## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D. C. 20549

## FORM 10-Q

X	QUARTERLY REPORT PURSUANT TO SECTION	ON 13 OR 15(d) OF THE SECURITIES EX	CHANGE ACT OF 1934
	For	r the quarterly period ended March 31, 2006	
		Or	
	TRANSITION REPORT PURSUANT TO SECTION	ON 13 OR 15(d) OF THE SECURITIES EX	CHANGE ACT OF 1934
	For the tran	nsition period from to	
		Commission File Number: 0-30235	
		Exelixis, Inc.	
	(Exact	name of registrant as specified in its charter	r)
	<b>Delaware</b> (State or other jurisdiction of incorporation or organization)		04-3257395 (I.R.S. Employer Identification No.)
	(Add	170 Harbor Way P.O. Box 511 South San Francisco, CA 94083 dress of principal executive offices, including zip code)	
	(F	(650) 837-7000 Registrant's telephone number, including area code)	
the ]	cate by check mark whether the registrant (1) has filed all preceding 12 months (or for such shorter period that the repast 90 days. Yes $\ oxdot$ No $\ \Box$		
	cate by check mark whether the registrant is a large accel e accelerated filer" in Rule 12b-2 of the Exchange Act. (0		lerated filer. See definition of "accelerated filer and
	Large accelerated filer $\ \square$	Accelerated filer $\boxtimes$	Non-accelerated filer $\ \Box$
Indi	cate by check mark whether the registrant is a shell comp	pany (as defined in Rule 12b-2 of the Exchange	e Act). Yes □ No ⊠
On .	April 28, 2006 there were 83,925,538 shares of common	stock, par value \$.001 per share, of Exelixis, I	nc. outstanding.

#### EXELIXIS, INC.

## QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2006

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#### ITEM 1. FINANCIAL STATEMENTS

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

	March 31, 	December 31, 2005 <sup>(1)</sup>
ASSETS	( , , , , , ,	
Current assets:		
Cash and cash equivalents	\$ 140,101	\$ 96,471
Marketable securities	36,995	67,307
Investments held by Symphony Evolution, Inc.	30,279	34,039
Other receivables	5,936	7,102
Prepaid expenses and other current assets	4,951	5,442
Total current assets	218,262	210,361
Restricted cash and investments	12,123	12,682
Property and equipment, net	33,715	35,577
Goodwill	67,364	67,364
Other intangibles, net	3,154	3,425
Other assets	2,964	3,303
Total assets	\$ 337,582	\$ 332,712
LIABILITIES, NONCONTROLLING INTEREST AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 3,120	\$ 1,689
Other accrued expenses	13,060	13,774
Accrued compensation and benefits	6,791	7,817
Current portion of capital lease obligations	8	98
Current portion of notes payable and bank obligations	12,081	11,893
Convertible promissory note	30,000	30,000
Deferred revenue	59,259	43,484
Total current liabilities	124,319	108,755
Notes payable and bank obligations	21,250	21,858
Convertible promissory note and loans	85,000	85,000
Other long-term liabilities	16,184	14,475
Deferred revenue	56,307	45,329
Total liabilities	303,060	275,417
Noncontrolling interest in Symphony Evolution, Inc.	20,234	23,752
Commitments		
Stockholders' equity:		
Common stock	85	84
Additional paid-in-capital	644,096	636,263
Accumulated other comprehensive income	1,007	973
Accumulated deficit	(630,900)	(603,777)
Total stockholders' equity	14,288	33,543
Total liabilities, noncontrolling interest and stockholders' equity	\$ 337,582	\$ 332,712

The condensed consolidated balance sheet at December 31, 2005 has been derived from the audited consolidated 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 Mon Marc 2006	
Revenues:		
Contract	\$ 12,246	\$ 10,090
License	5,873	2,784
Total revenues	18,119	12,874
Operating expenses:		
Research and development	39,897	33,321
General and administrative	9,007	6,242
Amortization of intangible assets	272	272
Total operating expenses	49,176	39,835
Loss from operations	(31,057)	(26,961)
Other income (expense):		
Interest income	1,944	928
Interest expense	(1,534)	(1,552)
Other income, net	6	174
Total other income (expense)	416	(450)
Loss before noncontrolling interest in Symphony Evolution, Inc.	(30,641)	(27,411)
Loss attributed to noncontrolling interest in Symphony Evolution, Inc.	3,518	
Net loss	\$(27,123)	\$(27,411)
Net loss per share, basic and diluted		\$ (0.36)
Shares used in computing basic and diluted net loss per share		75,918

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

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

	Three Months Ended March 31,	
	2006	2005
Cash flows from operating activities:		
Net loss	\$ (27,123)	\$(27,411)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	4,313	4,178
Loss attributed to noncontrolling interest	(3,518)	_
Stock-based compensation expense	4,636	(16)
Amortization of intangibles	272	272
Gain on the sale of equipment	_	(122)
Other	135	117
Changes in assets and liabilities:		
Other receivables	1,313	(8,400)
Prepaid expenses and other current assets	486	(925)
Other assets	(134)	(1,062)
Accounts payable and other accrued expenses	1,192	(6,789)
Other long-term liabilities	1,709	1,612
Deferred revenue	26,753	6,261
Net cash provided by (used in) operating activities	10,034	(32,285)
Cash flows from investing activities:		
Purchases of investments held by Symphony Evolution, Inc.	(343)	_
Proceeds on sale of investments held by Symphony Evolution, Inc.	4,102	_
Purchases of property and equipment	(2,057)	(3,986)
Proceeds from sale of equipment	_	152
Change in restricted cash and investments	559	560
Proceeds from maturities of marketable securities	45,443	35,512
Purchases of marketable securities	(15,180)	(21,285)
Net cash provided by investing activities	32,524	10,953
Cash flows from financing activities:		
Proceeds from the issuance of common stock, net of offering costs	_	8,854
Proceeds from exercise of stock options and warrants	1,562	54
Payments on capital lease obligations	(90)	(664)
Proceeds from notes payable and bank obligations	2,424	_
Principal payments on notes payable and bank obligations	(2,842)	(3,678)
Net cash provided by financing activities	1,054	4,566
Effect of foreign exchange rate changes on cash and cash equivalents	18	45
Net increase (decrease) in cash and cash equivalents	43,630	(16,721)
Cash and cash equivalents, at beginning of period	96,471	78,105
Cash and cash equivalents, at ordering of period	\$140,101	\$ 61,384
Cash and Cash equivalents, at end of period	\$140,101	Ψ 01,304

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

# EXELIXIS, INC. NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS MARCH 31, 2006 (unaudited)

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

#### Organization

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

#### **Basis of Presentation**

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

#### **Basis of Consolidation**

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

#### **Net Loss Per Share**

Basic and diluted net loss per share are computed by dividing the net loss for the period by the weighted average number of shares of common stock outstanding during the period adjusted for shares that are subject to repurchase. The calculation of diluted net loss per share excludes potential common stock because their effect is antidilutive. Potential common stock consists of common stock subject to repurchase, 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 adopted Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment*, ("SFAS 123R") effective January 1, 2006, which requires the recognition of stock-based compensation at fair value in our consolidated statements of operations. We adopted SFAS 123R under the modified prospective method and therefore we have not restated results for prior periods. Under the modified prospective method, we recorded compensation expense for all awards granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provision of SFAS No. 123, *Accounting for Stock-Based Compensation*, ("SFAS 123"). Stock-based compensation expense for all stock-based compensation awards granted after January 1, 2006 is based on the grant date fair value estimated in accordance with the provisions of SFAS 123R. We continued to apply the Black-Scholes option pricing model in determining the fair value of share based payments to employees, which will then be amortized on a straight-line basis over the requisite service period. Prior to the adoption of SFAS 123R, we recognized stock-based compensation expense in accordance with Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25"). See Note 3 to the Condensed Consolidated Financial Statements for a further discussion on stock-based compensation.

#### Reclassification

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

#### **NOTE 2 Comprehensive Loss**

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

	Three Months Ended March 31.	
	2006	2005
Net loss	\$(27,123)	\$(27,411)
Increase (decrease) in unrealized gains on available-for-sale securities	68	(236)
Increase (decrease) in cumulative translation adjustment	(34)	144
Comprehensive loss	\$(27,089)	\$(27,503)

#### **NOTE 3 Stock-Based Compensation**

#### Stock Option Plans

We have several stock option plans under which we have granted incentive stock options and non-qualified stock options to employees, directors and consultants. The Board of Directors or a designated Committee of the Board is responsible for administration of Exelixis' employee stock option plans and determines the term, exercise price and vesting terms of each option. In general, our options have a four-year vesting term, an exercise price equal to the fair market value on the date of grant, and a ten year life from the date of grant. At March 31, 2006, a total of 7.9 million shares were available for grant under our stock option plans.

#### Stock Purchase Plan

In January 2000, we adopted the 2000 Employee Stock Purchase Plan (the "ESPP"). The ESPP allows for qualified employees (as defined in the ESPP) to purchase shares of our common stock at a price equal to the lower of 85% of the closing price at the beginning of the offering period or 85% of the closing price at the end of each six month purchase period. At March 31, 2006, we had 1.6 million shares available for grant under our ESPP.

#### Adoption of SFAS 123R

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

As a result of adopting SFAS 123R, we recorded employee stock-based compensation of \$4.6 million for the three months ended March 31, 2006. The impact on both basic and diluted net loss per share for the three months ended March 31, 2006 was \$0.05. Employee stock-based compensation expenses of \$3.1 million and \$1.5 million were allocated to research and development expenses and general and administrative expenses, respectively. Prior to March 31, 2006, we provided pro forma disclosures amounts in accordance with SFAS 123, as if the fair value method defined by SFAS 123 had been applied to our stock-based compensation. The following table illustrates the effect on net loss and loss per share for the three-month period ending March 31, 2005, had we applied the fair value recognition provisions of SFAS 123 (in thousands, except per share amounts):

	Months Ended, rch 31, 2005
Net loss:	
As reported	\$ (27,411)
Add: Stock-based employee compensation expense (reversal) included in reported net	
loss	(16)
Deduct: Total employee stock-based compensation expense determined under fair value	
method for all awards	(4,421)
Pro forma	\$ (31,848)
Net loss per share (basic and diluted):	
As reported	\$ (0.36)
Pro forma	\$ (0.42)

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

	Stock O <sub>l</sub>	ptions	ESPI	P
	Three Mont		Three Month	
	March	31,	March	31,
	2006	2005	2006	2005
Weighted average grant date fair value of grants	\$ 5.31	\$ 5.18	\$ 2.20	\$ 2.46
Risk-free interest rate	4.31%	3.46%	4.12%	1.11%
Dividend yield	0%	0%	0%	0%
Volatility	64%	72%	56%	63%
Expected life	4.7 years	4.0 years	0.5 years	0.5 years

A summary of all option activity for the three months ended March 31, 2006 is presented below:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Options outstanding at December 31, 2005	13,157,431	\$ 10.73		
Granted	3,581,155	9.46		
Exercised	(196,852)	7.52		
Cancelled	(230,908)	16.05		
Options outstanding at March 31, 2006	16,310,826	10.42	7.9 years	\$46,541,025
Exercisable at March 31, 2006	8,598,680	11.59	6.5 years	\$24,138,158

The aggregate intrinsic value in the table above represents the total intrinsic value (the difference between our closing stock price on the last trading day of the first quarter of fiscal 2006 and the exercise prices, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on March 31, 2006. Total intrinsic value of options exercised for the three months ended March 31, 2006 was \$0.6 million. Total fair value of options vested and expected to vest was \$4.4 million and compensation expense related to our ESPP was \$0.2 million for the three months ended March 31, 2006.

As of March 31, 2006, \$47.0 million of total unrecognized compensation expense related to stock options is expected to be recognized over a weighted-average period of 3.2 years. Cash received from option exercises for the first three months ended March 31, 2006 was \$1.5 million.

#### **NOTE 4 Bristol-Myers Squibb**

In December 2005, Exelixis and Bristol-Myers Squibb ("BMS") entered into a collaboration agreement for the discovery, development and commercialization of novel therapies targeted against the Liver X Receptor ("LXR"), a nuclear hormone receptor implicated in a variety of cardiovascular and metabolic disorders. Upon closing of the transaction in January 2006, we granted BMS an exclusive, worldwide license with respect to certain intellectual property primarily relating to compounds that modulate LXR. During the research term, Exelixis and BMS expect to jointly identify drug candidates that are ready for IND-enabling studies. After the selection of a drug candidate for further clinical development by BMS, BMS will be solely responsible for further preclinical development as well as clinical development, regulatory, manufacturing and sales/marketing activities for such drug candidate.

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

#### **NOTE 5 Sankyo Company**

In March 2006, Exelixis and Sankyo Company, a wholly-owned subsidiary of Daiichi Sankyo Company, Limited ("Sankyo"), entered into a collaboration agreement for the discovery, development and commercialization of novel therapies targeted against the mineralocorticoid receptor ("MR"), a nuclear hormone receptor implicated in a variety of cardiovascular and metabolic diseases. Under the terms of the agreement, we granted to Sankyo an exclusive, worldwide license with respect to certain intellectual property primarily relating to compounds that modulate MR. After completion of the research term, Sankyo will be responsible for all further preclinical and clinical development, regulatory, manufacturing and commercialization activities for the compounds.

Sankyo paid us a nonrefundable upfront payment in the amount of \$20.0 million and is obligated to provide research and development funding of \$3.8 million over a 15-month research term. Exelixis and Sankyo may mutually agree to extend the research term for an additional two years. The upfront payment and research and development funding will be recognized as revenue over the research term commencing as of April 1, 2006. Under the agreement, Sankyo is required to pay us pre-specified development, regulatory and commercialization milestones. In addition, we are also entitled to receive royalties on sales of certain products commercialized under the agreement.

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

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

This discussion and analysis should be read in conjunction with our financial statements and accompanying notes included in this report and the 2005 audited financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2005, filed with the Securities and Exchange Commission on March 9, 2006. Operating results are not necessarily indicative of results that may occur in future periods. We undertake no obligation to update any forward-looking statement to reflect events after the date of this report.

#### Overview

Exelixis is committed to developing innovative therapies for cancer and other serious diseases. Through our 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.

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

To date, we have filed eight investigational new drug applications (INDs). We believe that our deep pool of drug candidates will enable us to continue to file multiple new INDs each year for the foreseeable future. As our compounds advance into clinical development, we expect to generate a critical mass of data that will help us understand the full clinical and commercial potential of our product candidates. In addition to guiding the potential commercialization of our innovative therapies, these data may contribute to the understanding of disease and help improve treatment outcomes.

Our current pipeline includes the following compounds:

Compound Targets		Indication	Stage of Development
XL119*	Topoisomerase 2	Biliary tract cancer	Phase 3
XL999**	VEGFR, PDGFR, FGFR	Renal cell carcinoma, colon, ovarian, non-small cell lung cancers, multiple myeloma and acute myelogenous leukemia	Phase 2
XL784**	ADAM 10	Diabetic nephropathy	Phase 2
XL647**	EGFR, HER2, VEGFR	Cancer	Phase 1
XL880	c-MET, VEGFR2	Cancer	Phase 1
XL820	c-KIT, VEGFR2 and PDGFR	Cancer	Phase 1
XL844	CHK 1 and 2	Cancer	Phase 1
XL184	c-MET, VEGFR2	Cancer	Phase 1
XL281	RAF	Cancer	Preclinical
XL418	AKT/S6K	Cancer	Preclinical
XL228	ABL, SRC	Cancer	Preclinical
XL550	MR	Hypertension	Preclinical
XL335*	FXR	Atherosclerosis	Preclinical
EXEL2255*	LXR	Atherosclerosis	Preclinical

<sup>\*</sup> XL119, XL335 and EXEL2255 are out-licensed to Helsinn, Wyeth and BMS, respectively.

<sup>\*\*</sup> Out-licensed to Symphony Evolution, Inc. and subject to exclusive repurchase options.

Pursuant to a product development and commercialization agreement between Exelixis and GlaxoSmithKline, GlaxoSmithKline has the option, after completion of clinical proof-of-concept by Exelixis, to elect to develop up to three compounds in Exelixis' product pipeline, which may include XL784 and the cancer compounds identified in the table above (other than XL119).

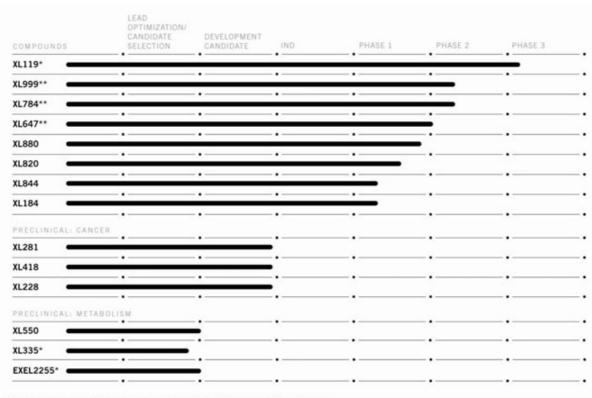
We have established collaborations with major pharmaceutical and biotechnology companies based on the strength of our technologies and expertise in biology, drug discovery and development that allow us to retain economic participation in compounds and support additional development of our proprietary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

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 our company by enabling us to achieve an appropriate functional balance within our organization.

#### **Recent Developments**

#### **Development Update**

We have an extensive pipeline of compounds in various stages of development that will potentially treat cancer, renal disease and various metabolic and cardiovascular disorders. The following table summarizes the status of our clinical and preclinical development pipeline.



<sup>\*</sup> XL119, XL335 and EXEL2255 are out-licensed to Helsinn, Wyeth and BMS, respectively

Pursuant to a product development and commercialization agreement between Exelixis and GlaxoSmithKline, GlaxoSmithKline has the option, after completion of clinical proof-of-concept by Exelixis, to elect to develop up to three compounds in Exelixis' product pipeline, which may include XL784 and the cancer compounds identified in the table above (other than XL119).

#### **Pipeline Update**

We currently have eight compounds in clinical development. XL119, which has been exclusively licensed to Helsinn Healthcare S.A. of Switzerland, is in a multi-national Phase 3 clinical trial for the treatment of bile duct tumors. XL999 is being evaluated in Phase 2 clinical trials in patients with renal cell carcinoma, colon, ovarian, non-small cell lung cancer, multiple myeloma and acute myelogenous leukemia (AML). We commenced a Phase 2 clinical trial of XL784 in the first quarter of 2006 to test its efficacy in patients with renal failure. We have completed a Phase 1 clinical trial of XL647 and the Phase 2 clinical program for XL647 in patients with tumors where kinases inhibited by XL647 are known to play a role is expected to start in the middle of 2006. Additionally, in oncology, we have Phase 1 clinical trials ongoing for 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 (CLL).

All of our compounds, with the exception of XL119 (which was in-licensed from Bristol-Myers Squibb), were generated through our internal drug discovery efforts. The oncology program currently is comprised of ten compounds – seven in clinical development and three in preclinical development. We plan to continue preclinical work on XL281, XL418 and XL228 with the goal of filing three INDs in 2006.

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

<sup>\*\*</sup> Out-licensed to Symphony Evoluation, Inc. and subject to a repurchase option.

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

In December 2005, Exelixis and Bristol-Myers Squibb entered into a collaboration agreement for the discovery, development and commercialization of novel therapies targeted against the Liver X Receptor (LXR), a nuclear hormone receptor implicated in a variety of cardiovascular and metabolic disorders. Upon closing of the transaction in January 2006, we granted Bristol-Myers Squibb an exclusive, worldwide license with respect to certain intellectual property primarily relating to compounds that modulate LXR. During the research term, Exelixis and Bristol-Myers Squibb expect to jointly identify drug candidates that are ready for IND-enabling studies. After the selection of a drug candidate for further clinical development by Bristol-Myers Squibb, Bristol-Myers Squibb will be solely responsible for further preclinical development as well as clinical development, regulatory, manufacturing and commercialization activities for such drug candidate.

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

#### Sankyo Company

In March 2006, Exelixis and Sankyo Company, a wholly-owned subsidiary of Daiichi Sankyo Company Limited (Sankyo) entered into a collaboration agreement for the discovery, development and commercialization of novel therapies targeted against the mineralocorticoid receptor (MR), a nuclear hormone receptor implicated in a variety of cardiovascular and metabolic diseases. Under the terms of the agreement, we have granted to Sankyo an exclusive, worldwide license with respect to certain intellectual property primarily relating to compounds that modulate MR. After completion of the research term, Sankyo will be responsible for all further preclinical and clinical development, regulatory, manufacturing and commercialization activities for the compounds.

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

#### **Certain Factors That May Affect Our Business**

Industry-wide Factors

Successful development of drugs is highly difficult and uncertain. Our business requires significant investments in research and development over many years, often for products that fail during the research and development process. Our long-term prospects depend upon our ability and the ability of our partners to successfully commercialize new therapeutics in highly competitive areas such as cancer.

#### Company-specific Factors

Our financial performance will be driven by many factors, including:

• Clinical Trials. We currently have multiple compounds in clinical testing and expect to continue to advance more compounds into clinical development. Our compounds may fail to show safety or efficacy in clinical testing. Furthermore, predicting the timing of the completion or initiation of clinical trials is exceedingly difficult and our trials may be delayed due to many factors, including factors outside of our control. The future development path of each of our compounds depends upon the results of each stage of clinical

development. In general, we will incur increased operating expenses for compounds that advance to the next stage of clinical development, whereas expenses will end for compounds that do not warrant further clinical development.

- Liquidity. As of March 31, 2006, we had \$219.5 million in cash and cash equivalents and marketable securities, which included restricted cash and investments of \$12.1 million and investments held by Symphony Evolution, Inc. (SEI) of \$30.3 million. We currently anticipate that our current cash and cash equivalents, marketable securities, investments held by SEI, additional committed financing from SEI and other 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 scheduled repayment of a \$30.0 million convertible promissory note to Protein Design Labs due in May 2006. We will have to obtain additional funding in order to support the aggressive development of our broad clinical and preclinical pipelines. Our minimum liquidity needs are also determined by certain financial covenants contained in our loan and security agreement with GlaxoSmithKline, which require us to maintain working capital of at least \$25.0 million and cash and investments of at least \$50.0 million. Our ability to raise additional funds may be severely impaired if any of our product candidates fails to show safety or efficacy in clinical testing.
- Reliance on Partners. We currently have no pharmaceutical products that have received marketing approval, and we have generated no revenues from the sale of such products. We do not expect to generate product revenues from the sale of pharmaceutical products in the near term and expect that all of our revenues, such as milestone and royalty revenues, will be generated from collaboration agreements with our partners. Milestones under these agreements may be tied to factors that are outside of our control, such as significant clinical or regulatory events with respect to compounds that have been licensed to our partners.
- GlaxoSmithKline Compound Selection. Pursuant to our product development and commercialization agreement with GlaxoSmithKline,
  GlaxoSmithKline has the option, after completion of clinical proof-of-concept by us, to elect to develop up to three compounds in our product pipeline,
  which may include XL784, XL647, XL999, XL880, XL184, XL820, XL844, XL281, XL418, XL228 and two earlier stage oncology programs. A
  compound selection by GlaxoSmithKline could potentially trigger significant milestone payments. The size of these milestone payments depends
  largely on how quickly we can advance compounds to proof-of-concept. Delays in obtaining clinical proof-of-concept for compounds subject to
  GlaxoSmithKline's election rights may decrease the size of any GlaxoSmithKline milestones and negatively impact our financial position.
- Symphony Evolution. In 2005, we licensed three of our lead compounds (XL784, XL647 and XL999) to SEI in return for up to \$80.0 million in investment for the clinical development of these compounds. We continue to be primarily responsible for the development of these compounds in accordance with specified development plans and related development budgets. We have retained exclusive options to reacquire the compounds from SEI at specified purchase prices. If GlaxoSmithKline elects any of the compounds licensed to SEI for further development, we would have to repurchase such compound or compounds from SEI. If selection milestones received under our GlaxoSmithKline collaboration are insufficient to cover the repurchase price, we may have to raise additional funds to cover the repurchase price. In addition, the repurchase prices for the compounds licensed to SEI increase over the length of the option period.

#### **Critical Accounting Estimates**

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

An accounting policy is considered to be critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, and if different estimates that reasonably could have been used, or changes in the accounting estimates that are reasonably likely to occur periodically, could materially impact the financial statements. There have been no changes during the three months ended March 31, 2006 to the items that we disclosed as our critical accounting estimates in Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the fiscal year ended December 31, 2005.

#### **Results of Operations**

#### Revenues

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

		Three Months Ended March 31,	
	2006	2005	
Contract revenue:			
Research and development funding	\$ 10.7	\$ 9.8	
Milestones	1.5	0.3	
License revenue:			
Amortization of upfront payments, including premiums paid on equity purchases	5.9	2.8	
Total revenues	\$ 18.1	\$ 12.9	
Dollar increase	\$ 5.2		
Percentage increase	41%		

The increase of \$0.9 million in research and development funding for the three months ended March 31, 2006, as compared to the comparable prior year period, was driven primarily by increases in funding of \$2.1 million from Bristol-Myers Squibb, \$0.8 million from Genentech and \$0.8 million attributable to customers of our German subsidiary. These increases were offset by decreases of \$2.0 million related to the conclusion of our Genoptera collaboration in June 2005 and \$1.0 million due to the completion of our first collaboration with Sankyo in March 2005.

The increase of \$1.2 million in milestone revenues for the three months ended March 31, 2006, as compared to the comparable prior year period, was driven by revenues associated with achieving two milestones under our collaboration with GlaxoSmithKline in May 2005.

The increase of \$3.1 million in the amortization of upfront payments, including premiums paid on equity purchases for the three months ended March 31, 2006, as compared to the comparable prior year period, was driven primarily by additional revenues of \$2.5 million from upfront payments from Wyeth and \$1.2 million from Bristol-Myers Squibb, offset by a decrease of \$0.6 million related to the conclusion of our Genoptera collaboration in June 2005.

#### 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 Month March	
	2006	2005
Research and development expenses	\$ 39.9	\$ 33.3
Dollar increase	\$ 6.6	
Percentage increase	20%	

Research and development expenses consist primarily of personnel expenses, employee stock-based compensation expenses, laboratory supplies, consulting and facilities costs. The increase for the three months ended March 31, 2006, as compared to the comparable period in 2005, resulted primarily from the following:

- Employee Stock-Based Compensation Employee stock-based compensation expense increased by \$3.1 million due to our adoption of SFAS 123R effective January 1, 2006.
- Consulting and Professional Consulting and professional expense, which includes services performed by third-party contract research organizations and other vendors, increased by \$2.2 million, or 64%, primarily due to an increase in activities associated with advancing our clinical and preclinical development programs. These activities included Phase 2 clinical trial activity for XL999 and XL784 and Phase 1 clinical trial activity for XL647, XL880, XL844, XL820 and XL184 as well as pre-clinical activity for XL228, X281 and XL418.
- Personnel Personnel expense, which includes salaries, bonuses, related fringe benefits, recruiting and relocation costs, increased by \$1.3 million, or 10%, primarily due to the expansion of our headcount supporting drug development operations to advance our clinical and preclinical development programs.

We currently estimate that typical Phase 1 clinical trials last approximately one year, Phase 2 clinical trials last approximately one to two years and Phase 3 clinical trials last approximately two to four years. However, the length of time may vary substantially according to factors relating to the 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 for a particular drug candidate to reach the market. Our potential therapeutic products are subject to a lengthy and uncertain regulatory process that may involve unanticipated additional clinical trials and 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 Mont March	
	2006	2005
General and administrative expenses	\$ 9.0	2005 \$ 6.2
Dollar increase	\$ 2.8	
Percentage increase	44%	

General and administrative expenses consist primarily of personnel expenses, employee stock-based compensation expense, facility costs and consulting and professional expenses, such as legal and accounting fees. The increase in expenses for the three months ended March 31, 2006, as compared to the comparable period in 2005, resulted primarily from the increase of \$1.5 million in employee stock-based compensation expense due to our adoption of SFAS 123R as well as consulting and personnel expenses to support our general operating activities.

#### **Amortization of Intangibles**

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

	March	
	2006	2005
Amortization of intangible assets	\$ 0.3	\$ 0.3
Dollar increase	\$ —	
Percentage increase	0%	

Three Months Ended

Intangible assets result from our acquisitions of X-Ceptor, Genomica, Artemis and Agritope (renamed Exelixis Plant Sciences). Amortization of intangibles expense was consistent for the three months ended March 31, 2006, as compared to the comparable period in 2005.

#### **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 Mon March	
	2006	2005
Total other income (expense)	\$ 0.4	\$ (0.5)
Dollar increase	\$ 0.9	
Percentage increase	192%	

Total other income (expense) consists primarily of interest income earned on cash and cash equivalents, marketable securities and investments held by SEI, offset by interest expense incurred on our notes payable, bank obligations, capital lease obligations and convertible notes and loans. The increase in total other income (expense) for the three months ended March 31, 2006, as compared to the comparable period in 2005, was primarily due to increases in interest income as a result of higher cash and investment balances as well as higher average interest rates.

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

We have consolidated SEI's financial condition and results of operations in accordance with Financial Accounting Standards Board (FASB) Interpretation No. 46 (revised 2003), *Consolidation of Variable Interest Entities* (FIN 46R). While we have consolidated SEI's financial condition and results of operations in accordance with FIN 46R, SEI is wholly-owned by the noncontrolling interest holders. Therefore, we have deducted the losses attributed to the noncontrolling interest (SEI's losses) from our net loss in the condensed consolidated statement of operations and we have also reduced the noncontrolling interest holders' ownership interest in SEI in the condensed consolidated balance sheet by SEI's losses. For the three-month periods ended March 31, 2006 and 2005, the losses attributed to the noncontrolling interest holders were \$3.5 million and none, respectively.

#### Liquidity and Capital Resources

#### Sources and Uses of Cash

The following table summarizes our cash flow activities for the three-month periods ended March 31, 2006 and 2005 (dollar amounts are presented in thousands):

		Three Months Ended March 31,	
	2006	2005	
Net loss	\$ (27,123)	\$(27,411)	
Adjustments to reconcile net loss to net cash provided by (used in) operating activities	5,838	4,429	
Changes in operating assets and liabilities	31,319	(9,303)	
Net cash provided by (used in) operating activities	10,034	(32,285)	
Net cash provided by investing activities	32,524	10,953	
Net cash provided by financing activities	1,054	4,566	
Effect of foreign exchange rate changes on cash and cash equivalents	18	45	
Net increase (decrease) in cash and cash equivalents	43,630	(16,721)	
Cash and cash equivalents, at beginning of year	96,471	78,105	
Cash and cash equivalents, at end of year	\$140,101	\$ 61,384	

To date, we have financed our operations primarily through the sale of equity, payments and loans from collaborators, equipment financing facilities and interest income. We have also financed certain of our research and development activities under our agreements with SEI. As of March 31, 2006, we had \$219.5 million in cash and cash equivalents and marketable securities, which includes restricted cash and investments of \$12.1 million and investments held by SEI of \$30.3 million.

#### **Operating Activities**

Our operating activities provided cash of \$10.0 million and used cash of \$32.3 million for the three months ended March 31, 2006 and 2005, respectively. Cash provided by operating activities for the 2006 period relates primarily to upfront payments received from Bristol-Myers Squibb of \$17.5 million and Sankyo of \$20.0 million. Significant differences between our net loss and cash provided by operating activities in 2006 include non-cash stock-based compensation expense recognized due to our adoption of SFAS 123R and non-cash charges related to depreciation and amortization. Cash used in operating activities for the 2005 period relates primarily to funding net losses and changes in other receivables and accounts payable and other accrued expenses, partially offset by changes in deferred revenues from collaborators.

Changes in cash from operating activities are primarily a result of differences in the timing of cash receipts and earnings recognition, expenses related to the noncontrolling interest and non-cash charges. For example, we recorded an

increase in deferred revenues of \$20.5 million during the 2006 period as compared to the 2005 period. This increase in deferred revenues represented the excess of cash received in 2006 over the revenues which were recognized and included in the calculation of net loss. In addition, net loss for the 2006 period excluded losses which are attributed to the noncontrolling interest in SEI. However, our cash used in operating activities for the 2006 period included expenses related to \$3.5 million in losses attributed to the noncontrolling interest. We expect to use cash for operating activities for the next several years as we continue to incur net losses associated with our research and development activities, including manufacturing and development expenses for compounds in preclinical and clinical studies.

#### **Investing Activities**

Our investing activities provided cash of \$32.5 million and \$11.0 million for the three months ended March 31, 2006 and 2005, respectively. Cash used in investing activities was primarily due to purchases and proceeds from maturities of marketable securities, proceed on sale of investments held by SEI and purchases of property and equipment.

The increase of \$21.6 million in cash provided by investing activities for the 2006 period as compared with the prior year period was primarily driven by an increase of \$9.9 million from proceeds from maturities of marketable securities, a decrease of \$6.1 million from purchases of marketable securities and \$4.1 million from proceeds on sale of investments held by SEI. In the three months ended March 31, 2006 and 2005, we made purchases of \$2.1 million and \$4.0 million, respectively, of property and equipment. We expect to continue to make significant investments in research and development and our administrative infrastructure, including purchases of property and equipment to support our expanding preclinical and clinical development operations.

#### Financing Activities

Our financing activities provided cash of \$1.1 million and \$4.6 million for the three months ended March 31, 2006 and 2005, respectively. Cash provided by our financing activities for the 2006 period was primarily driven by net proceeds of \$2.4 million from an equipment financing facility and \$1.6 million from the exercise of stock options and warrants. These increases were partially offset by \$2.8 million in payments made on notes payable and bank obligations. Cash provided by our financing activities for the 2005 period was primarily driven by proceeds of \$11.1 million received from the purchase of 1.0 million shares of our common stock by GlaxoSmithKline, which included a \$2.2 million premium. These increases were partially offset by \$3.7 million in payments made on notes payable and bank obligations.

We finance property and equipment purchases through equipment financing facilities, such as capital leases, notes and bank obligations. Proceeds from collaboration loans and common stock issuances are used for general working capital purposes, such as research and development activities and other general corporate purposes. During 2006, we have the ability to draw up to an additional \$40.0 million from SEI. Over the next several years, we are required to make certain payments on notes, bank obligations and loans from collaborators, including a \$30.0 million convertible promissory note due in May 2006.

#### **Cash Requirements**

We have incurred net losses since inception, including a net loss of \$27.1 million for the three-month period ended March 31, 2006, and expect to incur substantial losses for at least the next several years as we continue our research and development activities, including manufacturing and development expenses for compounds in preclinical and clinical studies. We currently anticipate that our current cash and cash equivalents, marketable securities, investments held by SEI, additional committed financing from SEI and other 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 scheduled repayment of a \$30.0 million convertible promissory note to PDL BioPharma, Inc. (formerly Protein Design Labs) due in May 2006. 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 collaboration 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 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.

In addition, we will have to obtain additional funding in order to stay in compliance with financial covenants contained in our collaboration with GlaxoSmithKline. Under a loan and security agreement, our working capital must not be less than \$25.0 million and our cash and investments must not be less than \$50.0 million. If we were to default on the financial covenants under the loan and security agreement, GlaxoSmithKline may, among other remedies, declare immediately due and payable all outstanding obligations thereunder.

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.

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 March 31, 2006 (in thousands):

	Fayments Due by Feriou				
		Less than	1-3	4-5	More than 5
Contractual Obligations	Total	1 year	years	years	years
Notes payable and bank obligations	\$ 33,331	\$12,361	\$16,702	\$ 4,268	\$ —
Licensing agreements	2,627	1,129	1,354	144	_
Capital lease obligations	8	8	_	_	_
Convertible promissory note and loan	122,633	30,000	30,569	62,064	_
Operating leases	159,961	15,391	28,496	27,681	88,393
Total contractual cash obligations	\$318,560	\$58,889	\$77,121	\$94,157	\$ 88,393

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

Our market risks at March 31, 2006 have not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2005 on file with the Securities and Exchange Commission. Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio and our long-term debt. We have estimated the effects on our interest rate sensitive assets and liabilities based on a one percentage point hypothetical adverse change in interest rates as of March 31, 2006 and December 31, 2005, respectively. As of March 31, 2006 and December 31, 2005, a decrease in the interest rates of one percentage point would have had a net adverse change in the fair value of interest rate sensitive assets and liabilities of \$3.1 million and \$3.3 million, respectively.

#### ITEM 4. CONTROLS AND PROCEDURES

*Evaluation of disclosure controls and procedures.* Based on the evaluation of our disclosure controls and procedures (as defined in Securities Exchange Act of 1934 Rules 13a-15(e) and 15d-15(e)) required by Securities Exchange Act Rules 13a-15(b) or 15d-15(b), our Chief Executive Officer and 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.* On January 1, 2006, we implemented an Enterprise Resource Planning (ERP) system, using SAP software, replacing our general ledger, financial reporting, order management and procurement systems.

Other than the changes discussed above, there were no other changes in our internal control over financial reporting that occurred during the period covered by this Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### PART II. OTHER INFORMATION

#### ITEM 1A. RISK FACTORS

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

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

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

We will need to raise additional capital to:

- fund our operations and clinical trials;
- continue our research and development efforts; and
- · commercialize our product candidates, if any such candidates receive regulatory approval for commercial sale.

As of March 31, 2006, we had \$219.5 million in cash and cash equivalents and marketable securities, which included restricted cash and investments of \$12.1 million and investments held by SEI of \$30.3 million. We currently anticipate that our current cash and cash equivalents, marketable securities, investments held by SEI, additional committed financing from SEI and other 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 scheduled repayment of a \$30.0 million convertible promissory note to Protein Design Labs, Inc. due in May 2006.

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

- the level of payments received under collaboration 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 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 will have to obtain additional funding in order to stay in compliance with financial covenants contained in agreements with third parties. For example, as part of our collaboration with GlaxoSmithKline, we entered into a loan and security agreement, dated October 28, 2002, which, as amended, contains financial covenants pursuant to which our working capital (the amount by which our current assets exceed our current liabilities as defined by the agreement) must not be less than \$25.0 million and our cash and investments (total cash, cash equivalents and investments as defined by the agreement, which excludes restricted cash and investments) must not be less than \$50.0 million. As of March 31, 2006, our working capital was \$93.9 million and our cash and investments were \$219.5 million, which included restricted cash and investments of \$12.1 million and investments held by SEI of \$30.3 million. If we were to default on the financial covenants under the loan and security agreement, GlaxoSmithKline may, among other remedies, declare immediately due and payable all obligations under the loan and security agreement. Outstanding borrowings and accrued interest under the loan and security agreement totaled \$92.6 million at March 31, 2006.

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

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

We have incurred net losses each year since our inception, including a net loss of \$27.1 million for the three-month period ended March 31, 2006. As of that date, we had an accumulated deficit of \$630.9 million. We expect these losses to continue and anticipate negative operating cash flow for the foreseeable future. We have not yet completed the development, including obtaining regulatory approval, of any of our pharmaceutical product candidates and, consequently, have not generated revenues from the sale of pharmaceutical products. Except for revenues associated with the transgenic mouse business of our German subsidiary, Artemis, our only revenues to date are license revenues and revenues under contracts with our partners. The size of our net losses will depend, in part, on the rate of growth, if any, in our license and contract revenues and on the level of our expenses. These losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Our research and development expenditures and general and administrative expenses have exceeded our revenues to date, and we expect to spend significant additional amounts to fund research and development in order to enhance our technologies and undertake product development. We currently have numerous product candidates in various stages of clinical development and we anticipate filing IND applications for additional product candidates within the next 12 months. As a result, we expect that our operations will continue to increase, and, consequently, we will need to generate significant additional revenues to achieve profitability. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do increase our revenues and achieve profitability, we may not be able to maintain or increase profitability.

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

We have licensed to SEI our intellectual property rights, including commercialization rights, to our product candidates XL647, XL999 and XL784 in exchange for SEI's investment of 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 product candidates licensed to SEI, in which case we would have to repurchase the selected candidate or candidates through the exercise of our purchase option or program option. If, after receiving any selection milestones from GlaxoSmithKline, we do not have sufficient resources to exercise the purchase option or program option following a product candidate selection by GlaxoSmithKline, we could be in breach of our collaboration agreement with GlaxoSmithKline. In the event of such breach, GlaxoSmithKline could terminate the collaboration and, among other remedies, declare all amounts under our loan facility with GlaxoSmithKline immediately due and payable, which would harm our business.

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

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

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

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

- our product candidates may not prove to be efficacious or may cause harmful side effects;
- · negative or inconclusive clinical trial results may require us to conduct further testing or to abandon projects that we had expected to be promising;
- patient registration or enrollment in our clinical testing may be lower than we anticipate, resulting in the delay or cancellation of clinical testing; and
- 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 the commercialization of XL119.

Under our exclusive license agreement with Helsinn, Helsinn is responsible for all aspects of clinical development of XL119. If XL119 receives regulatory approval, Helsinn will be responsible for the marketing and sale of the commercial product worldwide unless we reaquire the commercialization rights for North America. Because Helsinn is responsible for these functions, we have no control over the development schedule or, if XL119 receives regulatory approval, the marketing plan for XL119. If the clinical trials for XL119 are not successful, XL119 will not be commercialized. Moreover, 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:

- · Potential disputes regarding milestone payments may arise in the future, which may postpone or disrupt payments under the license agreement;
- if Helsinn fails to successfully advance XL119 in clinical development or fails to obtain regulatory approvals for XL119, we will not be able to generate revenues from milestones or the commercialization of XL119;
- we cannot control whether Helsinn will devote sufficient resources to the clinical program and, if XL119 is approved by the FDA or other regulatory agencies, the marketing plan for the commercialization of the drug product in countries where we do not hold commercialization rights;
- although we have no history of royalty payment disputes, even if XL119 is approved and commercialized, disputes may arise in the future with respect to the calculation of royalty payments based on net sales related to XL119; and
- if Helsinn perceives that the market opportunity for XL119 or its profit margin from the sale of XL119 is too small to justify commercialization, the interests and motivations of Helsinn may not be, or may not remain, aligned with ours.

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

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

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

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

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

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

We are conducting proprietary research programs in specific disease, therapeutic modality and agricultural product areas that are not covered by our collaboration agreements. Our pursuit of opportunities in pharmaceutical and agricultural markets could result in conflicts with our collaborators in the event that any of our collaborators takes the position that our internal activities overlap with those areas that are exclusive to our collaboration agreements, and we should be precluded from such internal activities. Moreover, disagreements with our collaborators could develop over rights to our intellectual property. In addition, our collaboration agreements may have provisions that give rise to disputes regarding the respective rights and obligations of the parties, including the rights of collaborators with respect to our internal programs and disease area research. Any conflict with or among our collaborators could lead to the termination of our collaborative agreements, delay collaborative activities, impair our ability to renew agreements or obtain future collaboration agreements or result in litigation or arbitration and would negatively impact our relationship with existing collaborators. If our collaborators fail to develop or commercialize any of our compounds or product candidates, we would not receive any future royalties or milestone payments for such compounds or product candidates. We have limited or no control over the resources that our collaborators may choose to devote to our joint efforts. Our collaborators may breach or terminate their agreements with us or fail to perform their contractual obligations. Also, our collaboration agreements may be subject to early termination by

mutual agreement. Further, our collaborators may elect not to develop products arising out of our collaboration arrangements, may experience financial difficulties, may undertake business combinations or significant changes in business strategy that adversely affect their willingness or ability to complete their obligations under any arrangement with us or may fail to devote sufficient resources to the development, manufacture, marketing or sale of such products. Certain of our collaborators could also become competitors in the future. If our collaborators develop competing products, preclude us from entering into collaborations with their competitors, fail to obtain necessary regulatory approvals, terminate their agreements with us prematurely or fail to devote sufficient resources to the development and commercialization of our products, our product development efforts could be delayed or otherwise adversely effected and may fail to lead to commercialized products.

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

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

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

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

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

Materials necessary to manufacture some of our compounds currently under development may not be available on commercially reasonable terms, or at all, which may delay our development and commercialization of these 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 affecting our ability to develop the product candidates. Similarly, if we are unable to obtain critical manufacturing materials after regulatory approval has been obtained for a product candidate, the commercial launch of that product candidate could be delayed or there could be a shortage in supply, which could materially affect our ability to generate revenues from that product candidate. If suppliers increase the price of manufacturing materials, the price for one or more of our products may increase, which may make our products less competitive in the marketplace. If it becomes necessary to change suppliers for any of these materials or if any of our suppliers experience a

shutdown or disruption at the facilities used to produce these materials, due to technical, regulatory or other reasons, it could harm our ability to manufacture our products.

#### Risks Related to Regulatory Approval of Our Product Candidates

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

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

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

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

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

- · the effectiveness, or perceived effectiveness, of our products in comparison to competing products;
- · the existence of any significant side effects, as well as their severity in comparison to any competing products;
- potential advantages over alternative treatments;
- the ability to offer our products for sale at competitive prices;
- relative convenience and ease of administration;
- · the strength of marketing and distribution support; and
- sufficient third-party coverage or reimbursement.

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

We have no experience as a company in the sales, marketing and distribution of pharmaceutical products and do not currently have a sales and marketing organization. Developing a sales and marketing force would be expensive and time-consuming, could delay any product launch, and we may never be able to develop this capacity. To the extent that we enter into arrangements with third parties to provide sales, marketing and distribution services, our product revenues are likely to

be lower than if we market and sell ourselves any products that we develop. If we are unable to establish adequate sales, marketing and distribution capabilities, independently or with others, we may not be able to generate product revenues.

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

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

A primary trend in the United States health care industry is toward cost containment. In December 2003, 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 price 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 allow direct reimportation under certain circumstances. If legislation or regulations were passed allowing the reimportation of drugs, it could decrease the price we receive for any products that we may develop, thereby negatively affecting our revenues and prospects for profitability.

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

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

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

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

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

#### **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 to obtain or could require substantial time and expense.

Third parties may accuse us of employing their proprietary technology without authorization. In addition, third parties may obtain patents that relate to our technologies and claim that use of such technologies infringes on 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. Also, we do not currently have sufficient technical personnel to fully execute our business plan. Recruiting and retaining qualified scientific and clinical personnel will be critical to support activities related to advancing our clinical and preclinical development programs, and supporting our collaborative arrangements and our internal proprietary research and development efforts. Competition is intense for experienced technical personnel, and we may be unable to retain or recruit scientists with the expertise or experience necessary to allow us to pursue collaborations, develop our products and core technologies or expand our operations to the extent otherwise possible. Further, all of our employees are employed "at will" and, therefore, may leave our employment at any time.

#### Our collaborations with outside scientists may be subject to restriction and change.

We work with scientific and clinical advisors and collaborators at academic and other institutions that assist us in our research and development efforts. These advisors and collaborators are not our employees and may have other commitments that limit their availability to us. Although they generally agree not to do competing work, if a conflict of interest between their work for us and their work for another entity arises, we may lose their services. In addition, although our advisors and collaborators sign agreements not to disclose our confidential information, it is possible that valuable proprietary knowledge may become publicly known through them.

#### Difficulties we may encounter managing our growth may divert resources and limit our ability to successfully expand our operations.

We have experienced a period of rapid and substantial growth that has placed, and our anticipated growth in the future will continue to place, a strain on our research, administrative and operational infrastructure. As our operations expand, we will need to continue to manage multiple locations and additional relationships with various collaborative partners, suppliers and other third parties. Our ability to manage our operations and growth effectively requires us to continue to improve our reporting systems and procedures as well as our operational, financial and management controls. In addition, SEC rules and regulations have increased the internal control and regulatory requirements under which we operate. We may not be able to successfully implement improvements to our management information and control systems in an efficient or timely manner to meet future requirements.

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

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

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

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

#### Risks Related to Environmental and Product Liability

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

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

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

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

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

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

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

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

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

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

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

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

#### **Risks Related to Our Common Stock**

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

Our quarterly operating results have fluctuated in the past and are likely to fluctuate in the future. A number of factors, many of which we cannot control, could subject our operating results and stock price to volatility, including:

- recognition of upfront licensing or other fees;
- payments of non-refundable upfront or licensing fees to third parties;
- acceptance of our technologies and platforms;
- the success rate of our discovery efforts leading to milestone payments and royalties;
- the introduction of new technologies or products by our competitors;

- the timing and willingness of collaborators to commercialize our products;
- our ability to enter into new collaborative relationships;
- the termination or non-renewal of existing collaborations;
- · the timing and amount of expenses incurred for clinical development and manufacturing of our product candidates;
- the impairment of acquired goodwill and other assets; and
- · general and industry-specific economic conditions that may affect our collaborators' research and development expenditures.

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

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

#### Our stock price may be extremely volatile.

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

- adverse results or delays in clinical trials;
- announcement of FDA approval or non-approval, or delays in the FDA review process, of our or our collaborators' product candidates or those of our competitors or actions taken by regulatory agencies with respect to our, our collaborators' or our competitors' clinical trials;
- the announcement of new products by us or our competitors;
- quarterly variations in our or our competitors' results of operations;
- litigation, including intellectual property infringement lawsuits, involving us;
- failure to achieve operating results projected by securities analysts;
- changes in earnings estimates or recommendations by securities analysts;
- financing transactions;
- developments in the biotechnology or pharmaceutical industry;
- · sales of large blocks of our common stock or sales of our common stock by our executive officers, directors and significant stockholders;
- · departures of key personnel or board members;
- · developments concerning current or future collaborations;
- FDA or international regulatory actions;
- · third-party reimbursement policies;
- acquisitions of other companies or technologies;
- · disposition of any of our subsidiaries, technologies or compounds; and

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

These factors, as well as general economic, political and market conditions, may materially adversely affect the market price of our common stock.

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

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

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

- difficulties and increased costs in connection with integration of the personnel, operations, technologies and products of acquired companies;
- diversion of management's attention from other operational matters;
- · the potential loss of key employees;
- the potential loss of key collaborators;
- · lack of synergy, or the inability to realize expected synergies, resulting from the acquisition; and
- acquired intangible assets becoming impaired as a result of technological advancements or worse-than-expected performance of the acquired company.

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

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

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

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

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

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

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

· a classified Board of Directors;

- a prohibition on actions by our stockholders by written consent;
- · the inability of our stockholders to call special meetings of stockholders;
- the ability of our Board of Directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our Board of Directors;
- · limitations on the removal of directors; and
- advance notice requirements for director nominations and stockholder proposals.

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

#### ITEM 6. EXHIBITS

(a) Exhibits

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

#### **SIGNATURES**

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

Date: May 9, 2006

EXELIXIS, INC.

/s/ Frank Karbe

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

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# EXHIBIT INDEX

10.1*	Collaboration Agreement, dated March 20, 2006, between Exelixis, Inc. and Sankyo Company, Limited.
31.1	Certification required by Rule 13a-14(a) or Rule 15d-14(a).
31.2	Certification required by Rule 13a-14(a) or Rule 15d-14(a).
32.1**	Certification by the Chief Executive Officer and the Chief Financial Officer of Exelixis, Inc., as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).

<sup>\*</sup> Confidential treatment requested for certain portions of this exhibit.

**Exhibit Description** 

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

[\*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

**EXHIBIT 10.1** 

# **COLLABORATION AGREEMENT**

THIS COLLABORATION AGREEMENT (the "Agreement") is made and entered into as of March 20<sup>th</sup>, 2006 (the "Effective Date") by and between EXELIXIS, INC., a Delaware corporation having its principal place of business at 170 Harbor Way, P.O. Box 511, South San Francisco, California 94083-0511 ("Exelixis"), and SANKYO COMPANY, LIMITED, a Japanese corporation having its principal place of business at 3-5-1 Nihonbashi-honcho, Chuo-ku, Tokyo 103-8426 Japan ("Sankyo"). Exelixis and Sankyo are sometimes referred to herein individually as a "Party" and collectively as the "Parties".

# RECITALS

- A. Sankyo is a multinational health care company that has expertise and capability in researching, developing and commercializing human pharmaceuticals.
- **B.** Exelixis is a drug discovery company that has expertise and proprietary technology relating to compounds that modulate the Mineralocorticoid Receptor.
- C. Sankyo and Exelixis desire to establish a collaboration to apply such Exelixis technology and such expertise of Exelixis and Sankyo to the lead optimization and characterization of small molecule compounds that modulate the Mineralocorticoid Receptor, and to the development and commercialization of novel therapeutic and prophylactic products based on such compounds.

NOW THEREFORE, Exelixis and Sankyo agree as follows:

# 1. **DEFINITIONS**

Capitalized terms used in this Agreement (other than the headings of the Sections or Articles) shall have the following meaning set forth in this **Article 1**, or, if not listed in this **Article 1**, the meaning as designated in the text of this Agreement.

- **1.1 "Affiliate"** means, with respect to a particular Party, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such Party. For the purposes of the definition in this **Section 1.1**, **the word "control"** (including, with correlative meaning, the terms **"controlled by"** or **"under the common control with"**) means the actual power, either directly or indirectly through any intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of at least fifty percent (50%) of the voting stock of such entity, or by contract or otherwise.
- **1.2 "Annual FTE Rate"** means the amount to be paid by Sankyo to support one (1) FTE for one (1) year. The Annual FTE Rate during the Initial Research Term is [\*] per year.

The Annual FTE Rate for the Research Term Extension, if any, shall be as agreed upon by the Parties pursuant to **Section 2.5**.

- **1.3** "Back-up Compounds" means: (a) the following Small Molecule Compounds: [\*]; and (b) [\*].
- **1.4 "Back-up Compound Know-How"** means all Information that is Controlled by Exelixis and its Affiliates [\*] that comprises Inventions [\*]. Back-up Compound Know-How does not include any Back-up Compound Patent or any information licensed to Exelixis or its Affiliate [\*].
- **1.5 "Back-up Compound Patents"** means all Patents that are Controlled by Exelixis and its Affiliates [\*] and that claim Inventions [\*]. Back-up Compound Patents do not include any Joint Patents or any Patents licensed to Exelixis or its Affiliate [\*].
  - 1.6 "Collaboration" means all the activities performed by or on behalf of Exelixis or Sankyo in the course of performing work contemplated in Article 2.
- **1.7 "Commercialize"** or **"Commercialization"** means all activities that are undertaken after Regulatory Approval for a particular Product and that relate to the commercial marketing and sale of such Product including advertising, marketing, promotion, distribution, and post-approval clinical studies.
- **1.8 "Control"** or "Controlled" means, with respect to any Small Molecule Compound, material, Information or intellectual property right, that the Party owns or has a license to such Small Molecule Compound, material, Information or intellectual property right and has the ability to grant to the other Party access, a license or a sublicense (as applicable) to such Small Molecule Compound, material, Information or intellectual property right as provided for herein without violating the terms of any agreement or other arrangements with any Third Party existing at the time such Party would be first required hereunder to grant the other Party such access, license or sublicense.
  - **1.9 "Derivatives"** means all: (a) Small Molecule Compounds that [\*]; and (b) [\*].
- **1.10 "Develop"** or **"Development"** means, with respect to the Product, the performance of all research, pre-clinical, clinical and regulatory activities required to obtain Regulatory Approval of a Product.
- 1.11 "Diligent Efforts" means the carrying out of obligations or tasks in a sustained manner consistent with the efforts a Party devotes to a product or a research, development or marketing project of similar market potential, profit potential or strategic value resulting from its own research efforts, based on conditions then prevailing. Diligent Efforts requires that the Party: (a) promptly assign responsibility for such obligations to specific employee(s) who are held accountable for progress and monitor such progress on an on-going basis; (b) set and consistently seek to achieve specific and meaningful objectives for carrying out such obligations;

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and (c) consistently make and implement decisions and allocate resources designed to advance progress with respect to such objectives.

- **1.12 "EU"** means the European Union, as its membership may be altered from time to time, and any successor thereto. The member countries of the European Union as of the Effective Date are Belgium, Denmark, Germany, Greece, Spain, France, Ireland, Italy, Luxemburg, Netherlands, Austria, Portugal, Finland, Sweden, the United Kingdom, Estonia, Latvia, Lithuania, Poland, the Czech Republic, Slovakia, Hungary, Slovenia, Malta, and Cyprus.
  - 1.13 "Exelixis Know-How" means the Existing Compound Know-How and the Back-up Compound Know-How.
- **1.14 "Exelixis Net Sales"** means net sales of any Product by Exelixis or its sublicensees pursuant to the license granted by Sankyo in **Section 10.3(b)** and **Section 10.4(c)** and as determined on the same basis as Net Sales, substituting Exelixis for Sankyo.
  - 1.15 "Exelixis Patents" means the Existing Compound Patents and the Back-up Compound Patents.
  - **1.16** "Existing Compounds" mean all: (a) the following Small Molecule Compounds: [\*]; and (b) [\*].
- **1.17 "Existing Compound Know-How"** means all Information that is Controlled by Exelixis and its Affiliates [\*] Existing Compounds. Existing Compound Know-How does not include any Existing Compound Patent or any information licensed to Exelixis or its Affiliate [\*].
- **1.18 "Existing Compound Patents"** means all Patents: (a) that are Controlled by Exelixis and its Affiliates [\*] in Exhibit 1.18; or (b) issuing from or claiming priority to any of the foregoing. Existing Compound Patents do not include any Back-up Compound Patents, Joint Patents or any Patents licensed to Exelixis or its Affiliate [\*].
- 1.19 "FTE" means the equivalent of a single person working full time for Exelixis over a twelve (12) month period (including normal vacations, sick days and holidays).
- **1.20 "IND"** means: (a) an Investigational New Drug Application filed with the U.S. Food and Drug Administration (the "**FDA**") or its equivalent in any country outside the United States where a regulatory filing is required or obtained to conduct a clinical trial; or (b) with respect to any country where a regulatory filing is not required or obtained to conduct a clinical trial, the first enrollment of a human subject in the first trial involving the first use of a Product in humans.
- **1.21 "Information"** means information, material, results and data of any type whatsoever, in any tangible or intangible form whatsoever, including databases, inventions, practices, methods, techniques, specifications, formulations, formulae, cell lines, cell media, knowledge, know-how, skill, experience, manufacturing materials, financial data, test data

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including pharmacological, biological, chemical, biochemical, toxicological and clinical test data, analytical and quality control data, quality assurance data, stability data, studies and procedures, and patent and other legal information or descriptions.

- 1.22 "Initial Research Term" means the period commencing on the Effective Date and ending fifteen (15) months later.
- **1.23 "Initiation"** means, with respect to a Phase II Trial or Phase III Trial, the first enrollment of a patient in such trial.
- **1.24 "Invention"** means any invention or improvement that in each case is made, conceived or reduced to practice by or on behalf of a Party or both Parties in the course of performing under this Agreement.
  - **1.25 "Joint Patents"** has the meaning set forth in **Section 7.1**.
  - 1.26 "Joint Research Committee" or "JRC" means the committee described in Section 2.2.
- **1.27 "Launch"** means, for each Product in each country, the first arm's-length sale to a Third Party (or an Affiliate of a Party if such Affiliate is the end user of such Product) in such country after Regulatory Approval of such Product in such country. A Launch shall not include any Product sold for use in clinical trials, for research or for other non-commercial uses, or that is supplied as part of a compassionate use or similar program.
  - **1.28 "Lead Compound"** means the Existing Compound, [\*].
  - 1.29 "Licensed Compound" means any Existing Compound, Back-up Compound or Derivative.
  - 1.30 "Major Country" means any of the following countries, and their respective territories and possessions: [\*].
- **1.31 "MR"** means: (a) the gene for the Mineralocorticoid Receptor (for any species); (b) the protein encoded by such gene; and (c) all subtypes, mutants, variants and fragments thereof.
- **1.32 "NDA"** means: (a) a New Drug Application (as more fully defined in 21 C.F.R. 314.5 *et seq.*) and all amendments and supplements thereto filed with the FDA in order to obtain Regulatory Approval in the United States; or (b) an application for Regulatory Approval required before commercial sale or use of a Product as a drug in a regulatory jurisdiction other than the United States.
- **1.33 "NDA Acceptance"** means the submission to the FDA in the United States or the corresponding authorities in a country other than the United States of an NDA for the Product and filing of such NDA in such country.

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1.34 "Net Sales" means, for any period, the gross amount invoiced or otherwise charged by Sankyo or its Affiliates or Sublicensees for the sale of any Product to any Third Party, less the following deductions to the extent actually incurred or allowed in connection with the sale of such Product (and in accordance with the integrated system of International Accounting Standards and International Financial Reporting Standards, consistently applied): (a) trade, quantity and cash discounts allowed; (b) commissions, discounts, refunds, rebates, charge-backs, retroactive price adjustments, and any other allowances which effectively reduce the net selling price; (c) actual Product returns and allowances; (d) delayed ship order credits and discounts pursuant to indigent patient programs and patient discount programs, including, but not limited to, "Together Rx" and coupon discounts; and (e) any tax imposed on the production, sale, delivery or use of the Product, including, without limitation, sales, use, excise or value added taxes.

In the event a Product is sold as an end-user product consisting of a combination of active functional elements or as a combined product and/or service, Net Sales, for purposes of determining royalty payments on such Product, shall be calculated by multiplying the Net Sales of the end-user product and/or service by the fraction A over A+B, in which A is the gross selling price of the Product portion of the end-user product and/or service when such Product is sold separately during the applicable accounting period in which the sales of the end-user product were made, and B is the gross selling price of the other active elements and/or service, as the case may be, of the end-user product and/or service sold separately during the accounting period in question. All gross selling prices of the elements of such end-user product and/or service shall be calculated as the average gross selling price of the said elements during the applicable accounting period for which the Net Sales are being calculated. In the event that, in any country or countries, no separate sale of either such above-designated Product or such above designated elements of the end-user product and/or service are made during the accounting period in which the sale was made or if gross retail selling price for an active functional element, component or service, as the case may be, cannot be determined for an accounting period, Net Sales allocable to the Product in each such country shall be determined by mutual agreement reached in good faith by the Parties prior to the end of the accounting period in question based on an equitable method of determining same that takes into account, on a country-by-country basis, variations in potency, the relative contribution of each active agent, component or service, as the case may be, in the combination, and relative value to the end user of each active agent, component or service, as the case may be. Notwithstanding the foregoing, the Parties agree that, for purposes of this paragraph, drug delivery vehicles, a

**1.35 "Non-Disclosure Agreements"** means: (a) the Confidential Disclosure Agreement among Sankyo, Exelixis and Exelixis' Affiliate X-Ceptor Therapeutics, Inc., effective as of July 27, 2005, and all amendments thereto; and (b) the Consultant's Confidential Disclosure Agreement among Exelixis, Sankyo, and Sankyo's consultant Jim Zeller Consulting LLC, effective as of October 18, 2005.

**1.36 "Patents"** means all: (a) United States patents, re-examinations, reissues, renewals, extensions and term restorations, inventors' certificates and non-U.S. counterparts

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thereof; (b) pending applications for United States patents, including provisional applications, continuations, continuations-in-part, continued prosecution, divisional and substitute applications; and (c) non-U.S. counterparts of the foregoing.

- **1.37 "Phase II Trial"** means a human clinical trial of the Product, the principal purpose of which is to make a preliminary determination that such Product is safe for its intended use and to obtain sufficient information about such Product's efficacy to permit the design of further clinical trials, and generally consistent with 21 C.F.R. § 312.21(b), as amended (or its successor regulation).
- **1.38 "Phase III Trial"** means a pivotal human clinical trial of a Product, which trial is designed to: (a) establish that the Product is safe and efficacious for its intended use; (b) define warnings, precautions and adverse reactions that are associated with the Product in the dosage range to be prescribed; (c) support Regulatory Approval of such Product; and (d) be generally consistent with 21 C.F.R. § 312.21(c), as amended (or its successor regulation).
  - 1.39 "Product" means any human therapeutic or prophylactic product that contains or comprises any Licensed Compounds as a main ingredient.
- **1.40 "Regulatory Approval"** means any and all approvals (including supplements, amendments, pre- and post-approvals, pricing and reimbursement approvals), licenses, registrations or authorizations of any national, supra-national (e.g., the European Commission or the Council of the European Union), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, that are necessary for the manufacture, distribution, use or sale of a Product in a regulatory jurisdiction.
  - **1.41 "Research Plan"** shall have the meaning set forth in **Section 2.3**.
  - **1.42 "Research Term"** means the period of the Initial Research Term plus any extension agreed upon by the Parties pursuant to **Section 2.5**.
- **1.43 "Sankyo Know-How"** means all Information that is Controlled by Sankyo or its Affiliates [\*], excluding any Information jointly owned by the Parties. Sankyo Know-How does not include any Sankyo Patents.
  - 1.44 "Sankyo Patents" means all Patents Controlled by Sankyo or its Affiliates [\*], but excluding any Joint Patents.
  - 1.45 "Small Molecule Compound" means a molecule with a molecular weight less than or equal to [\*].
- **1.46 "Sublicensee"** means a person, corporation, partnership or other entity, other than an Affiliate, that is granted a sublicense by Sankyo under the grant in **Section 4.1** or that is granted a license to develop and/or commercialize Products.
  - 1.47 "Term" means the period beginning on the Effective Date and ending on the expiration or earlier termination of this Agreement.

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**1.48** "Third Party" means any person or entity other than Exelixis, Sankyo or an Affiliate of Exelixis or Sankyo.

**1.49 "Valid Claim"** means: (a) any claim of an issued Patent in the Exelixis Patents, Joint Patents or the Sankyo Patents that has not (i) expired or been abandoned, (ii) been held invalid or unenforceable by a court of competent jurisdiction from which no appeal can be taken or has been taken within the required time period or (iii) been admitted to be invalid or unenforceable through reissue, disclaimer or otherwise; or, [\*], (b) any claim under a application for a Patent in the Exelixis Patents, Joint Patents or the Sankyo Patents that has not been abandoned, canceled, withdrawn from consideration, or finally determined to be unallowable in a decision from which no appeal can be taken.

# 2. COLLABORATION

**2.1 Overview.** The general goals and intent of the Collaboration are to apply each Party's technology and expertise to optimize and characterize Licensed Compounds that may be developed into Products. During the Initial Research Term of the Collaboration: (a) Sankyo will focus on the completing the characterization of the Lead Compound for the filing of an IND and on the optimization of Licensed Compounds (other than the Lead Compound) through the creation and testing of Derivatives; and (b) Exelixis will focus on the optimization of Licensed Compounds (other than the Lead Compound) through the creation and testing of Derivatives. The details of the work to be conducted under the Collaboration will be set forth in the Research Plan, as described in **Section 2.3**.

# 2.2 Joint Research Committee.

- (a) Membership. The Joint Research Committee (the "JRC") shall be composed of [\*] members. Within [\*] days after the Effective Date, each Party shall appoint [\*] to the JRC, with one (1) of those representatives being the individual at the Party with primary responsibility for the day-to-day management and execution of the Research Plan. Each Party may replace its appointed JRC representatives at any time upon written notice to the other Party. [\*] shall designate one (1) of its representatives as Chairperson of the JRC. The Chairperson shall be responsible for scheduling meetings, preparing and circulating an agenda in advance of each meeting, and preparing and issuing minutes of each meeting within [\*] days thereafter. Any JRC member may add topics to the draft agenda.
- **(b) Decision-making.** The [\*] JRC representatives of each Party shall collectively have one (1) vote, and the JRC shall operate by unanimous consent of all JRC members present and in accordance with the principles set forth in this **Article 2**. In the event of a dispute between the Parties with regard to the performance of the Collaboration, the matter shall be elevated to the [\*]. If these two (2) individuals are unable to agree, then the matter shall be elevated to the [\*]. Notwithstanding anything to the contrary, no decision by a Party shall require the other Party to: (i) breach any obligation or agreement that such other Party may have with or to a Third Party; (ii) perform any activities that are materially different or greater in

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scope than those provided for in the then-current Research Plan; or (iii) incur any material financial costs in addition to those expressly described in **Article** 5 of this Agreement.

- (c) Responsibilities. The JRC shall be responsible for the planning and execution of the Collaboration, and it may appoint various scientific working groups that will report to the JRC and that will manage the day-to-day activities and decisions required under the Collaboration. At its meetings, the JRC shall evaluate the data generated by the Parties in the course of carrying out the Research Plan, shall prioritize projects within the Research Plan, shall perform those activities specifically described in this Agreement, and may propose revisions to the Research Plan in accordance with Section 2.3. To the extent necessary to carry out its responsibilities, a Party's JRC members shall be granted access to the other Party's Confidential Information relevant to any decision required to be made by the JRC.
- (d) Meetings. During the Research Term, the JRC shall meet quarterly by audio or video teleconference and, at a minimum, once each [\*] in person. Such quarterly meetings of the JRC shall be held on an alternating basis at Sankyo's facilities in Shinagawa, Tokyo and at Exelixis' facilities in South San Francisco or San Diego (as applicable). With the consent of the representatives of each Party serving on a particular committee, other representatives of each Party may attend meetings of that committee as nonvoting observers. Meetings of the JRC shall be effective only if at least one (1) representative of each Party is present or participating. Each Party shall be responsible for all of its own expenses of participating in the committee meetings. The Parties shall endeavor to schedule meetings of the JRC at least [\*] in advance.
- **2.3 Research Plan.** The Parties have agreed in writing upon a detailed plan for the research to be carried out by the Parties during the Research Term, which is incorporated herein by reference to the Disclosure Letter (the "**Disclosure Letter**") between the Parties of even date herewith (the "**Research Plan**"). The Research Plan includes each Party's respective obligations in furtherance of the Collaboration and timelines for performance of such obligations. The Research Plan shall call for at least [\*] FTEs throughout the Initial Research Term. Sankyo shall compensate Exelixis, in accordance with **Section 5.2**, for all FTEs called for in the Research Plan, and Exelixis shall not have any obligation to devote more than such number of FTEs in the performance of its obligations under the Research Plan. The JRC shall review the Research Plan at least [\*] and may propose revisions to the Research Plan that are consistent with the terms of this Agreement. The revised Research Plan may only be approved with the mutual written agreement of the Parties. Once so approved, such revised Research Plan shall replace the prior Research Plan.
- **2.4 Compound Transfer.** Within [\*] of the Effective Date, Exelixis shall use commercially reasonable efforts to transfer to Sankyo the items listed on **Exhibit 2.4.** Upon Sankyo's reasonable request, Exelixis shall facilitate the transfer of technology relating to the manufacturing process, if any, for the Existing Compounds to Sankyo, at any time during the period of [\*] following the Effective Date. During the Research Term, within [\*] of receiving Sankyo's reasonable request for one or more particular items of Information that is in Exelixis' possession, including any [\*], and that is generated by Exelixis under the Research Plan,

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Exelixis shall use commercially reasonable efforts to transfer such items to Sankyo. Sankyo shall reimburse Exelixis for any out-of-pocket costs incurred by Exelixis in connection with this **Section 2.4** and for reasonable travel expenses incurred by Exelixis to attend, at Sankyo's request, any meetings not held at an Exelixis facility.

- **2.5 Extension of Research Term.** The Parties may mutually agree to extend the Research Term beyond the end of the Initial Research Term for an additional two (2) year period, during which time Sankyo shall fund at least [\*] FTEs per year at the Annual FTE Rate(s) to be agreed upon by the Parties and such FTEs shall either: (a) [\*]; or (b) develop [\*]. If the Parties intend to so extend the Research Term, then at least [\*] prior to the end of the Initial Research Period, the Parties shall agree upon a written Research Plan that covers such extension period and specifies the applicable Annual FTE Rate(s) and shall amend this Agreement as necessary including, if applicable, to clarify each Parties' rights and obligations with respect to the [\*] and [\*].
- **2.6 Obligations of Parties.** Exelixis and Sankyo shall provide the JRC and its authorized representatives with reasonable access during regular business hours to all records, documents, and Information relating to the Collaboration which such committee may reasonably require in order to perform its obligations hereunder, provided that if such documents are under a bona fide obligation of confidentiality to a Third Party, then Exelixis or Sankyo, as the case may be, may withhold access thereto to the extent necessary to satisfy such obligation.
- **2.7 Collaboration Guidelines.** Subject to the terms of this Agreement, the activities and resources of each Party shall be managed by such Party, acting independently and in its individual capacity. The relationship between Exelixis and Sankyo is that of independent contractors, and neither Party shall have the power to bind or obligate the other Party in any manner, other than as is expressly set forth in this Agreement.
- **2.8 Conduct of Research.** The Parties shall use Diligent Efforts to conduct their respective tasks throughout the Collaboration and shall conduct the Collaboration in good scientific manner, and in compliance in all material respects with the requirements of applicable laws, rules and regulations and all applicable good laboratory practices to attempt to achieve their objectives as efficiently and expeditiously as reasonably practicable. Except as set forth in **Section 5.2**, each Party shall bear its own costs in performing its obligations under the Collaboration.
- **2.9 Records.** Each Party shall maintain complete and accurate records of all work conducted under the Collaboration and all results, data and developments made pursuant to its efforts under the Collaboration. Such records shall be complete and accurate and shall fully and properly reflect all work done and results achieved in the performance of the Collaboration in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes.
- **2.10 Reports.** During the Research Term, each Party shall report to the JRC no less than [\*] and will submit to the other Party and the JRC a [\*] written progress report summarizing the work performed under the Collaboration. If reasonably necessary for a Party to perform its work under the Collaboration or to exercise its rights under the Agreement, such

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Party may request that the other Party provide more detailed information and data regarding such results reported by such other Party, and such other Party shall promptly provide the requesting Party with information and data as is reasonably related to such request. All such reports shall be considered Confidential Information of the Party providing same.

**2.11 Review of Licensed Compounds.** As part of the criteria for the submission of a Licensed Compound for [\*] (a "**Development Candidate**"), Exelixis shall review the results of all [\*] conducted by either Party in the normal course of performing research under the Research Plan or by Sankyo in the normal course of performing research after the expiration of the Research Term. In the event review by Exelixis is after the expiration of the Research Term, Sankyo shall provide Exelixis with the results of all [\*] for such Development Candidate, and sufficient samples of any such Development Candidate to have such assays conducted. Exelixis may use such results and samples for the sole purpose of performing assays to verify that such Development Candidate does not display [\*] ("[\*] Activity"). [\*] shall be responsible for having such assays conducted as well as any costs associated with such assays. If Exelixis notifies Sankyo in writing within [\*] of receiving a sample of a submitted Development Candidate that such Development Candidate displays [\*] Activity, then Sankyo shall not [\*] such Development Candidate, and Sankyo's licenses [\*] such Development Candidate shall terminate (solely with respect to such Development Candidate). In the event that Exelixis does not provide written notice to Sankyo with respect to the [\*] Activity of a submitted Development Candidate within such [\*] period, then Sankyo shall be free to develop and commercialize such Development Candidate on the terms and conditions set forth in this Agreement.

If Sankyo is required to [\*] of a Development Candidate under this Section 2.11 due to a [\*], Sankyo may choose from the following options:

- **(a)** Sankyo may [\*] or derivatize away the [\*] Activity; or
- (b) Sankyo may select a different Licensed Compound for [\*]. Furthermore, any substitution of a Licensed Compound under this Section 2.11 [\*].

### 3. DEVELOPMENT AND COMMERCIALIZATION OF PRODUCTS

3.1 Sankyo Development and Commercialization. As between the Parties, Sankyo (or its Affiliates or sublicensees) have sole authority to conduct, at its own expense, all clinical development, manufacturing and commercialization activities, including all regulatory activities, with respect to any Products. All regulatory applications with respect to the Products will be owned by Sankyo and/or its Affiliates or sublicensee(s), as applicable. Upon [\*], Exelixis shall cooperate with Sankyo in connection with regulatory submissions related to any Product, including, but not limited to [\*]. Sankyo shall have sole control and responsibility for, and shall bear all of its costs and expenses associated with, the development, manufacture (including formulation) and commercialization of all Products, as applicable.

**3.2 Diligence.** Sankyo shall use Diligent Efforts to [\*] and shall be deemed to have fully discharged its diligence obligation upon [\*]. Exelixis may notify Sankyo in writing if

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Exelixis in good faith believes that Sankyo is not meeting its diligence obligations set forth in this **Section 3.2**, and may further request review of Sankyo's records generated and maintained as required under **Section 3.5**, to the extent those records relate to [\*]. Promptly after receiving such notice, Sankyo shall meet with Exelixis and discuss the matter in good faith. Exelixis may terminate this Agreement pursuant to **Section 10.4** if Sankyo fails to meet such diligence obligations.

- **3.3 Progress Reporting.** Sankyo will keep Exelixis appropriately informed about Sankyo's Development and Commercialization efforts with respect to Products. Without limiting the generality of the foregoing, Sankyo shall provide Exelixis with written notice within [\*] of the occurrence of any of the milestone events listed in **Section 5.3**. Sankyo shall also provide Exelixis with [\*] written reports on the general progress of Sankyo's efforts to Develop and Commercialize Products, including a [\*]. Additionally, Sankyo shall provide Exelixis with a [\*] written report describing Sankyo's progress at Developing and Commercializing Products. If reasonably necessary or useful for Exelixis to exercise its rights under this Agreement, Exelixis may request that Sankyo provide more detailed information and data regarding the work reported by Sankyo, and Sankyo will, without delay, provide Exelixis with information and data as is reasonably related to such request. All such reports shall be considered Confidential Information of Sankyo.
- **3.4 Compliance with Laws.** Sankyo shall perform, and shall ensure that its Affiliates, Sublicensees and Third Party contractors perform, all Development and Commercialization activities for which it is responsible under this Agreement in good scientific and medical manner and in compliance with all applicable laws, rules and regulations.
- **3.5 Records.** Sankyo shall maintain complete and accurate records of all Development, manufacturing and Commercialization conducted by it or on its behalf related to each Product, and all Information generated by it or on its behalf in connection with development under this Agreement with respect to each such Product. Sankyo shall maintain such records until the later of: (a) [\*] after such records are created, or (b) [\*] after the Launch of the Product to which such records pertain. Such records shall be at a level of detail appropriate for [\*] purposes. Exelixis shall have the right to review and copy such records of Sankyo at reasonable times to the extent necessary or useful for Exelixis to conduct its obligations or enforce its rights under this Agreement.

# 4. LICENSES AND OTHER RIGHTS

# 4.1 Exclusive Licenses.

(a) Subject to the terms and conditions of this Agreement, Exelixis hereby grants to Sankyo a worldwide, exclusive, royalty-bearing license (with the right to sublicense), under the Existing Compound Patents, the Existing Compound Know-How and Exelixis' interest in the Joint Patents, to make, have made, use, develop, sell, offer for sale and import Products containing or comprising Existing Compounds or Derivatives thereof (but not Back-up Compounds or Derivatives thereof).

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- **(b)** Subject to the terms and conditions of this Agreement, Exelixis hereby grants to Sankyo a worldwide, exclusive, royalty-bearing license (with the right to sublicense), under the Back-up Compound Patents, the Back-up Compound Know-How and Exelixis' interest in the Joint Patents, to make, have made, use, develop, sell, offer for sale and import Products containing or comprising Back-up Compounds or Derivatives thereof.
- **4.2 Retained Rights.** Exelixis retains the right under the Existing Compound Patents, the Existing Compound Know-How, the Back-up Compound Patents, the Back-up Compound Know-How and Exelixis' interest in the Joint Patents to make, have made, use, and test Licensed Compounds solely for internal research purposes. For clarity, Exelixis retains all rights with respect to compounds that are not Licensed Compounds.
- **4.3 Sublicenses.** Any sublicense grant by Sankyo under this Agreement shall be made subject to the terms of this Agreement and shall impose restrictions and conditions upon Affiliates and Sublicensees that are consistent with those imposed upon Sankyo by this Agreement. Sankyo shall remain fully responsible for the conduct of its Affiliates and Sublicensees under the terms of this Agreement, including any breach of the terms hereof by such Affiliates and Sublicensees. In the event of a material default by an Affiliate or Sublicensee under a sublicense agreement with Sankyo, Sankyo will inform Exelixis and take such action as necessary or appropriate to cure such default.
- **4.4 Negative Covenants.** Sankyo and its Affiliates shall not, and shall ensure that their Sublicensees do not, practice Exelixis Patents and/or Exelixis Know-How outside the scope of the licenses granted in **Section 4.1**. Sankyo hereby covenants that it shall not, and shall not enable any Affiliate or Third Party to, use any Exelixis Know-How, Exelixis Patents or the assays transferred by Exelixis pursuant to **Section 2.4**, [\*].
- **4.5 Licenses to Exelixis.** Subject to the terms of this Agreement, Sankyo hereby grants Exelixis a non-exclusive, worldwide, royalty-free license (with the right to sublicense to Affiliates, but without the right to sublicense to Third Parties except with prior written consent of Sankyo) under the Sankyo Know-How and Sankyo Patents, solely to perform research during the Research Term in accordance with the Research Plan.
- **4.6 No Additional Licenses.** No right or license under any Patents or other intellectual property rights Controlled by a Party is granted or shall be granted by implication. All such rights or licenses are or shall be granted only as expressly provided in the terms of this Agreement.
  - 4.7 Exclusivity. During the Research Term, neither Party shall [\*], except for either Party to conduct activities set forth in the Research Plan [\*].

# 5. FINANCIAL TERMS

**5.1 Upfront Fee.** Sankyo shall pay Exelixis an upfront fee of twenty million dollars (\$20,000,000) no later than five (5) business days after the Effective Date. The upfront fee payment made by Sankyo to Exelixis pursuant to this **Section 5.1** shall be noncreditable and nonrefundable.

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- **5.2 Research Support.** No later than the first day of each calendar quarter during the Research Term, Sankyo shall pay Exelixis an amount equal to the product of one-quarter ( ¹/4) of the Annual FTE Rate multiplied by the number of FTEs set forth in the Research Plan for such quarter. All payments made by Sankyo pursuant to this Section 5.2 shall be non-refundable and non-creditable [ \* ].
- **5.3 Milestone Payments.** With regard to each Product containing a separate Licensed Compound and for a separate indication, Sankyo shall make the nonrefundable and non-creditable ([\*]) milestone payments set forth below to Exelixis within [\*] after first achievement of each of the following events by Sankyo or any of its Affiliates or Sublicensees:
  - (a) [\*] upon filing of an IND for such Product anywhere in the world;
  - **(b)** [\*] upon first Initiation of a Phase II Clinical Trial anywhere in the world;
  - **(c)** [\*] upon first Initiation of a Phase III Clinical Trial anywhere in the world;
  - **(d)** [\*] upon first NDA Acceptance for such Product anywhere in the world;
  - **(e)** [\*] upon Launch of such Product in the United States;
  - (f) [\*] upon Launch of such Product in any country in Europe (including the EU) or Asia (including Southeast Asia and the Pacific Rim);
  - (g) [\*] upon the first time the annual, worldwide, aggregate Net Sales of such Product reach or exceed [\*]; and
  - (h) [\*] upon the first time the annual, worldwide, aggregate Net Sales of such Product reach or exceed [\*].

If any milestone event (the "Later Milestone") is achieved during the development of a Product prior to the achievement of a milestone event listed above it (an "Earlier Milestone") for the same Product, then Sankyo shall pay to Exelixis, within [\*] of the achievement of such Later Milestone, the amount for such Later Milestone plus the amount for each and every Earlier Milestone not yet achieved; *provided*, *however*, that [\*].

Furthermore, if development of a Licensed Compound for a Product ceases or is suspended, then Sankyo shall [\*] Licensed Compound. However, if any subsequent Licensed Compound is developed for a separate Product, then Sankyo shall [\*]. For clarity, the Parties agree that a separate Product shall not include [\*].

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The development of any combination product containing the same Licensed Compound as an existing Product as one of its active ingredients, or the development of an existing Product for [\*] shall not be considered as a separate Product subject to the milestone payments stated in Section [\*]. Following the [\*] of a combination product containing the same Licensed Compound as an existing Product, Sankyo shall pay the milestones stated in Section [\*] as they become applicable. Following the inclusion of a [\*] of an existing Product [\*], Sankyo shall pay [\*] the milestones stated in Section [\*] as they become applicable. For clarity, the Parties agree that Sankyo shall not pay any of the milestones stated in Section [\*] for the Launch of an existing Product for [\*]. Sankyo shall also pay the sales milestones stated in Section 5.3(g)-(h) as they become applicable, and, notwithstanding the previous distinctions, the aggregate Net Sales of all Products containing the same Licensed Compound may be combined when determining whether such sales milestones have been achieved.

# 5.4 Royalty Payments.

- (a) For each Product that is covered by a Valid Claim of any Exelixis Patents or Joint Patents, Sankyo shall make noncreditable, nonrefundable royalty payments to Exelixis at the following royalty rates:
  - (i) [\*] of the Net Sales of the annual (based on Sankyo's fiscal year), worldwide, aggregate Net Sales for each Product up to [\*]; and
  - (ii) [\*] of the Net Sales of the annual (based on Sankyo's fiscal year), worldwide, aggregate Net Sales for each Product that exceeds [\*].
- **(b)** For each Product that is covered solely by a Valid Claim of any Sankyo Patent, Sankyo shall make noncreditable, nonrefundable royalty payments to Exelixis at: (i) [\*] of the royalty rates set forth in Section 5.4(a)(i) or Section 5.4(a)(ii) for Patents [\*]; and (ii) [\*] of the royalty rates set forth in Section 5.4(a)(i) or Section 5.4(a)(ii) for all other Patents, as applicable, for the annual, worldwide aggregate Net Sales of such Product.
  - (c) In the event that a [\*], the Parties agree to hold good faith discussions to [\*].
- 5.5 Term of Royalties. Exelixis' right to receive royalties under Section 5.4(a) shall expire on a country-by-country and Product-by-Product basis upon the [\*] of: (a) [\*]. Exelixis' right to receive royalties under Section 5.4(b) shall expire on a country-by-country and Product-by-Product basis upon the [\*] of: (a) [\*].
- **5.6 Reports.** Within [\*] after the end of the calendar quarter in which Launch in any country occurs, and each calendar quarter thereafter, Sankyo shall send to Exelixis: (a) a payment of all royalties owed to Exelixis for such quarter; and (b) a report of Net Sales of Products in sufficient detail on a country-by-country basis to permit confirmation of the accuracy of the royalty payment made, including the number of Products sold, the gross sales and Net Sales of Products, the royalties payable (in dollars), the method used to calculate the royalty, and the exchange rates used.

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- **5.7 Sublicenses.** In the event Sankyo grants licenses or sublicenses to others to sell Products which are subject to milestone payments under **Section 5.3** or royalty payments under **Section 5.4**, such licenses or sublicenses shall include an obligation for the licensee or sublicensee to account for and report its sales of Products on the same basis as if such sales were Net Sales by Sankyo, and Sankyo shall pay, or shall ensure that sublicensee shall pay, to Exelixis, the milestone and royalty payments set forth in **Sections 5.3** and **5.4** as if such milestone-triggering events or sales of the licensee or sublicensee were performed or made by Sankyo.
- **5.8 Acknowledgment of Exelixis Contribution.** The Parties hereby acknowledge that the value contributed by Exelixis to any Product developed and/or commercialized by or on behalf of Sankyo, its Affiliates and Sublicensees is the access to the Exelixis Know-How and Exelixis Patents and that the milestone and royalty payments described above in this **Article 5** will be payable by Sankyo regardless of whether a Product is covered by an Exelixis Patent, and/or Joint Patent.
- **5.9 Payments.** All references to "dollars" or "\$" means the legal currency of the United States. All amounts due to Exelixis by Sankyo under this Agreement shall be paid in dollars by wire transfer in immediately available funds to an account designated by Exelixis. If any currency conversion shall be required in connection with any royalty payment under this Agreement, such conversion shall be made by using the average of buying and selling exchange rates for conversion of foreign currency and dollars as published in *The Wall Street Journal*, *Western Edition*, on the last business day of the applicable reporting period. If Sankyo is prevented from paying Exelixis any royalties in a given country because the local currency is blocked and cannot be removed from the country, then Sankyo shall promptly pay Exelixis in the local currency by deposit in a local bank designated by Exelixis, to the extent permitted by local law.
- **5.10 Withholding of Taxes.** Sankyo may withhold from payments due to Exelixis amounts for payment of any withholding tax that is required by law to be paid to any taxing authority with respect to such payments. Sankyo shall provide to Exelixis all relevant documents and correspondence, and shall also provide to Exelixis any other cooperation or assistance on a reasonable basis as may be necessary to enable Exelixis to claim exemption from such withholding taxes and to receive a full refund of such withholding tax or claim a non-U.S. tax credit. Sankyo shall give proper evidence from time to time as to the payment of such tax.
- **5.11 Late Payments.** Any amounts not paid by Sankyo when due under this Agreement shall be subject to interest from and including the date payment is due through and including the date upon which Exelixis has received payment at a rate equal to: (a) the sum of [\*] plus the prime rate of interest quoted in the Money Rates section of *The Wall Street Journal*, *Western Edition* (or similar reputable data source), calculated daily on the basis of a 365-day year; or, if lower, (b) the highest rate permitted under applicable law.
- **5.12 Records and Audit.** During the term of this Agreement and for a period of [\*] thereafter, each Party shall keep complete and accurate records pertaining to the development,

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manufacture, use, sale or other disposition of the Products, in sufficient detail to permit the other Party to confirm the accuracy of all payments due hereunder. Each Party shall have the right to cause an independent, certified public accountant to audit such records to confirm the accuracy of the other Party's payments; provided, however, that such auditor shall not disclose the other Party's confidential information, except to the extent such disclosure is necessary to verify the payments due under this Agreement. Each Party shall bear the full cost of such audit unless such audit discloses a variance of more than [\*] from the amount of payments previously paid for the audited period. In such case, the audited Party shall bear the full cost of such audit. The audited Party shall remit any underpayment identified by such audit (plus applicable interest) within [\*] of the results of such audit. The terms of this Section 5.12 shall survive any termination or expiration of this Agreement for a period of [\*].

#### 6. CONFIDENTIALITY

- **6.1 Nondisclosure of Confidential Information.** For all purposes hereunder, "**Confidential Information**" shall mean all Information disclosed by each Party to the other Party pursuant to this Agreement, including any Information disclosed by each Party to the other Party pursuant to the Non-Disclosure Agreements. [\*], a Party receiving such item of Confidential Information of the other Party will: (a) maintain in confidence such Confidential Information to the same extent such Party maintains its own proprietary information (but at a minimum each Party shall use reasonable efforts); (b) not disclose such item of Confidential Information to any Third Party without prior written consent of the other Party; and (c) not use the other Party's Confidential Information for any purpose except those permitted by this Agreement.
- **6.2 Exceptions.** The obligations in **Section 6.1** shall not apply with respect to any portion of the Confidential Information that the receiving Party can show by competent written proof:
  - (a) Is publicly disclosed by the disclosing Party, either before or after it is disclosed to the receiving Party hereunder;
  - (b) Was known to the receiving Party or any of its Affiliates, without obligation to keep it confidential, prior to disclosure by the disclosing Party;
  - (c) Is subsequently disclosed to the receiving Party or any of its Affiliates by a Third Party lawfully in possession thereof and without obligation to keep it confidential;
  - (d) Is published by a Third Party or otherwise becomes publicly available or enters the public domain, either before or after it is disclosed to the receiving Party; or
  - **(e)** Has been independently developed by employees or contractors of the receiving Party or any of its Affiliates without the aid, application or use of Confidential Information of the disclosing Party.

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- **6.3 Authorized Disclosure.** Each Party may disclose the Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following instances:
  - (a) Filing or prosecuting Patents relating to Products;
  - (b) Regulatory filings;
  - **(c)** Prosecuting or defending litigation;
  - (d) Complying with applicable governmental regulations; and
  - **(e)** Disclosure, in connection with the performance of this Agreement, to Affiliates, sublicensees, research collaborators, employees, consultants, or agents, each of whom prior to disclosure must be bound by similar obligations of confidentiality and non-use at least equivalent in scope to those set forth in this **Article 6**.

Before a Party may disclose the Confidential Information of the other Party under this **Section 6.3**, it shall notify the other Party of a request for disclosure. Furthermore, in the case of a disclosure under Section 6.3(c), the notifying Party will provide such other Party with an opportunity to oppose such disclosure or seek a protective order limiting such disclosure. Upon timely notice of a proposed disclosure to comply with applicable governmental regulations or a request from a governmental authority, the notifying Party shall be relieved of all liability for unauthorized disclosure.

The Parties acknowledge that the terms of this Agreement shall be treated as Confidential Information of both Parties. Such terms may be disclosed by a Party to investment bankers, investors, and potential investors, each of whom prior to disclosure must be bound by similar obligations of confidentiality and non-use at least equivalent in scope to those set forth in this **Article 6**. In addition, a copy of this Agreement may be filed, furnished or submitted to the Securities and Exchange Commission by Exelixis. In connection with any such filing, Exelixis shall endeavor to obtain confidential treatment of economic and trade secret information.

In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information except as permitted hereunder.

**6.4 Press Releases.** If either Party desires to make a public announcement (e.g., press release) concerning the terms of this Agreement or the activities hereunder, such Party shall give reasonable advance notice of the proposed text of such announcement to the other Party for its review and approval prior to announcement, such approval shall not be unreasonably delayed or withheld. Such other Party shall provide its comments, if any, within [\*] business days after receipt of the proposed text and the Party making such announcement shall consider and address all such comments in good faith. Notwithstanding anything to the contrary, such approval shall not be needed if such public announcement: (a) is required pursuant to the disclosure requirements of the U.S. Securities and Exchange Commission or the national securities exchange or other stock market on which such Party's securities are traded; (b) solely discloses that a milestone event under this Agreement has been achieved; or (c) solely discloses information that has previously been approved for disclosure by the other Party.

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**6.5 Scientific Publications.** Each Party shall not publish or present the results of studies carried out under this Agreement without the opportunity for prior review by the other Party. Subject to **Section 6.3**, each Party agrees to provide the other Party the opportunity to review any proposed abstracts, manuscripts or presentations (including verbal presentations) which relate to Products at least [\*] prior to its intended submission for publication and agrees to revise such proposed publication to take into account all reasonable comments provided by the other Party within such [\*]. Each Party shall not have the right to publish or present Confidential Information of the other Party that is subject to **Section 6.1**.

#### 7. INTELLECTUAL PROPERTY

- **7.1 Ownership of Inventions.** Each Party shall own any all right, title and interest in and to inventions made, conceived or reduced to practice solely by its employees, agents or independent contractors in their activities hereunder, and any Patents claiming or disclosing such inventions. Inventions hereunder made, conceived or reduced to practice jointly by employees, agents or independent contractors of each Party in the course of performing under this Agreement, and any intellectual rights in such joint inventions, including Patents claiming or disclosing such joint inventions ("Joint Patents"), shall be owned jointly by the Parties in accordance with the joint ownership interests of co-inventors under U.S. patent laws. Inventorship shall be determined in accordance with U.S. patent laws.
- **7.2 Disclosure.** Each Party shall submit a written report to the JRC within [\*] of the end of each quarter describing any Invention arising during the prior quarter in the course of the Collaboration which it believes may be patentable.

# 7.3 Patent Prosecution, Maintenance and Enforcement.

- (a) Patent Prosecution and Maintenance. Exelixis will prosecute and maintain, at [\*] cost, the Exelixis Patents in those countries covered by its normal patent prosecution strategy (i.e., the [\*]), including conducting any interferences, reexaminations, reissues, oppositions, or request for patent term extension relating thereto. If Sankyo requests that Exelixis prosecute and maintain Exelixis Patents in countries beyond those covered by its normal patent prosecution strategy, Sankyo will [\*] in connection with such prosecution and maintenance. Sankyo's obligation to [\*] will cease for a particular Exelixis Patent when such Exelixis Patent no longer claims the composition, method of making, or method of using any Licensed Compound. Sankyo will prosecute and maintain the Sankyo Patents in its discretion, including conducting any interferences, reexaminations, reissues, oppositions, or request for patent term extension relating thereto, at its expense.
- **(b) Joint Patents.** The Parties shall mutually determine which Party shall be responsible for obtaining, prosecuting and/or maintaining Joint Patents, in appropriate countries throughout the world. The prosecuting Party shall consult with the other Party as to the preparation, filing, prosecution and maintenance of such Joint Patents reasonably prior to any deadline or action with the U.S. Patent & Trademark Office or any foreign patent office, and

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shall furnish to the other Party copies of all relevant documents reasonably in advance of such consultation. Exelixis and Sankyo shall share equally the costs for filing, prosecuting and/or maintaining such Joint Patents throughout the world; *provided*, *however*, that either Party may decline to bear its share of the costs and expenses to file, prosecute and/or maintain any particular Joint Patent in any countries. In that case the other Party may undertake the responsibility for filing, prosecuting and/or maintaining such Joint Patent at its own expense, and if it does so, the declining Party shall assign to the other Party all its right, title and interest to any such Joint Patent(s), and, upon such assignment, such Joint Patent(s) shall become the sole property of other Party.

(c) Enforcement of Patent Rights. If either Party becomes aware of a suspected infringement of Exelixis Patents [\*] (collectively, "Enforceable Patents") through the development, manufacture or sale of a Product by a Third Party, such Party shall notify the other Party promptly, and following such notification, the Parties shall confer. Sankyo shall have the first right, but shall not be obligated, to bring an infringement action against such Third Party with respect to the Enforceable Patents at its own expense and by counsel of its own choice, and shall control the progress of the litigation. If Sankyo desires to bring an infringement action against such Third Party, but is prevented by law from initiating such an action on its own, Exelixis will bring the claim on behalf of Sankyo (at Sankyo's expense), and Sankyo shall be treated as if it brought the action directly. Exelixis shall have the right to participate in such action, at its own expense and by counsel of its own choice and Sankyo shall consider all reasonable requests and comments from Exelixis. If Sankyo fails to bring such an action or proceeding within: (i) [\*] following the notice of alleged infringement; or (ii) [\*] before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such actions, whichever comes first, then Exelixis shall have the right to bring and control any such action, at its own expense and by counsel of its own choice, and Sankyo shall have the right to be represented in any such action, at its own expense and by counsel of its own choice. If a Party brings an infringement action pursuant to this Section 7.3(c), the other Party will reasonably assist the enforcing Party (at the enforcing Party's expense) in such actions or proceedings if so requested, and will lend its name to such actions or proceedings if required by law in order for the enforcing Party to bring such action. Neither Party shall have the right to settle any patent infringement litigation under this Section 7.3(c) in a manner that diminishes the rights or interests of the other Party without the prior written consent of such other Party. Except as otherwise agreed to by the Parties as part of a cost sharing arrangement, any recovery realized as a result of such litigation, after reimbursement of any litigation expenses of Sankyo and Exelixis, shall be treated as follows: (i) if Sankyo brings and controls the litigation any recovery for [\*], and, if Exelixis brings and controls the litigation, any recovery for [\*]; and (ii) any other recovery realized by either Party as a result of such litigation [\*].

**7.4 Third Party Infringement Claims**. If an allegation is made or claim is brought by a Third Party that any activity related to a Product infringes the intellectual property rights of such Third Party, each Party will give prompt written notice to the other Party of such claim. Each Party shall have the right to defend against such allegation or claim at its own expense, in its own name, and under its own direction and control and shall reasonably assist the other Party (at the other Party's expense) if so requested. Neither Party shall enter into any settlement of any

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claim described in this **Section 7.4** that affects the other Party's rights or interests without such other Party's written consent, which consent shall not be unreasonably withheld or delayed. If a Party is entitled to indemnification pursuant to **Article 9** with respect to a claim described in this **Section 7.4**, it shall follow the procedures set forth in **Article 9** if it wishes to obtain such indemnification.

#### 8. REPRESENTATIONS AND WARRANTIES

- **8.1 Mutual Warranties**. Each Party represents and warrants to the other Party that: (a) it has the authority and right to enter into and perform this Agreement; (b) this Agreement is a legal and valid obligation binding upon it and is enforceable in accordance with its terms, subject to applicable limitations on such enforcement based on bankruptcy laws and other debtors' rights; and (c) its execution, delivery and performance of this Agreement will not conflict in any material fashion with the terms of any other agreement or instrument to which it is or becomes a party or by which it is or becomes bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having authority over it.
  - 8.2 Exelixis Warranties. Exelixis represents and warrants to Sankyo, to Exelixis' knowledge as of the Effective Date, that:
  - (a) Exelixis has the full right and power to grant the license set forth in **Section 4.1** in the manner and to the extent set forth in this Agreement, free and clear of any adverse assignment, grant or other encumbrances inconsistent with such grant;
    - (b) Exelixis has not received any written notice or other written communication alleging that [\*]; and
    - (c) None of the [ \* ].

# 8.3 No Additional Representations.

- (a) Exelixis, its Affiliates, and its and their directors, officers, employees, agents or contractors shall not have or be subject to any liability to Sankyo or any Third Party resulting from the provision to Sankyo, or Sankyo's use of, any such information, documents or material made available to Sankyo in any "data rooms", management presentations or in any other form in expectation of the transactions contemplated hereby, except to the extent such information, documents or materials are included in the representations or warranties of Exelixis expressly set forth in this **Article 8**, provided that all such information, documents or material be made available in their original state, without redaction or alteration.
- **(b)** Except as expressly set forth in the representations and warranties set forth in **Sections 8.1** and **8.2** of this Agreement: (i) there are no representations or warranties by Exelixis of any kind, express or implied, with respect to Licensed Compounds (including its research, development or commercialization); and (ii) **EXELIXIS NEITHER MAKES OR EXTENDS ANY OTHER EXPRESS OR IMPLIED REPRESENTATION OR WARRANTY, INCLUDING ANY EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE**

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OR USE OF ANY PRODUCT OR ANY REPRESENTATIONS OR WARRANTIES WITH RESPECT TO INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS.

8.4 Collaboration Disclaimer. EXCEPT AS PROVIDED IN ARTICLE 8 ABOVE, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL OTHER WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES WITH RESPECT TO ANY RESEARCH RESULTS, LICENSED COMPOUNDS, DATA, OR INVENTIONS (AND ANY PATENT RIGHTS OBTAINED THEREON) IDENTIFIED, MADE OR GENERATED BY SUCH PARTY AS PART OF THE COLLABORATION OR OTHERWISE MADE AVAILABLE TO THE OTHER PARTY PURSUANT TO THE TERMS OF THE AGREEMENT.

#### 9. INDEMNIFICATION

- **9.1 Exelixis**. Exelixis shall indemnify, defend and hold harmless Sankyo, its Affiliates, and their respective directors, officers and employees (each a "Sankyo Indemnitee") from and against any and all liabilities, damages, losses, costs or expenses (including attorneys' and professional fees and other expenses of litigation and/or arbitration) ("Liabilities") resulting from any claim, suit or proceeding made or brought by a Third Party against a Sankyo Indemnitee to the extent arising from or occurring as a result of [\*]; except to the extent that: [\*].
- **9.2** Sankyo. Sankyo shall indemnify, defend and hold harmless Exelixis, its Affiliates, and their respective directors, officers and employees (each an "Exelixis Indemnitee") from and against any and all Liabilities resulting from any claim, suit or proceeding made or brought by a Third Party against an Exelixis Indemnitee to the extent arising from or occurring as a result of: [\*] except to the extent that: [\*].
- **9.3 Procedure.** In the event that a Party indemnified hereunder (an "**Indemnitee**") intends to claim indemnification under this **Article 9**, such Indemnitee shall promptly notify the other Party (the "**Indemnitor**") in writing of such alleged Liability. The Indemnitor shall have the sole right to control the defense and settlement thereof. The Indemnitee shall cooperate with the Indemnitor and its legal representatives in the investigation of any action, claim or liability covered by this **Article 9**. The Indemnitee shall not, except at its own cost and risk, voluntarily make any payment or incur any expense with respect to any claim or suit without the prior written consent of the Indemnitor, which the Indemnitor shall not be required to give. The Indemnitor shall not be required to provide indemnification with respect to a Liability the defense of which is prejudiced by the failure to give notice by the Indemnitee or the failure of the Indemnitee to cooperate with the Indemnitor or where the Indemnitee settles or compromises a Liability without the written consent of the Indemnitor. Each Party shall cooperate with the other Party in resolving any claim or Liability with respect to which a Party is obligated to indemnify the other Party under this Agreement, including by making commercially reasonable efforts to mitigate or resolve any such claim or Liability.

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9.4 Limitations on Liability. Notwithstanding any provision herein, a Party shall in no event be liable to the other Party or its Affiliates, officers, directors, employees, stockholders, agents or representatives for any indirect, consequential or punitive damages (including, but not limited to, lost profits, loss of use, damage to goodwill or loss of business), unless such damages: (a) are owed under the liable Party's indemnification obligations under Article 9; (b) arise from a breach of Article 6; or (c) are due to the gross negligence or willful misconduct of the liable Party.

#### 10. TERM AND TERMINATION

- **10.1 Term.** The term of this Agreement shall commence on the Effective Date and continue until the expiration of all Sankyo's payment obligations under this Agreement, unless earlier terminated pursuant to **Section 10.2**, **Section 10.3**, or **Section 10.4**.
- **10.2 Termination due to [\*].** If, **[\*]**, the JRC determines that **[\*]**, this Agreement shall terminate unless the Parties mutually agree to extend the Research Term.

Upon termination of this Agreement pursuant to this **Section 10.2**:

- (a) all rights under the licenses granted by either Party shall automatically terminate and revert to the granting Party; and
- (b) except as specifically prohibited by a surviving obligation in this Agreement, each Party may [\*].
- **10.3 Termination by Sankyo.** If, at any time [\*], Sankyo determines that it wishes to withdraw from further development or commercialization of Products, it may terminate this Agreement by giving written notice to Exelixis at least [\*] prior to the proposed date of termination.

Upon termination of this Agreement by Sankyo pursuant to this Section 10.3:

- (a) all rights under the licenses granted under Section 4.1 shall automatically terminate and revert to Exelixis;
- **(b)** Sankyo shall, and hereby does, grant to Exelixis a worldwide, irrevocable, perpetual license, with the right to sublicense, under Sankyo Know-How, Sankyo Patents, and Sankyo's interest in Joint Patents to the extent that such are necessary to make, have made, use, sell, have sold, offer for sale and import Products. For Products on which Sankyo [\*] prior to termination, the license described in this **Section 10.3(b)** shall be non-exclusive, [\*]. For Products on which Sankyo [\*] prior to termination and that [\*], the license described in this **Section 10.3(b)** shall be exclusive. The licenses for all other Sankyo Patents shall be non-exclusive. [\*] shall bear a combined royalty of [\*] of Exelixis Net Sales of such Product by Exelixis or its sublicensee. Sankyo's right to receive royalties under this **Section 10.3(b)** shall expire on a country-by-country and Product-by-Product basis upon the [\*] of: (i) [\*]; and

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- (c) Sankyo shall transfer and assign to Exelixis: (i) all Information relating to the Product, and all regulatory filings and Regulatory Approvals (including all INDs, NDAs, drug dossiers and master files) with respect to Product in Sankyo's name (ii) all agreements with Third Parties related to the Product, to the extent that they may be assigned, (iii) all trademark related to the Product, and (iv) all supplies of Product (including any intermediates, retained samples and reference standards) that in each case are in Sankyo's Control and that relate to the Product. Sankyo shall take such other actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights hereunder to Exelixis.
- **10.4 Termination for Material Breach**. If either Party has breached any of its material obligations hereunder, and such breach has continued for [\*] after written notice thereof was provided to the breaching Party by the non-breaching Party, the non-breaching Party may terminate this Agreement. Any termination shall become effective at the end of such [\*] period unless the breaching Party has cured or made a good faith effort to cure any such breach prior to the expiration of the [\*] period.

Upon termination of this Agreement by the non-breaching Party pursuant to this Section 10.4:

- (a) all rights under the licenses granted by the non-breaching Party shall automatically terminate and revert to the non-breaching Party;
- (b) in the case of termination by Sankyo, Exelixis shall, and it hereby does, grant to Sankyo, a worldwide, exclusive (even as to Exelixis), irrevocable, perpetual license, with the right to sublicense, under the Exelixis Know-How, Exelixis Patents, and Exelixis' interest in the Joint Patents, to make, have made, use, sell, have sold, offer for sale and import Products. For Products on which Sankyo [\*] prior to termination, the license described in this Section 10.4(b) shall be [\*]. For Products on which Sankyo [\*] prior to termination and that [\*], the license described in this Section 10.4(b) shall [\*]. Exelixis' right to receive royalties under this Section 10.4(b) shall expire on a country-by-country and Product-by-Product basis upon the [\*] of: (i) [\*];
- (c) in the case of termination by Exelixis, Sankyo shall, and hereby does, grant to Exelixis, a worldwide, irrevocable, perpetual license, with the right to sublicense, under the Sankyo Know-How, Sankyo Patents, and Sankyo's interest in the Joint Patents, to make, have made, use, sell, have sold, offer for sale and import Products. For Products on which Sankyo [\*] prior to termination, the license described in this Section 10.4(c) shall be [\*]. For Products on which Sankyo [\*] prior to termination and that [\*], the license described in this Section 10.4(c) shall be exclusive. The license for all other Sankyo Patents shall be non-exclusive. All licenses shall [\*]. Sankyo's right to receive royalties under this Section 10.4(c) shall expire on a country-by-country and Product-by-Product basis upon the [\*] of: (i) [\*]; and
- (d) the breaching Party shall transfer and assign to the non-breaching Party: (i) all Information relating to the Product, and all regulatory filings and Regulatory Approvals (including all INDs, NDAs, drug dossiers and master files) with respect to Product in the Breaching Party's name (ii) all agreements with Third Parties related to the Product, to the extent that they may be assigned, (iii) all trademark related to the Product, and (iv) all supplies of

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Product (including any intermediates, retained samples and reference standards) that in each case are in the breaching Party's Control and that relate to the Product. The breaching Party shall take such other actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights hereunder to the non-breaching Party.

**10.5 Accrued Rights.** Termination or expiration of this Agreement for any reason shall not release either Party hereto from any liability which, at the time of such termination or expiration, has already accrued to the other Party or which is attributable to a period prior to such termination or expiration or preclude either Party from pursuing any rights and remedies it may have hereunder or at law or in equity with respect to any breach of, or default under, this Agreement. It is understood and agreed that monetary damages may not be a sufficient remedy for any breach of this Agreement and that the non-breaching Party may be entitled to specific performance as a partial remedy for any such breach.

10.6 Survival. The following provisions of this Agreement shall survive expiration or termination of this Agreement for any reason: [\*].

# 11. MISCELLANEOUS

- **11.1 Dispute Resolution.** In the event of any controversy or claim arising out of, relating to or in connection with any provision of the Agreement (except as described in **Section 11.3**), the Parties shall try to settle their differences amicably between themselves first, by referring the disputed matter to the CEO of Exelixis and the General Manager of the Research and Development Headquarters of Sankyo or their designees. Either Party may initiate such informal dispute resolution by sending written notice of the dispute to the other Party, and, within [\*] after such notice, such officers of the Parties shall meet for attempted resolution by good faith negotiations. If such officers are unable to resolve such dispute within [\*] of their first meeting for such negotiations, such dispute shall be finally settled by arbitration. The arbitration shall be held in New York, New York, U.S.A. and be administered by the American Arbitration Association in accordance with its International Arbitration Rules. The arbitration proceeding shall be conducted in English. The award shall be final and binding upon both Parties. Judgment upon the award may be entered in any court having jurisdiction thereof.
- **11.2 Governing Law.** Resolution of all disputes arising out of or related to the Agreement or the performance, enforcement, breach or termination of the Agreement and any remedies relating thereto, shall be governed by and construed under the substantive laws of the State of New York, without regard to conflicts of law rules applying a different law.
- **11.3 Patents and Trademarks.** Notwithstanding anything to the contrary in this Agreement, any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any Patent rights covering the manufacture, use or sale of any Product or of any trademark rights related to any Product shall be submitted to a court of competent jurisdiction in the territory in which such Patent or trademark rights were granted or arose.
- **11.4 Performance by Affiliates.** The Parties recognize that each may perform some or all of its obligations under this Agreement through Affiliates; *provided, however*, that each

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Party shall remain responsible and be guarantor of the performance by its Affiliates and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. In particular, if any Affiliate of a Party participates under this Agreement with respect to Licensed Compounds or Products: (a) the restrictions of this Agreement which apply to the activities of a Party with respect to Licensed Compounds or Products (as applicable) shall apply equally to the activities of such Affiliate; and (b) the Party affiliated with such Affiliate shall assure, and hereby guarantees, that any intellectual property developed by such Affiliate shall be governed by the provisions of this Agreement (and subject to the licenses set forth in **Articles 4** and **10**) as if such intellectual property had been developed by the Party.

- 11.5 Entire Agreement; Amendments. This Agreement sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto and supersedes and terminates all prior agreements and understandings between the Parties. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party. The Parties hereby agree to terminate the Non-Disclosure Agreement by mutual consent, and to have this Agreement supersede the Non-Disclosure Agreement.
- **11.6 Export Control.** This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States of America or other countries which may be imposed upon or related to Exelixis or Sankyo from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity.
- 11.7 Force Majeure. Each Party shall be excused from the performance of its obligations under this Agreement to the extent that such performance is prevented by force majeure (defined below) and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, "force majeure" shall include conditions beyond the control of the Parties, including an act of God, voluntary or involuntary compliance with any regulation, law or order of any government, war, civil commotion, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe. The payment of invoices due and owing hereunder shall in no event be delayed by the payer because of a force majeure affecting the payer.
- **11.8 Notices.** Any notices given under this Agreement shall be in writing, addressed to the Parties at the following addresses, and delivered by person, by facsimile (with receipt confirmation), or by FedEx or other reputable courier service. Any such notice shall be deemed

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to have been given: (a) as of the day of personal delivery; (b) one (1) day after the date sent by facsimile service; or (c) on the day of successful delivery to the other Party confirmed by the courier service. Unless otherwise specified in writing, the mailing addresses of the Parties shall be as described below.

For Exelixis: Exelixis, Inc.

170 Harbor Way P.O. Box 511

South San Francisco, CA 94083 Attention: SVP, Patents and Licensing

With a copy to: Cooley Godward LLP

Five Palo Alto Square 3000 El Camino Real Palo Alto, CA 94306

Attention: Robert L. Jones, Esq.

For Sankyo: Sankyo Co. Ltd.

1-2-58 Hiromachi

Shinagawa-ku, Tokyo 140-8710

Japan

Attention: Director, Pharmacology and Molecular Biology Research Laboratories

With a copy to: Sankyo Co. Ltd.

1-2-58 Hiromachi

Shinagawa-ku, Tokyo 140-8710

Attention: Koji Kiyofuji, Research and Development Strategy Department

- **11.9 Consents Not Unreasonably Withheld or Delayed.** Whenever provision is made in this Agreement for either Party to secure the consent or approval of the other, that consent or approval shall not unreasonably be withheld or delayed, and whenever in this Agreement provisions are made for a Party to object to or disapprove a matter, such objection or disapproval shall not unreasonably be exercised.
- **11.10 Maintenance of Records.** Each Party shall keep and maintain all records required by law or regulation with respect to Products and shall make copies of such records available to the other Party upon request.
- **11.11 Assignment.** Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except a Party may make such an assignment without the other Party's consent to an Affiliate or to a Third Party successor to substantially all of the business of such Party to which this Agreement relates, whether in a merger, sale of stock, sale of assets or other transaction; *provided* that any such permitted successor or assignee of rights and/or obligations hereunder is obligated, by reason of operation

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of law or pursuant to a written agreement with the other Party, to assume performance of this Agreement or such rights and/or obligations; and *provided*, *further*, that if assigned to an Affiliate, the assigning Party shall remain jointly and severally responsible for the performance of this Agreement by such Affiliate. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this **Section 11.11** shall be null and void and of no legal effect.

- **11.12 Electronic Data Interchange.** If both Parties elect to facilitate business activities hereunder by electronically sending and receiving data in agreed formats (also referred to as Electronic Data Interchange or "EDI") in substitution for conventional paper-based documents, the terms and conditions of this Agreement shall apply to such EDI activities.
- **11.13 Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.
- **11.14 Severability.** If any of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable provision such that the objectives contemplated by the Parties when entering this Agreement may be realized.
- **11.15 No Waiver.** Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, excepting only as to an express written and signed waiver as to a particular matter for a particular period of time.
- 11.16 Construction of this Agreement. Except where the context otherwise requires, wherever used, the singular will include the plural, the plural the singular, the use of any gender will be applicable to all genders, and the word "or" are used in the inclusive sense. When used in this Agreement, "including" means "including without limitation". References to either Party include the successors and permitted assigns of that Party. The headings of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The Parties have each consulted counsel of their choice regarding this Agreement, and, accordingly, no provisions of this Agreement will be construed against either Party on the basis that the Party drafted this Agreement or any provision thereof. If the terms of this Agreement conflict with the terms of any Exhibit, then the terms of this Agreement shall govern. The official text of this Agreement and any Exhibits hereto, any notice given or accounts or statements required by this Agreement, and any dispute proceeding related to or arising hereunder, shall be in English. In the event of any dispute concerning the construction or meaning of this Agreement, reference shall be made only to this Agreement as written in English and not to any other translation into any other language.

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**11.17 Counterparts.** This Agreement may be executed in two (2) or more counterparts, each of which shall be an original and all of which shall constitute together the same document. Counterparts may be signed and delivered by facsimile, each of which shall be binding when sent.

Signature page follows.

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**IN WITNESS WHEREOF**, Exelixis and Sankyo have executed this Agreement by their respective duly authorized representatives as of the Effective Date.

SANKYO COMPANY, LIMITED

EXELIXIS, INC.

By: <u>/s/</u> Yukio Sugimura

Title: Executive Vice President and

Representative Director, General Manager Research and Development Headquarters By: /s/ George A. Scangos

Title: President and Chief Executive Officer

Date: 3/22/06 Date: 3/20/06

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# Exhibit 1.18 Existing Compound Patents

[\*]

# Exhibit 2.4 Compound Transfer List

[\*]

#### 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 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 fiscal 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 the 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: May 9, 2006

/s/ George A. Scangos

George A. Scangos

President and Chief Executive Officer

#### 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 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 fiscal 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 the 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: May 9, 2006

/s/ Frank Karbe

Frank Karbe

Senior Vice President, Chief Financial Officer

# 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 March 31, 2006 (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 9th day of May 2006.

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