086	—	5,515	—
Net loss	$ (22,775)	$ (27,189)	$ (59,882)	$ (85,323)
Net loss per share, basic and diluted	$ (0.29)	$ (0.38)	$ (0.77)	$ (1.19)
Shares used in computing basic and diluted net loss per share	79,540	72,170	77,288	71,898

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

EXELIXIS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2005	2004
Cash flows from operating activities:		
Net loss	$(59,882)	$(85,323)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	12,554	12,542
Loss attributed to noncontrolling interest	(5,515)	—
Stock compensation expense	35	40
Non-cash portion of restructuring charge	—	(150)
Acquired in-process research and development	—	395
Amortization of intangibles	815	501
Gain on the sale of equipment	(138)	—
Other	446	227
Changes in assets and liabilities:		
Other receivables	(2,347)	(739)
Prepaid expense and other current assets	(2,843)	(3,170)
Related-party receivables	45	142
Other assets	(1,011)	(1,384)
Accounts payable and other accrued expenses	(2,238)	(2,310)
Other long-term liabilities	4,754	1,718
Deferred revenue	15,141	(12,185)
Net cash used in operating activities	(40,184)	(89,696)
Cash flows from investing activities:		
Cash received from acquisition, net of cash paid	—	860
Purchases of investments held by Symphony Evolution, Inc.	(40,330)	—
Proceeds on sale of investments held by Symphony Evolution, Inc.	2,788	—
Purchases of property and equipment	(11,119)	(9,183)
Proceeds on sale of equipment	153	—
Change in restricted cash and investments	2,518	(11,552)
Proceeds from maturities of short-term investments	81,156	118,676
Purchases of short-term investments	(77,973)	(78,158)
Net cash provided by (used in) investing activities	(42,807)	20,643
Cash flows from financing activities:		
Proceeds from issuance of common stock, net	58,468	—
Proceeds from exercise of stock options, net of repurchases	1,089	2,531
Proceeds from employee stock purchase plan	1,116	1,166
Repayment of notes from stockholders	—	53
Payments on capital lease obligations	(1,682)	(3,805)
Proceeds from notes payable and bank obligations	6,618	9,366
Principal payments on notes payable and bank obligations	(7,581)	(3,882)
Proceeds from purchase of noncontrolling interest by preferred shareholders in Symphony Evolution, Inc., net of fees	37,000	—
Net cash provided by financing activities	95,028	5,429
Effect of foreign exchange rates on cash and cash equivalents	(132)	(211)
Net increase (decrease) in cash and cash equivalents	11,905	(63,835)
Cash and cash equivalents, at beginning of period	78,105	111,828
Cash and cash equivalents, at end of period	$ 90,010	$ 47,993
Supplemental cash flow disclosure:		
Warrants issued in conjunction with the Symphony Evolution, Inc. transaction	$ (2,842)	$ —

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

EXELIXIS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2005
(unaudited)

NOTE 1 Organization and Summary of Significant Accounting Policies

Organization

Exelixis, Inc. ("Exelixis," "we," "our" or "us") is a biotechnology company whose primary mission is to use its biological expertise and integrated drug discovery capabilities to develop high-quality, differentiated pharmaceutical products in the treatment of cancer, metabolic disorders, cardiovascular disease and other serious diseases. Our research is designed to identify important genes and proteins that, when expressed at altered levels, either decrease or increase the activity of a specific disease pathway in a therapeutically relevant manner. These genes and proteins represent either potential product targets or drugs that may treat disease or prevent disease initiation or progression. Our most advanced pharmaceutical programs focus on drug discovery and development of small molecules in cancer, metabolic disorders, cardiovascular disease and other serious diseases. We use our drug discovery and medicinal chemistry capabilities to identify lead compounds against important targets that are validated and modified into candidates for clinical development. 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 the DNA or proteins, including the agrochemical, agricultural and diagnostic industries.

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, 2005 are not necessarily indicative of the results that may be expected for the year ended December 31, 2005 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, 2004 included in our Annual Report on Form 10-K filed with the SEC on March 15, 2005.

Basis of Consolidation

The condensed 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 inter-company balances and transactions have been eliminated. We recorded our minority ownership interest in Genoptera LLC using the equity method of accounting.

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, adjusted for shares that are subject to repurchase. The calculation of diluted net loss per share excludes potential common stock because its 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 note and loans.

Stock-Based Compensation

We recognize employee stock-based compensation under the intrinsic value method of accounting as prescribed by Accounting Principles Board Opinion 25, *Accounting for Stock Issued to Employees* ("APB 25") and related interpretations. Accordingly, no compensation expense is recognized in our condensed consolidated financial statements for the stock options granted to employees, which had an exercise price equal to the fair value of the underlying common stock on the date of grant. The following table illustrates the effect on net loss and net loss per share if we had applied the fair value recognition provisions of the Statement of Financial Accounting Standard No. 123, *Accounting for Stock-Based Compensation* ("SFAS 123"), as amended by SFAS No. 148, *Accounting for Stock-Based Compensation – Transition and Disclosure – an amendment of FASB Statement No. 123* ("SFAS 148") (in thousands, except per share amounts):

	Three Months Ended September 30,	
	2005	2004
Net loss:		
As reported	$(22,775)	$(27,189)
Add: Stock-based employee compensation expense (reversal) included in reported net loss	—	(34)
Deduct: Total stock-based employee compensation expense determined under fair value method for all awards	(2,667)	(3,568)
Pro forma net loss	$(25,442)	$(30,791)
Net loss per share (basic and diluted):		
As reported	$ (0.29)	$ (0.38)
Pro forma	$ (0.32)	$ (0.43)

	Nine Months Ended September 30,	
	2005	2004
Net loss:		
As reported	$(59,882)	$(85,323)
Add: Stock-based employee compensation expense (reversal) included in reported net loss	(16)	38
Deduct: Total stock-based employee compensation expense determined under fair value method for all awards	(9,450)	(12,786)
Pro forma net loss	$(69,348)	$(98,071)
Net loss per share (basic and diluted):		
As reported	$ (0.77)	$ (1.19)
Pro forma	$ (0.90)	$ (1.36)

Since options vest over several years and additional option grants are expected to be made in future years, the pro forma impact on the results of operations for the three- or nine-month periods ended September 30, 2005 and 2004, respectively, is not necessarily representative of the pro forma effects on the results of operations for future periods.

Recent Accounting Pronouncements

In December 2004, the FASB issued SFAS No. 123 (revised 2004), *Share-Based Payment* ("SFAS 123R"), which replaces SFAS 123 and supersedes APB 25. SEC registrants were originally required to adopt SFAS 123R's provisions effective the first reporting period beginning after June 15, 2005. However, on April 14, 2005, the SEC announced that the registrants could delay adoption of SFAS 123R's provisions until the beginning of the next fiscal year, which makes SFAS 123R effective for Exelixis in the first quarter of 2006. The pro forma disclosures previously permitted under SFAS 123 no longer will be an alternative to financial statement recognition. Under SFAS 123R, we must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at date of adoption. The transition methods include a modified retrospective method and a modified prospective method. Under the modified retrospective method, prior periods are restated for all periods presented and compensation expense must be recorded for all unvested stock options and restricted stock beginning with the first period restated. Under the modified prospective method, compensation expense must be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of the adoption of SFAS 123R.

We are evaluating the requirements of SFAS 123R and expect that the adoption of SFAS 123R will have a material impact on our consolidated results of operations and net loss per share. We have not yet determined the method of adoption or the effect of adopting SFAS 123R nor whether the adoption will result in amounts that are similar to our current pro forma disclosures under SFAS 123.

NOTE 2 Comprehensive Income (Loss)

Comprehensive income (loss) represents net income (loss) plus the results of certain stockholders' equity changes, which are comprised of unrealized gains and losses on available-for-sale securities and cumulative translation adjustments, not reflected in the consolidated statements of operations. Comprehensive income (loss) for the three- and nine-month periods ended September 30, 2005 and 2004 were as follows (in thousands):

	Three Months Ended September 30,	
	2005	2004
Net loss	$(22,775)	$(27,189)
Increase (decrease) in unrealized gains on available-for-sale securities	(37)	198
Increase (decrease) in cumulative translation adjustment	5	(139)
Comprehensive loss	$(22,807)	$(27,130)

	Nine Months Ended September 30,	
	2005	2004
Net loss	$(59,882)	$(85,323)
Decrease in unrealized gains on available-for-sale securities	(66)	(497)
Increase (decrease) in cumulative translation adjustment	254	(187)
Reclassification of cumulative translation adjustment to income	—	(228)
Comprehensive loss	$(59,694)	$(86,235)

NOTE 3 Restructurings

2004 Restructuring Charges

During the second quarter of 2004, we implemented a restructuring and consolidation of our research and discovery organizations designed to optimize our ability to generate multiple new, high-quality investigational new drug applications per year and rapidly advance these new drug candidates through clinical development. We accounted for the restructuring activity in accordance with SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* ("SFAS 146"). The restructuring included a reduction in force of 62 employees, the majority of which were research personnel located in South San Francisco, California. We recorded a restructuring charge of $1.7 million during the second quarter of 2004 comprised primarily of involuntary termination benefits. As of March 31, 2005, all amounts under this restructuring liability had been fully paid. The restructuring liabilities as of December 31, 2004 were included under the caption "Other Accrued Expenses" on the balance sheet and are summarized in the following table (in thousands):

	Restructuring Liability at December 31, 2004	Cash Payments	Restructuring Liability at March 31, 2005
Severance and benefits	$ 59	$ (59)	$ —
Legal and other fees	48	(48)	—
	$ 107	$ (107)	$ —

2003 Restructuring Charges

During the third quarter of 2003, we implemented a worldwide restructuring of our research and development organization designed to reallocate resources and enhance the efficiency of our operations. The restructuring included a reduction in force of 61 research personnel located in South San Francisco, California and Tübingen, Germany, closure of our Tübingen location and relocation of certain research activities and employees from Tübingen to South San Francisco. We recorded a cumulative charge of $1.5 million in accordance with SFAS 146, of which $0.5 million and $1.0 million was recorded during the years ended December 31, 2004 and 2003, respectively. The restructuring plan was substantially complete as of March 31, 2004. This charge primarily consists of severance payments, retention bonuses, relocation costs, lease buyout costs and legal and outplacement services fees. As of June 30, 2005, all amounts under this restructuring liability had been fully paid. The restructuring liabilities as of December 31, 2004 were included under the caption "Other Accrued Expenses" on the balance sheet and are summarized in the following table (in thousands):

	Restructuring Liability at December 31, 2004	Cash Payments	Restructuring Liability at June 30, 2005
Severance and benefits	$ 31	$ (31)	$ —
Legal and other fees	45	(45)	—
Lease buyout costs	66	(66)	—
	$ 142	$ (142)	$ —

NOTE 4 GlaxoSmithKline Collaboration

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

In January 2005, we amended the terms of our collaboration with GlaxoSmithKline. Under the original PDA, an option period commenced in October 2004 during which GlaxoSmithKline was required to elect a pre-defined limited or expanded program option. The terms of the amended PDA reflect GlaxoSmithKline's decision to select a modified program election that is neither the limited nor the expanded option envisioned in the original PDA. If GlaxoSmithKline had elected the limited program option, then GlaxoSmithKline would have been able to select up to 12 targets, along with the respective compounds directed against those targets, which would have narrowed the focus of further work under the collaboration. If GlaxoSmithKline had elected the expanded program option, there would not be a narrowing of focus, and all of the collaboration targets, and their respective compounds, would have remained in the collaboration. Under the amended PDA, GlaxoSmithKline selected a modified program election through which the focus of the collaboration is shifted to 12 internal programs at various stages of development (XL784, XL647, XL999, XL880, XL184, XL820, XL844 and five earlier stage oncology programs). Each program centers on compounds that are directed against one or more targets identified in the collaboration. Under the modified program, GlaxoSmithKline has the right to select from these programs up to two compounds at proof-of-concept (completion of Phase 2a clinical trial) or three compounds if GlaxoSmithKline extends the collaboration. If GlaxoSmithKline selects three compounds, we could receive up to $240.0 million in acceptance milestones. Prior to the end of a specified development term, GlaxoSmithKline retains exclusivity rights to the approximately 32 specified targets that are encompassed by the 12 programs. However, we retain rights to all compounds not encompassed by the 12 programs selected by GlaxoSmithKline and may work on any targets with the exception of the approximately 32 targets subject to GlaxoSmithKline's exclusivity rights.

The terms of the amended PDA allow us to use third-party financing vehicles to fund the further clinical development of our compounds XL784, XL647 and XL999 but any such compounds developed through clinical financing vehicles continue to be subject to GlaxoSmithKline's compound selection rights. In June 2005, we entered into a transaction to fund the clinical development of XL784, XL647 and XL999 through Symphony Evolution, Inc., a third-party financing vehicle.

Under the amended PDA, GlaxoSmithKline was required to pay us a new $30.0 million milestone upon (i) the filing of investigational new drug applications ("INDs") for three out of four compounds (XL880, XL184, XL820 and XL844) prior to the end of 2005 or (ii) the successful completion in 2005 of a Phase 1 clinical trial for one of these four compounds. In May 2005, we filed the third of three INDs required by the amended PDA to achieve the $30.0 million milestone, which we received from GlaxoSmithKline in May 2005. The revenue from this milestone is being recognized over the term of the amended PDA on a straight-line basis from January 2005 to November 2009. In return for the new $30.0 million milestone, GlaxoSmithKline will receive a $30.0 million credit and a specified reduction against the first acceptance milestone as well as a temporary reduction in the royalty rate it owes us on net sales of products developed under the collaboration. If the acceptance milestone is less than the $30.0 million credit and the specified reduction, then the remaining balance will reduce any future product commercialization milestones that GlaxoSmithKline owes to us. Under the amended PDA, GlaxoSmithKline also was obligated to pay us a new $5.0 million milestone upon achieving specified progress with respect to certain other candidates. In May 2005, we submitted two new development candidates to GlaxoSmithKline, thereby triggering the additional $5.0 million milestone, which we received in May 2005. Under the original PDA, GlaxoSmithKline would have paid the first milestone upon its selection of a compound that had completed proof-of-concept for further development. We may also receive additional development related milestones and royalties on product sales and have certain co-promotion rights to products in North America. In addition, under the amended PDA, GlaxoSmithKline is obligated to provide research funding of $47.5 million over the remaining three-year term of the collaboration.

Pursuant to the terms of the original SPA and as a result of its modified program election, GlaxoSmithKline purchased an additional 1.0 million shares of our common stock in January 2005 at an aggregate purchase price of $11.1 million, of which $2.2 million was a premium to the then fair value of the shares. We have no further option to sell, and GlaxoSmithKline has no further obligation to purchase, additional shares of our common stock. The premium portion of the equity purchase has been deferred and is being recognized as revenue over the development term.

NOTE 5 Genoptera Collaboration

In March 2005, Exelixis, BayerCropScience LP ("Bayer") and Genoptera LLC ("Genoptera") agreed to amend the terms of the collaboration agreement, dated January 1, 2000, among Exelixis, Bayer and Genoptera. Exelixis and Bayer formed Genoptera, a joint venture focused on the discovery of novel insecticides and nematicides for crop protection, in January 2000. The amended agreement provides for an early termination of the research term and requires Bayer to acquire our 40% ownership interest in Genoptera within six months after the termination of the research term. The amended agreement also requires Bayer to pay us an early termination fee of $10.9 million, which was paid in April 2005.

In June 2005, the final knowledge transfer was completed and we recognized $21.1 million in revenues, which included the early termination fee paid in April 2005, and accelerated recognition of deferred revenues related to upfront payments and milestones. Pursuant to the terms of the amended agreement, Bayer, through Genoptera, will have exclusive rights in the field of agriculture to assays, compounds and products developed under the collaboration and we will have exclusive rights in all other fields. In addition, the obligations of Bayer to fund further research ceased and we have no further obligations to perform research.

NOTE 6 Genentech Collaboration

In May 2005, Exelixis and Genentech, Inc. ("Genentech") established a collaboration to discover and develop therapeutics for the treatment of cancer, inflammatory diseases, and tissue growth and repair. Under the terms of the agreement, we have granted to Genentech a license to certain intellectual property. Genentech has made an upfront license payment and is obligated to provide research and development funding over the three-year research term, totaling $16.0 million.

Under the agreement, Genentech will have primary responsibility in the field of cancer for research and development activities as well as rights for commercialization of any products. In the fields of inflammatory disease and tissue growth and repair, we will initially have primary responsibility for research activities and after the expiration of the research term, we will have the option to elect to share a portion of the costs and profits associated with the development, manufacturing and commercialization of products. The research term under the agreement is three years and may be extended upon mutual consent for one-year terms. For all products under the agreement that are not elected as cost/profit share products, we may receive milestone and royalty payments.

NOTE 7 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). Under the terms of the agreement, we have granted to Helsinn an exclusive worldwide, royalty bearing license to XL119. We have retained an option to reacquire the commercial rights to XL119 for North America for use in the indications of gall bladder cancer and bile duct tumors. If we decide to exercise the option, we have the right to negotiate with Helsinn to reach an agreement on commercially reasonable terms and conditions to reacquire the commercial rights to XL119 for North America for use in the indications of gall bladder cancer and bile duct tumors. Under the agreement, Helsinn has paid us a nonrefundable upfront payment in the amount of $4.0 million and is obligated to pay additional development and commercialization milestones of up to $21.0 million, as well as royalties on worldwide sales. Helsinn will also assume all future costs incurred for the ongoing multi-national Phase 3 clinical trial for XL119.

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. In addition, if we fail to supply Helsinn with certain clinical trial materials by the end of April 2006 and such failure prevents Helsinn from enrolling additional patients or from maintaining the then-current enrollment in the ongoing Phase 3 clinical trial, then Helsinn may terminate the license agreement or elect to continue the agreement at a reduced royalty rate.

NOTE 8 Symphony Evolution

On June 9, 2005 (the "Closing Date"), 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") has agreed to invest up to $80.0 million to fund the clinical development of these Programs and we have 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 $40.0 million in funding to SEI at closing, and which is obligated to fund, upon a capital call by SEI, at least an additional $20.0 million and not more than $40.0 million within one year of the Closing Date. We continue to be primarily responsible for the development of these Programs.

In accordance with FIN 46R, we have determined that SEI is a variable interest entity for which we are the primary beneficiary. As a result, we will include the financial condition and results of operations of SEI in our consolidated financial statements. Accordingly, we have deducted the losses attributable to the noncontrolling interest (SEI's losses) from our net loss in the consolidated statement of operations and we have also reduced the noncontrolling interest holders' ownership interest in SEI in the consolidated balance sheet by SEI's losses. For the three- and nine-month periods ended September 30, 2005, the losses attributed to the noncontrolling interest holders were $5.1 million and $5.5 million, respectively. We also reduced the noncontrolling interest holders' ownership interest in SEI in the consolidated balance sheet by (i) a $3.0 million structuring fee that we incurred in connection with the closing of the SEI transaction and (ii) a $2.8 million assigned value to the warrants that were issued upon closing.

Pursuant to the agreements, we have received an exclusive purchase option (the "Purchase Option") that gives us the right to acquire all of the equity of SEI, thereby allowing us to reacquire all of the Programs. This Purchase Option is exercisable at any time, beginning on the one-year anniversary of the Closing Date and ending on the four-year anniversary of the Closing Date (subject to an earlier exercise right in limited circumstances), at an exercise price equal to the sum of (i) the total amount of capital invested in SEI by Holdings and (ii) an amount equal to 25% per year on such funded capital (with respect to the initial funded capital, compounded from the Closing Date and, with respect to the second draw amount, compounded from the second draw date). The exercise price will be subject to a premium if we exercise the Purchase Option between 12 and 18 months after the Closing Date. The Purchase Option exercise price may be paid for in cash or in 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.

In addition, we have also received an exclusive purchase option (the "Program Option") from SEI, allowing us under certain conditions to separately reacquire from SEI one of the three Programs during a period beginning on the Closing Date and ending 18 months after the Closing Date. The Program Option is exercisable at our sole discretion and at a specified exercise price, which is payable in cash only and will be fully creditable against the exercise price for any subsequent exercise of the Purchase Option.

Pursuant to the agreements, we issued to Holdings a warrant to purchase 750,000 shares of our common stock at $8.90 per share, which expires in 2010. Contingent upon the second capital draw by SEI, we are obligated to issue to Holdings an additional warrant to purchase between 375,000 shares (if $20.0 million of additional funds are drawn) and 750,000 shares (if $40.0 million of additional funds are drawn) of our common stock at $8.90 per share, with a five-year term. In addition, if the Purchase Option expires unexercised at the four-year anniversary of the Closing Date, we are obligated to issue to Holdings an additional warrant to purchase 500,000 shares (if a total of $80.0 million of funds are drawn) of our common stock at a price per share equal to 125% of the market price of our common stock at the time of expiration of the Purchase Option, with a five-year term. The warrants issued upon closing were assigned a value of $2.8 million in accordance with the Black-Scholes option valuation methodology, which has been recorded as a reduction to the noncontrolling interest in SEI.

The Programs are subject to our collaboration with GlaxoSmithKline, and GlaxoSmithKline may continue to select at proof-of-concept for further development one or more of the Programs licensed to SEI, in which case we would have to repurchase the selected Program or Programs through the exercise of our Purchase Option or Program Option. Under the terms of the amended PDA, GlaxoSmithKline has agreed to increase the acceptance milestones for the programs that are funded through SEI.

NOTE 9 Sale of Equity Shares

In August 2005, we received net proceeds, after underwriting fees and offering expenses, of $49.6 million from the sale of 6.5 million shares of our common stock pursuant to our effective shelf registration statement filed in July 2001.

NOTE 10 Commitments

In May 2005, we entered into an agreement to lease approximately 48,000 square feet of additional office and laboratory facilities in South San Francisco, California (the "New Building"), primarily in order to accommodate the expansion of our clinical development group. Pursuant to the terms of the lease agreement, we have the right to terminate the lease for the New Building effective December 31, 2006, upon three months' written notice in exchange for a termination payment of $0.5 million. The lease term for the New Building is from July 2005 through July 2018. The future minimum payments under this operating lease are as follows (in thousands):

Year Ending December 31,	
2005	$ —
2006	371
2007	1,570
2008	1,609
2009	1,649
Thereafter	15,968
	$21,167

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 under the caption "Risk Factors" below, as well as those discussed elsewhere in this quarterly report on Form 10-Q.

This discussion and analysis should be read in conjunction with our financial statements and accompanying notes included in this report and the 2004 audited financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2004, filed with the Securities and Exchange Commission on March 15, 2005. 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

Exelixis is committed to developing innovative therapies that have the potential to significantly improve patient outcomes for cancer and other serious diseases. Through our own discovery research and clinical development initiatives, we are building a portfolio of novel compounds that we believe have the potential to be high-quality, differentiated pharmaceutical products to treat serious diseases. We believe that our ability to commercialize novel therapies will require building a critical mass of resources – personnel, technology, intellectual property and capital – at each step of the drug development process.

Starting with a library of more than four million high-quality compounds, we integrate high-throughput processes, bioinformatics, structural biology and early in vivo testing in parallel to characterize thousands of compounds, a process that is designed to enable us to move with significant speed in pre-clinical development. This approach seeks to leverage quantity to drive superior quality, and should allow us to select highly qualified drug candidates from a larger pool of compounds that meet our extensive list of stringent development criteria.

In the past two years, we have filed eight investigational new drug applications (IND). We believe that our deep pool of drug candidates will enable us to continue to file new INDs each year for the foreseeable future. As our compounds advance into the clinic, we expect to generate a critical mass of data that will help us to understand the full clinical and commercial potential of our product candidates. In addition to guiding the commercialization of innovative therapies, these data may contribute to the understanding of disease and help improve treatment outcomes. By investing more in each step of the path from bench to bedside, we believe we are enhancing our ability to create novel therapies that have meaningful clinical and commercial value.

Our clinical development pipeline currently includes the following compounds in cancer and renal disease: XL119 (becatecarin), for which a Phase 3 clinical trial is ongoing in patients with bile duct tumors and which has been exclusively licensed to Helsinn Healthcare S.A., with rights to reacquire the commercial rights for North America for the use in the indications of gall bladder cancer and bile duct tumors; XL784, which is being advanced as a treatment for renal disease and is currently in a Phase 1 clinical trial using a newly developed capsule formulation of the compound; and XL647, XL999, XL880, XL820, XL844 and XL184, anticancer compounds currently in Phase 1 clinical trials.

Our preclinical pipeline, which is comprised of six programs, includes three cancer programs (XL281, XL418 and XL228) focused on the inhibition of the RAF, Akt/S6k and insulin growth factor 1 receptor (IGF1R) kinases and three programs in metabolic and cardio-vascular disease that target the nuclear hormone receptors LXR (Liver X Receptor), FXR (Farnesoid X Receptor) and MR (Mineralocorticoid Receptor). We anticipate advancing these drug candidates in 2005, with the goal of filing INDs for some of them beginning in 2006.

We have incurred net losses since inception and expect to incur substantial losses for at least the next several years as we continue our research and development activities. As of September 30, 2005, we had $214.0 million in cash and cash equivalents and short-term investments, which included restricted cash and investments of $13.5 million and investments held by Symphony Evolution, Inc. of $37.5 million. We currently anticipate that our current cash and cash equivalents, short-term investments, investments in and expected to be made in SEI and funding that we expect to receive from collaborators, which includes a moderate level of business development activity, will enable us to maintain our operations for at least the next 12 months. This estimate includes the potential repayment of a $30.0 million convertible promissory note to Protein Design Labs, Inc. We may seek additional funding within this timeframe through collaborative relationships, private or public financing or other arrangements.

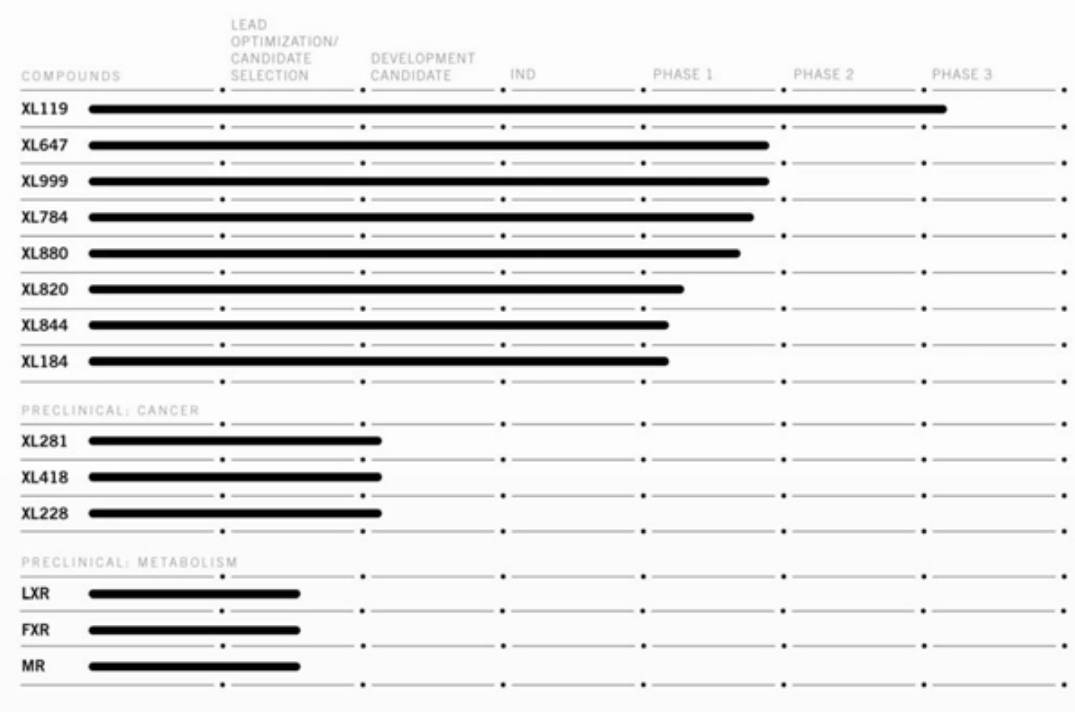
We have established collaborations with major pharmaceutical and biotechnology companies based on the strength of our technologies and expertise in biology, drug discovery and development to support additional development of our proprietary products. Through these collaborations, we obtain license fees, research funding, and the opportunity to receive milestone payments and royalties from research results and subsequent product development activities. In addition, many of our collaborations have been structured strategically to provide us with access to technologies that may help us to advance our internal programs more rapidly, while at the same time enabling us to retain rights to use these technologies in different industries. We have ongoing commercial collaborations with several leading pharmaceutical and biotechnology companies, including GlaxoSmithKline and Bristol-Myers Squibb Company. 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.

As our company has matured and our development efforts have intensified, we have restructured our organization as needed to reallocate resources and enhance the efficiency of our operations. We believe that these efforts have strengthened us by enabling us to achieve an appropriate functional balance within our organization.

Recent Developments

Development Update

We have an expansive pipeline of high-quality compounds in various stages of development to potentially treat cancer, renal disease and various metabolic and cardiovascular disorders. The following summarizes the status of our clinical and preclinical development pipeline.



Pipeline Update

We currently have eight compounds in active clinical trials, all of which continue to progress 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 and continues to recruit patients as anticipated. XL784 has been reformulated and a repeat-dose Phase 1 clinical trial is ongoing in healthy volunteers in preparation for a Phase 2 program to test efficacy in patients with renal failure. Additionally, in oncology, we have six Phase 1 clinical trials ongoing for XL647, XL999, XL880, XL820, XL844 and XL184. All

of these compounds are being tested in Phase 1 clinical trials 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.

All of our compounds, with the exception of XL119 (which was in-licensed from Bristol-Myers Squibb), were developed internally under our oncology program, which is focused on the development of highly potent, orally available diverse compounds that target specific kinases implicated in angiogenesis and cell proliferation. The oncology program is currently comprised of ten compounds – seven in clinical development and three in preclinical development. We are currently conducting Phase 1 clinical trials for XL999 and XL647, and we plan to initiate broad Phase 2 clinical trial programs for these compounds in the near future. The Phase 1 clinical trial for XL880 was initiated in the first quarter of 2005 and is ongoing, and we initiated four new Phase 1 clinical trials for XL820, XL844, XL184 and XL784 in the third quarter of 2005. Additionally, we have selected the following drug candidates for further development: XL281, which targets the RAF kinase, XL418, which targets Akt/S6k, and XL228, which targets the IGF1R kinase. We plan to continue preclinical work on XL281, XL418 and XL228 with the goal of potentially filing INDs for at least some of these compounds in 2006.

GlaxoSmithKline Collaboration

In January 2005, we amended the terms of our collaboration with GlaxoSmithKline. Under the original agreement, an option period commenced in October 2004 during which GlaxoSmithKline was required to elect a pre-defined limited or expanded program option. The terms of the amendment reflect GlaxoSmithKline's decision to select a modified program election that is neither the limited nor the expanded option envisioned in the original agreement. Under the amended terms, GlaxoSmithKline selected a modified program election through which the focus of the collaboration is shifted to 12 internal programs at various stages of development (XL784, XL647, XL999, XL880, XL184, XL820, XL844, XL281, XL418, XL228 and two earlier stage oncology programs). Each program centers on compounds that are directed against one or more targets identified in the collaboration. Under the modified program, GlaxoSmithKline has the right to select from these programs up to two compounds at proof-of-concept (completion of Phase 2a clinical trial) or three compounds if GlaxoSmithKline extends the collaboration.

If GlaxoSmithKline selects three compounds, we could receive up to $240.0 million in acceptance milestones. Prior to the end of a specified development term, GlaxoSmithKline retains exclusivity rights to the approximately 32 specified targets that are encompassed by the 12 programs. However, we retain rights to all compounds not encompassed by the 12 programs selected by GlaxoSmithKline and may work on any targets with the exception of the approximately 32 targets subject to GlaxoSmithKline's exclusivity rights.

The terms of the amended collaboration allow us to use third-party financing vehicles to fund the further clinical development of our compounds XL784, XL647 and XL999 but any such compounds, even if developed through third-party clinical financing vehicles continue to be subject to GlaxoSmithKline's compound selection rights. In June 2005, we entered into a transaction to fund the clinical development of XL784, XL647 and XL999 through Symphony Evolution, Inc., a third-party financing vehicle.

Under the amended terms, GlaxoSmithKline paid us a new $30.0 million milestone for filing INDs for XL880, XL820 and XL844 in the first-half of 2005. In return for the new $30.0 million milestone, GlaxoSmithKline will receive a $30.0 million credit and a specified reduction against the first acceptance milestone as well as a temporary reduction in the royalty rate it owes us on net sales of any products developed under the collaboration. Under the amended agreement, GlaxoSmithKline also paid us a new $5.0 million milestone for achieving specified progress with respect to certain other candidates. Under the original agreement, GlaxoSmithKline would have paid the first milestone upon its selection of a compound that had completed proof-of-concept for further development. In return, we may also receive additional development related milestones and royalties on product sales and have certain co-promotion rights to products in North America. In addition, GlaxoSmithKline is obligated to provide research funding of $47.5 million over the remaining three-year term of the collaboration.

In addition, we received cash from the purchase of 1.0 million shares of our common stock by GlaxoSmithKline at an aggregate purchase price of $11.1 million, which included a $2.2 million premium over the market price.

Genoptera Collaboration

In March 2005, Exelixis, Bayer CropScience LP and Genoptera LLC agreed to amend the terms of the collaboration agreement, dated January 1, 2000, among Exelixis, Bayer and Genoptera. Exelixis and Bayer formed Genoptera, a joint venture focused on the discovery of novel insecticides and nematicides for crop protection in January 2000. The amended agreement provides for an early termination of the research term and requires Bayer to acquire our 40% ownership interest in Genoptera within six months after the termination of the research term. The amended agreement also requires Bayer to pay us an early termination fee of $10.9 million, which was paid in April 2005. In June 2005, the final knowledge transfer was completed and we recognized $21.1 million in revenues, which reflects the early termination fee paid in April 2005 and accelerated recognition of deferred revenues related to upfront payments and milestones. Pursuant to the terms of the amendment, Bayer, through Genoptera, now has exclusive rights in the field of agriculture to assays, compounds and products developed under the collaboration and we will have exclusive rights in all other fields. In addition, the obligations of Bayer to fund further research ceased and we have no further obligations to perform research.

Genentech Collaboration

In May 2005, Exelixis and Genentech, Inc. established a collaboration to discover and develop therapeutics that target the Notch pathway for treatment of cancer, inflammatory diseases, and tissue growth and repair. Under the terms of the agreement, we have granted to Genentech a license to certain intellectual property relating to our Notch portfolio. Genentech has made an upfront license payment and the agreement provides for research and development funding over the three-year research term, totaling $16.0 million.

Under the agreement, Genentech will have primary responsibility in the field of cancer for research and development activities as well as rights for commercialization of any products. In the fields of inflammatory disease and tissue growth and repair, we will initially have primary responsibility for research activities and after the expiration of the research term, we will have the option to elect to share a portion of the costs and profits associated with the development, manufacturing and commercialization of products. The research term under the agreement is three years and may be extended upon mutual consent for one-year terms. For products that we do not elect as cost/profit products, we may also receive milestone and royalty payments.

Helsinn Healthcare

In June 2005, Exelixis and Helsinn Healthcare S.A. entered into a license agreement for the development and commercialization of XL119 (becatecarin). Under the terms of the agreement, we have granted to Helsinn an exclusive worldwide, royalty bearing license to XL119. We have retained an option to reacquire the commercial rights to XL119 for North America for use in the indications of gall bladder cancer and bile duct tumors. If we exercise the option, we have the right to negotiate with Helsinn to reach an agreement on commercially reasonable terms and conditions to reacquire the commercial rights to XL119 for North America for use in the indications of gall bladder cancer and bile duct tumors. Under the agreement, Helsinn has paid us a nonrefundable upfront payment in the amount of $4.0 million and is obligated to pay additional development and commercialization milestones of up to $21.0 million, as well as royalties on worldwide sales. Helsinn will also assume all future costs incurred for the ongoing multi-national Phase 3 clinical trial for XL119.

Symphony Evolution

In June 2005, we entered into a series of related agreements providing for the financing of the clinical development of our product candidate programs for XL784, XL647 and XL999. Symphony Evolution, Inc. (SEI) has agreed to invest up to $80.0 million to fund the clinical development of these product candidates and we have licensed to SEI our intellectual property rights related to XL784, XL647 and XL999. SEI is a wholly owned subsidiary of Symphony Evolution Holdings LLC (Holdings), which provided $40.0 million in funding to SEI at closing, and which will fund, upon a capital call by SEI, at least an additional $20.0 million and not more than $40.0 million within one year of the closing date. We will continue to be primarily responsible for the clinical development of the programs for XL784, XL647 and XL999.

Pursuant to the agreements, we received an exclusive option to reacquire all of the programs. This option is exercisable beginning on the one-year anniversary and ending on the four-year anniversary of the closing date at an exercise price equal to the sum of (i) the total amount of capital invested and (ii) an amount equal to 25% per year on such funded capital. The exercise price will also be subject to a premium if we exercise this purchase option between 12 and 18 months after the closing date. The purchase may be paid for in cash or in 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.

In addition, we have also received an exclusive option allowing us under certain conditions to separately reacquire from SEI one of the three program candidates during a period beginning on the closing date and ending 18 months after the closing date. This option is exercisable at our sole discretion and at a specified exercise price, which is payable in cash only and which will be fully creditable against the exercise price for any subsequent exercise of the purchase option to acquire all of the programs.

Pursuant to the agreements, we issued to Holdings a warrant to purchase 750,000 shares of our common stock at $8.90 per share, which expires in 2010. Contingent upon the second capital draw by SEI, we are obligated to issue to Holdings an additional warrant to purchase between 375,000 shares (if $20.0 million of additional funds are drawn) and 750,000 shares (if $40.0 million of additional funds are drawn) of our common stock at $8.90 per share, with a five-year term.

The Programs are subject to our collaboration with GlaxoSmithKline, and GlaxoSmithKline may continue to select at proof-of-concept for further development one or more of the programs licensed to SEI, in which case we would have to repurchase the selected program or programs through the exercise of our purchase option or program option. Under the terms of the amended PDA, GlaxoSmithKline has agreed to increase the acceptance milestones for the programs that are funded through SEI.

Results of Operations

Revenues

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Total revenues	$ 14.4	$ 12.7	$ 61.6	$ 37.1
Dollar increase	$ 1.7		$ 24.5	
Percentage increase	14%		66%	

Total revenues by category for the three- and nine-month periods ended September 30, 2005 and 2004 were as follows (in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Contract revenue:				
Research and development funding	$ 8.7	$ 7.6	$ 38.2	$ 22.5
Milestones	1.6	1.4	7.1	3.3
Delivery of compounds under chemistry collaborations	—	1.6	—	3.0
License revenue:				
Amortization of upfront payments, including premiums paid on equity purchases	4.1	2.1	16.3	8.3
Total revenues	$ 14.4	$ 12.7	$ 61.6	$ 37.1

The net increase in revenues of $1.7 million for the three months ended September 30, 2005, as compared to the comparable prior year period, was due to increases in revenue of $8.3 million related to milestones and research and development funding of $3.2 million from GlaxoSmithKline, upfront payments of $2.4 million from Helsinn, upfront payments and research and development funding of $1.3 million from Genentech and $1.4 million from other collaborations. The increase in revenues was partially offset by a decrease of $6.6 million in revenues primarily related to a loss of revenue of $3.5 million from the termination of our Genoptera collaboration, $1.6 million due to the termination of our combinatorial chemistry collaborations and $1.2 million related to the termination of one of our Bristol-Myers Squibb collaborations.

The net increase in revenues of $24.5 million for the nine months ended September 30, 2005, as compared to the comparable prior year period, was due to increases of $33.8 million related to revenue of $13.6 million from the acceleration of upfront payments, milestones and a termination payment associated with the termination of our Genoptera collaboration, milestone and research and development funding of $10.3 million from GlaxoSmithKline, upfront payments of $2.8 million from Helsinn, upfront payments and research and development funding of $1.8 million from Genentech and $5.3 million from other collaborations. The increase in revenues was partially offset by a decrease of $9.3 million in revenues primarily related to a loss of revenue being recognized of $4.7 million from the termination of one of our Bristol-Myers Squibb collaborations and $3.0 million due to the termination of our combinatorial chemistry collaborations.

Research and Development Expenses

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Research and development expenses	$ 35.2	$ 34.1	$ 105.1	$ 102.7
Dollar increase	$ 1.1		$ 2.4	
Percentage increase	3%		2%	

Research and development expenses consist primarily of personnel expenses, laboratory supplies, consulting and facilities costs. The increase for the three months ended September 30, 2005, as compared to the comparable period in 2004, resulted primarily from the following:

- Personnel – Personnel expense, which includes salaries, bonuses, related fringe benefits, recruiting and relocation costs, increased by $1.6 million, or 15%, primarily due to the expansion of our drug development operations to advance our clinical and preclinical development programs.
- Facilities – Facilities expense increased by $0.6 million, or 16%, primarily due to our expansion into an additional building in South San Francisco, California in July 2005 to accommodate our expanding development operations. The increase was also attributable to an additional building lease in San Diego, California, assumed in connection with our acquisition of X-Ceptor in October 2004.
- Consulting and Professional – Consulting and professional expense, which includes services performed by third-party contract research organizations and other vendors, increased by $0.3 million, or 5%, primarily due to an increase in activities associated with advancing our clinical and preclinical development programs. These activities included Phase 1 clinical trial activity for XL647, XL999 and XL880 and initiation of Phase 1 clinical trial activity for XL784, XL844, XL820 and XL184.
- Lab Supplies – Lab supplies expense decreased by $1.6 million, or 30%, primarily due to the termination of most of our combinatorial chemistry collaborations.

The increase for the nine months ended September 30, 2005, as compared to the comparable period in 2004, resulted primarily from the following:

- Consulting and Professional – Consulting and professional expense increased by $2.7 million, or 19%, primarily due to an increase in activities associated with advancing our clinical and preclinical development programs. These activities included Phase 3 clinical trial activity for XL119 through June 10, 2005, Phase 1 clinical trial activity for XL647, XL999 and XL880 and initiation of Phase 1 clinical trial activity for XL784, XL844, XL820 and XL184.
- Facilities – Facilities expense increased by $1.8 million, or 17%, primarily due to our expansion into two additional buildings in South San Francisco, California largely as a result of our expanding development operations. We occupied the first building in July 2004 and the second in July 2005. The increase is also attributable to an additional building lease in San Diego, California, assumed in connection with our acquisition of X-Ceptor in October 2004.
- Personnel – Personnel expense increased by $1.6 million, or 5%, primarily due to the expansion of our drug development operations to advance our clinical and preclinical development programs.
- Licenses and Royalties – License and royalty expense increased by $1.4 million, or 57%, primarily due to royalties payable as a result of the Genentech collaboration we entered into in May 2005.
- Lab Supplies – Lab supplies expense decreased by $5.6 million, or 32%, primarily due to the termination of most of our combinatorial chemistry collaborations.

The table below summarizes the status of our current drug candidates:

Program	Clinical Status
XL119	We have granted an exclusive license to Helsinn Healthcare S.A. and the Phase 3 clinical trial is ongoing
XL647	Phase 1 clinical trial is ongoing
XL999	Phase 1 clinical trial is ongoing
XL784	Initiated a Phase 1 clinical trial in September 2005 in preparation for a Phase 2 program to test efficacy in patients with renal failure
XL880	Phase 1 clinical trial is ongoing
XL820	Phase 1 clinical trial initiated in July 2005
XL844	Phase 1 clinical trial initiated in September 2005
XL184	Phase 1 clinical trial initiated in September 2005
XL281	Potential IND filing in 2006
XL418	Potential IND filing in 2006
XL228	Potential IND filing in 2006

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

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

General and Administrative Expenses

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
General and administrative expenses	$ 6.8	$ 5.1	$ 20.2	$ 15.4
Dollar increase	$ 1.7		$ 4.8	
Percentage increase	34 %		31%	

General and administrative expenses consist primarily of personnel expenses to support our research activities, facility costs and professional expenses, such as legal and accounting fees. The increase for the three months ended September 30, 2005, as compared to the comparable period in 2004, and for the nine months ended September 30, 2005, as compared to the comparable period in 2004, resulted primarily from an increase in personnel expenses to support research and development activities, consulting expenses, facility expenses as well as legal expenses.

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 Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Amortization of intangible assets	$ 0.3	$ 0.2	$ 0.8	$ 0.5
Dollar increase	$ 0.1		$ 0.3	
Percentage increase	62 %		63 %	

Intangible assets result from our acquisitions of X-Ceptor, Genomica, Artemis and Agritope (renamed Exelixis Plant Sciences). The increases for the three months ended September 30, 2005, as compared to the comparable period in 2004, and for the nine months ended September 30, 2005, as compared to the comparable period in 2004, were due to increases in amortization expenses for the assembled workforce related to our acquisition of X-Ceptor that occurred in October 2004. For the three- and nine-month periods ended September 30, 2005, amortization expenses increased $0.1 million and $0.3 million, respectively.

Restructuring Charge

During the second quarter of 2004, we implemented a restructuring and consolidation of our research and discovery organizations designed to optimize our ability to generate multiple new, high-quality investigational new drug applications per year and rapidly advance these new drug candidates through clinical development. The restructuring included a reduction in force of 62 employees, the majority of whom were research personnel located in South San Francisco, California. We recorded a restructuring charge of $1.7 million during the second quarter of 2004 comprised of involuntary termination benefits.

In the third quarter of 2003, we implemented a restructuring of our research and development organization designed to reallocate resources and enhance the efficiency of our operations. The restructuring included a reduction in force of 61 research personnel located in South San Francisco, California and Tübingen, Germany, closure of our Tübingen facility and relocation of certain research activities and employees from Tübingen to South San Francisco. The restructuring plan was substantially complete as of March 31, 2004. In connection with this restructuring plan, we recorded a cumulative charge of $1.5 million in accordance with Statement of Financial Accounting Standards No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, of which $0.5 million was recorded during the nine-month period ended September 30, 2004.

Acquired In-Process Research and Development

In May 2004, we purchased from Bayer CropScience its 50% interest in Agrinomics LLC, our joint venture with Bayer CropScience, in exchange for our release of all future obligations of Bayer to Agrinomics under the joint venture agreement. We recorded the assets acquired and the liabilities assumed based on their estimated fair values at the date of acquisition, as determined by management based on valuation techniques in accordance with generally accepted accounting principles. As a result, we recorded net tangible liabilities of $0.5 million, intangible assets of $0.1 million and expense associated with the purchase of in-process research and development of $0.4 million, representing the fair value of two primary research projects that had not yet reached technological feasibility and that have no alternative future use.

Total Other Income (Expense)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Total other income (expense)	$ —	$ (0.6)	$ (0.9)	$ (1.2)
Dollar decrease	$ 0.6		$ 0.3	
Percentage decrease	106%		26%	

Total other income (expense) consists primarily of interest income earned on cash, cash equivalents and short-term investments, offset by interest expense incurred on our notes payable, bank obligations, capital lease obligations and convertible notes and loans. The decrease in other expense for the three months ended September 30, 2005, as compared to the comparable period in 2004, and for the nine months ended September 30, 2005, as compared to the comparable period in 2004, was primarily due to increases in interest income as a result of increases in our investment balances. These increases were partially offset by increases in interest expense as a result of an increase in the principal balance of our loan with GlaxoSmithKline.

Noncontrolling Interest in Symphony Evolution, Inc.

Pursuant to the agreements that we entered into with SEI in June 2005, we have consolidated SEI's financial condition and results of operations in accordance with FIN 46R. Accordingly, we have deducted the losses attributable to the noncontrolling interest (SEI's losses) from our net loss in the consolidated statement of operations and we have also reduced the noncontrolling interest holders' ownership interest in SEI in the consolidated balance sheet by SEI's losses. For the three- and nine-month periods ended September 30, 2005, the losses attributed to the noncontrolling interest holders were $5.1 million and $5.5 million, respectively.

Liquidity and Capital Resources

Cash Requirements

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. In addition, we acquired Genomica in December 2001, including its $109.6 million in cash and investments. In August 2005, we received net proceeds, after underwriting fees and offering expenses, of $49.6 million from the sale of 6.5 million shares of our common stock under our shelf registration statement. As of September 30, 2005, we had $214.0 million in cash and cash equivalents and short-term investments, which includes restricted cash and investments of $13.5 million and investments held by SEI of $37.5 million.

We have incurred net losses since inception, including a net loss of $59.9 million for the nine months ended September 30, 2005, and expect to incur substantial losses for at least the next several years as we continue our research and development activities, including manufacturing and development expenses for compounds in preclinical and clinical studies. We currently anticipate that our current cash and cash equivalents, short-term investments, investments in and expected to be made in SEI and funding that we expect to receive from collaborators, which includes a moderate level of business development activity, will enable us to maintain our operations for at least the next 12 months. This estimate includes the potential repayment of a $30.0 million convertible promissory note to Protein Design Labs, Inc. We may seek additional funding within this timeframe through collaborative relationships, private or public financing or other arrangements. Changes to our current operating plan may require us to consume available capital resources significantly sooner than we expect.

Our future capital requirements will be substantial and will depend on many factors, including:

- the level of payments received under collaborative agreements, licensing agreements and other arrangements;
- 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 outlicensed product candidates XL647, XL999 and XL784, which will determine if and when we exercise our options to reacquire these product candidates;
- 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 establishing clinical and research supplies of our product candidates;
- our ability to remain in compliance with, or amend or cause to be waived, financial covenants contained in agreements with third parties;

- 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, although we currently have no commitments relating to any such transactions; and
- the cost and timing of establishing or contracting for sales, marketing and distribution capabilities.

Our capital needs in 2006 may include the repayment of a $30.0 million convertible promissory note that we issued in May 2001 to Protein Design Labs, Inc. in connection with a collaboration agreement. The note matures in May 2006 and is convertible by Protein Design Labs into our common stock. If the note is not converted, we will have to repay the entire note in May 2006.

In addition, we must raise additional capital in order to stay in compliance with financial covenants contained in our collaboration with GlaxoSmithKline. Under the 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 obligations under the agreement.

If our capital resources are insufficient to meet future capital requirements, we will have to raise additional funds. We currently have a universal 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.

Sources and Uses of Cash

Our operating activities used cash of $40.2 million and $89.7 million for the nine months ended September 30, 2005 and 2004, respectively. Cash used in operating activities relates primarily to funding net losses and the losses attributed to the noncontrolling interest, partially offset by changes in deferred revenue from collaborators and non-cash charges related to depreciation and amortization. The decrease of $49.5 million of cash used in operating activities for the 2005 period, as compared to the 2004 period, was primarily driven by a decrease in our net loss and an increase in deferred revenue. Our net loss decreased primarily due to the recognition of $21.1 million in revenues, which includes an early termination fee paid in April 2005, and accelerated recognition of deferred revenues related to upfront payments and milestones as a result of the termination of our Genoptera collaboration. Deferred revenue increased primarily due to the receipts of $35.0 million related to milestones achieved in May 2005 under our GlaxoKlineSmith collaboration. We expect to use cash for operating activities for at least 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.

Our investing activities used cash of $42.8 million and provided cash of $20.6 million for the nine months ended September 30, 2005 and 2004, respectively. Changes in cash from investing activities are primarily due to purchases of investments held by SEI, purchases and proceeds from maturities of short-term investments and purchases of property and equipment. In the nine months ended September 30, 2005 and 2004, we made purchases of $11.1 million and $9.2 million, respectively, of property and equipment. We expect to continue to make significant investments in research and development and administrative infrastructure, including the purchase of property and equipment, to support our expanding clinical and preclinical development operations.

Our financing activities provided cash of $95.0 million and $5.4 million for the nine months ended September 30, 2005 and 2004, respectively. Changes in cash from financing activities are primarily due to proceeds from the purchase of 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 cash from the purchase of 1.0 million shares of our common stock by GlaxoSmithKline at an aggregate purchase price of $11.1 million, 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. Over the next several years, we are required to make certain payments on capital leases, bank obligations, loans from collaborators and notes, including a $30.0 million convertible note due in May 2006.

We have contractual obligations in the form of operating and capital leases, notes payable and licensing agreements. The following chart details our contractual obligations as of September 30, 2005 (in thousands):

Contractual Obligations	Payments Due by Period				
	Total	Less than 1 year	1-3 years	4-5 years	After 5 years
Minimum purchase obligations	$ 1,500	$ 1,000	$ 500	$ —	$ —
Notes payable and bank obligations	29,363	9,691	15,010	4,662	—
Licensing agreements	2,493	961	1,302	230	—
Capital lease obligations	347	347	—	—	—
Convertible promissory note and loan	115,000	30,000	—	56,100	28,900
Operating leases	166,177	15,652	28,016	25,982	96,527
Total contractual cash obligations	$ 314,880	$ 57,651	$ 44,828	$ 86,974	$ 125,427

RISK FACTORS

In addition to the factors discussed elsewhere in this report and our other reports filed with the SEC, the following are important factors that could cause actual results or events to differ materially from those contained in any forward-looking statements made by or on behalf of us. The risks and uncertainties described below are not the only ones facing Exelixis. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. If any of the following risks or such other risks actually occur, our business could be harmed.

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, 2005, we had $214.0 million in cash and cash equivalents and short-term investments, which includes restricted cash and investments of $13.5 million and investments held by SEI of $37.5 million. We currently anticipate that our current cash and cash equivalents, short-term investments, investments in and expected to be made in SEI and funding that we expect to receive from collaborators, which includes a moderate level of business development activity, will enable us to maintain our operations for at least the next 12 months. This estimate includes the potential repayment of a $30.0 million convertible promissory note to Protein Design Labs, Inc.

Our capital needs in 2006 may include the repayment of a $30.0 million convertible promissory note that we issued in May 2001 to Protein Design Labs, Inc. in connection with a collaboration agreement. The note matures in May 2006 and is convertible into our common stock at Protein Design Labs' option any time after the first anniversary of the note. The note is convertible into our common stock at a conversion price per share equal to the lower of (i) $28.175 or (ii) 110% of the fair market value (as defined in the note) of a share of our common stock at the time of conversion. If the note is not converted by Protein Design Labs, we will be required to repay the entire note in May 2006.

Our future capital requirements will be substantial and will depend on many factors, including:

- the level of payments received under collaborative agreements, licensing agreements and other arrangements;
- 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 outlicensed product candidates XL647, XL999 and XL784, which will determine if and when we exercise our options to reacquire these product candidates;
- 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 establishing clinical and research supplies of our product candidates;
- our ability to remain in compliance with, or amend or cause to be waived, financial covenants contained in agreements with third parties;
- 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, although we currently have no commitments relating to any such transactions; 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 must raise additional capital 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) must not be less than $25.0 million and our cash and investments (total cash, cash equivalents and investments) must not be less than $50.0 million. As of September 30, 2005, our working capital was $125.6 million and our cash and investments were $214.0 million, which includes restricted cash and investments of $13.5 million and investments held by SEI of $37.5 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.

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 $59.9 million for the nine months ended September 30, 2005. As of that date, we had an accumulated deficit of $579.3 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 product candidates and, consequently, have not generated revenues from the sale of products. 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 IND applications for additional product candidates within the next 12 months. As a result, we expect that our operating expenses will increase significantly, 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 up to $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 XL647, XL999 and XL784. We may, at our sole discretion, exercise this purchase option at any time beginning on June 9, 2006 and ending on 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 between June 9, 2006 and 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, during a period beginning on June 9, 2005 and ending on 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 programs licensed to SEI, in which case we would have to repurchase the selected program or programs through the exercise of our purchase option or program option. If we do not have sufficient resources to exercise the purchase option or program option following a compound 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.

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

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

We have limited experience in conducting clinical trials and may not be able to rapidly or effectively continue the further development of our compounds or meet current or future requirements identified based on our discussions with the FDA. We do not know whether our planned clinical trials will begin on time, will be completed on schedule, or at all, will be sufficient for registration of these compounds or will result in approvable products.

Completion of clinical trials may take several years or more, but the length of time generally varies substantially according to the type, complexity, novelty and intended use of a product candidate. The duration and the cost of clinical trials may vary significantly over the life of a project as a result of factors relating to the clinical trial, including, among others:

- the number of patients that ultimately participate in the clinical trial;
- the duration of patient follow-up that is appropriate in view of the results;
- the number of clinical sites included in the trials; and
- the length of time required to enroll suitable patient subjects.

Our research and clinical testing may be delayed or abandoned if we or our competitors subsequently discover other compounds that we believe show significantly improved safety or efficacy compared to our product candidates, which could limit our ability to generate revenues, cause us to incur additional expense and cause the market price of our common stock to decline significantly.

Risks Related to Our Relationships With Third Parties

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

Under our exclusive license agreement with Helsinn, Helsinn will be responsible for all aspects of clinical development of XL119 upon completion of the transfer of the IND for XL119 and all of its foreign equivalents. If XL119 receives regulatory approval, Helsinn will be responsible for the marketing and sale of the commercial product worldwide, unless and to the extent we reaquire the commercialization rights for North America. Because Helsinn will be responsible for these functions after the IND has been transferred, 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, beginning June 10, 2006, 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 outlicense or abandon XL119.

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

- 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 revenue 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.

If we are unable to deliver certain clinical trial materials to Helsinn for the ongoing Phase 3 clinical trial of XL119, milestone payments under our license agreement with Helsinn would be reduced and Helsinn could under certain conditions terminate the license agreement or continue the agreement at reduced royalty rates.

Under our license agreement with Helsinn, we are required to supply to Helsinn certain clinical trial materials (at Helsinn's expense) by April 30, 2006 for the ongoing Phase 3 clinical trials of XL119. Our primary supplier of clinical materials for the ongoing XL119 trial previously informed us of an internal restructuring that impacted our ability to obtain drug substance from them. While we expect that we will be able to obtain clinical trial materials when necessary to satisfy our obligation to deliver the required materials to Helsinn, we cannot be certain that we will be able to obtain additional supplies in a timely manner. Our inability to obtain clinical trial materials would result in reduced milestone payments under the license agreement. Furthermore, if we fail to supply these materials and such failure prevents Helsinn from enrolling additional patients or from maintaining the then-current enrollment in the Phase 3 trials, then Helsinn may terminate the license agreement or elect to continue the agreement at a reduced royalty rate. If the license agreement is terminated, the rights to develop and market XL119 will revert to us and we would have to fund the clinical development of XL119 on our own. If Helsinn chooses to continue the agreement at a reduced royalty rate, potential future royalty payments by Helsinn will be reduced.

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 up to $80.0 million to advance the clinical development of XL647, XL999 and XL784. We will be 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 cannot resolve a particular development issue, the issue will be referred to the chief executive officers of Exelixis and Symphony. Any disagreements between SEI and us regarding a development decision may cause significant delays in the development and commercialization of our product candidates XL647, XL999 and XL784 as well as lead to development decisions that do not reflect our interests. Any such delays or development decisions not in our interest could negatively affect the value of XL647, XL999 and XL784.

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

We have derived substantially all of our revenues to date from collaborative research and development agreements. Revenues from research and development collaborations depend upon continuation of the collaborations, the achievement of milestones and royalties we earn from any future products developed from our 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 collaborative 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 collaborative 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 is subject to earlier termination at the discretion of GlaxoSmithKline starting in 2005 if we fail to meet certain diligence requirements. 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 key business. We may not be able to enter into new collaborative 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 collaborative 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 collaborative 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 collaborative 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 collaborative 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 collaborative 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 obligations thereunder. 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 collaborative 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 and may fail to lead to commercialized products.

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

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

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

We currently do not have the manufacturing capabilities or experience necessary to enable us to produce materials for clinical trials, including the trials for XL784, XL647, XL999, XL880 and XL119. We have a remaining obligation under our license agreement with Helsinn to deliver certain clinical trial materials to Helsinn for the ongoing Phase 3 clinical trials of XL119 by April 30, 2006. 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 drugs.

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 for the conduct of our clinical trials, product testing and potential regulatory approval could be delayed, adversely impacting our ability to develop the product candidates. Similarly, if we are unable to obtain critical materials after regulatory approval has been obtained for a product candidate, the commercial launch of that product could be delayed or there would be a shortage in supply, which could materially affect our ability to generate revenues from that product. If suppliers increase the price of these materials, the price for one or more of our products may increase, which may make our product 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 in the facilities used to produce these materials, due to technical, regulatory or other problems, it could harm our ability to manufacture our products.

Risks Related to Regulatory Approval of Our Product Candidates

Our product candidates are subject to a lengthy and uncertain regulatory process that may not result in the necessary regulatory approvals, which could adversely affect our ability to commercialize products.

Our product candidates, as well as the activities associated with their research, development and commercialization, are subject to extensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other

countries. Failure to obtain regulatory approval for a product candidate would prevent us from commercializing that product candidate. We have not received regulatory approval to market any of our product candidates in any jurisdiction and have only limited experience in preparing and filing the applications necessary to gain regulatory approvals. The process of obtaining regulatory approvals is expensive, 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 material 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 to perform sales, marketing and distribution services with third parties, 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 their medical needs. If third-party payors do not provide coverage or reimbursement for any products that we may develop, our revenues and prospects for profitability will suffer. In addition, even if third-party payors provide some coverage or reimbursement for our products, the availability of such coverage or reimbursement for prescription drugs under private health insurance and managed care plans often varies based on the type of contract or plan purchased.

A primary trend in the United States health care industry is toward cost containment. In December 2003, the President signed into law legislation creating a prescription drug benefit program for Medicare recipients. The prescription drug program established by the legislation may have the effect of reducing the prices that we are able to charge for products we develop and sell through these plans. This prescription drug legislation 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 amount that they will pay.

Another development that may affect the pricing of drugs is the proposed Congressional action regarding drug reimportation into the United States. The Medicare Prescription Drug Plan legislation gives additional discretion to the Secretary of Health and Human Services to allow drug reimportation from foreign countries into the United States under some circumstances, including countries where the drugs are sold at a lower price than in the United States. Proponents of drug reimportation may attempt to pass legislation, which would directly allow reimportation under certain circumstances. If legislation or regulations were passed allowing the reimportation of drugs, they 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 of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement 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 staffs and facilities, more experience in obtaining regulatory approvals and more extensive product manufacturing and marketing capabilities. As a result, our competitors may be able to more easily develop technologies and products that would render our technologies and products, and those of our collaborators, obsolete and noncompetitive. In addition, there may be product candidates of which we are not aware at an earlier stage of development that may compete with our product candidates.

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

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

Risks Related to Our Intellectual Property

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

Our success will depend in part upon our ability to obtain patents and maintain adequate protection of the intellectual property related to our technologies and products. The patent positions of biotechnology companies, including our patent position, are generally uncertain and involve complex legal and factual questions. We will be able to protect our intellectual property rights from unauthorized use by third parties only to the extent that our technologies are covered by valid and enforceable patents or are

effectively maintained as trade secrets. We will continue to apply for patents covering our technologies and products as and when we deem appropriate. However, these applications may be challenged or may fail to result in issued patents. In addition, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that cover the production, manufacture, commercialization or use of our product candidates. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Furthermore, others may independently develop similar or alternative technologies or design around our patents. In addition, our patents may be challenged or invalidated or may fail to provide us with any competitive advantages, if, for example, others were the first to invent or to file patent applications for these inventions.

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

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

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

Many of our employees and independent contractors were previously employed at universities, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, independent contractors or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and 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 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. However, 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, recent 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 and may discover deficiencies in existing systems and controls.

Our headquarters facilities are located near known earthquake fault zones, and the occurrence of an earthquake or other catastrophic disaster could cause damage to our facilities and equipment, which could require us to cease or curtail 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 worldwide to damage from other types of disasters, including fire, floods, power loss, communications failures, terrorism and similar events. If any disaster were to occur, our ability to operate our business at our facilities would 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. The insurance we maintain may not be adequate to cover our losses resulting from disasters or other business interruptions. Accordingly, an earthquake or other disaster could materially and adversely harm our ability to conduct business.

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

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

Risks Related to Environmental and Product Liability

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

Our research and development processes involve the controlled use of hazardous materials, including chemicals and radioactive and biological materials. Our operations produce hazardous waste products. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. We may 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 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 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 have banned products or require express 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, 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.

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 products;
- the impairment of acquired goodwill and other assets; and
- general and industry-specific economic conditions that may affect our collaborators' research and development expenditures.

A large portion of our expenses, including expenses for facilities, equipment and personnel, are relatively fixed in the short term. In addition, we expect operating expenses to increase significantly as we move more compounds into clinical development. Accordingly, if our revenues decline or do not grow as anticipated due to the expiration or termination of existing contracts, our failure to obtain new contracts or our inability to meet milestones or because of other factors, we may not be able to correspondingly reduce our operating expenses. Failure to achieve anticipated levels of revenues could therefore significantly harm our operating results for a particular fiscal period.

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

Our stock price may be extremely volatile.

The trading price of our common stock has been highly volatile, and we believe the trading price of our common stock will remain highly volatile and may fluctuate substantially due to factors such as the following:

- adverse results or delays in clinical trials;
- announcement of FDA approval or non-approval, or delays in the FDA review process, of our or our collaborators' product candidates or those of our competitors or actions taken by regulatory agencies with respect to our, our collaborators' or our competitors' clinical trials;
- 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;
- 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 and fluctuations, 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 deemed appropriate. For example, following an acquisition, a significant number of shares of our common stock held by new stockholders may become freely tradable or holders of registration rights could cause us to register their shares for resale. Sales of these shares of common stock held by existing stockholders could cause the market price of our common stock to decline.

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

Due to their combined stock holdings, our officers, directors and principal stockholders (stockholders holding more than 5% of our common stock), acting together, may be able to exert significant influence over all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. In addition, this concentration of ownership may delay or prevent a change in control of our company, even when a change may be in the best interests of our stockholders. In addition, the interests of these stockholders may not always coincide with our interests as a company or the interests of other stockholders. Accordingly, these stockholders could cause us to enter into transactions or agreements that you would not view 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 us, 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 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our market risks at September 30, 2005 have not changed significantly from those discussed in Item 7A of our Form 10-K for the year ended December 31, 2004 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, 2005 and December 31, 2004. As of September 30, 2005 and December 31, 2004, 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 $3.5 million and $4.3 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 our Chief Financial Officer have concluded that as of the end of the period covered by this report, our disclosure controls and procedures were effective.

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

PART II. OTHER INFORMATION

ITEM 6. EXHIBITS

(a) Exhibits

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

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.

EXELIXIS, INC.

Date: November 3, 2005

/s/ Frank Karbe

Frank Karbe
Senior Vice President, Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

Number	Exhibit Description
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).

* 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 the Company 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.

Exhibit 31.1

CERTIFICATION

I, George A. Scangos, Ph.D., Chief Executive Officer of Exelixis, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Exelixis, Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 3, 2005

/s/ George A. Scangos
George A. Scangos
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Frank Karbe, Chief Financial Officer of Exelixis, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Exelixis, Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 3, 2005

/s/ Frank Karbe

Frank Karbe
Senior Vice President, Chief Financial Officer

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), George A. Scangos, Chief Executive Officer of Exelixis, Inc. (the "Company"), and Frank Karbe, Chief Financial Officer of the Company, each hereby certifies, to his knowledge, that:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2005 (the "Periodic Report"), to which this Certification is attached as Exhibit 32.1, fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In Witness Whereof, the undersigned have set their hands hereto as of the 3rd day of November 2005.

/s/ George A. Scangos
George A. Scangos, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

/s/ Frank Karbe
Frank Karbe
Chief Financial Officer
(Principal Financial Officer)