

EXELIXIS INC
Form S-1/A
September 26, 2008
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As filed with the Securities and Exchange Commission on September 26, 2008

Registration No. 333-152166

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

Amendment No. 1 to
FORM S-1
REGISTRATION STATEMENT
UNDER THE SECURITIES ACT OF 1933

EXELIXIS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

8731
(Primary Standard Industrial
Classification Code Number)

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

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249 East Grand Ave.

P.O. Box 511

South San Francisco, CA 94083-0511

(650) 837-7000

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

George A. Scangos, Ph.D.

President and Chief Executive Officer

Exelixis, Inc.

249 East Grand Ave.

P.O. Box 511

South San Francisco, CA 94083-0511

(650) 837-7000

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copy to:

Suzanne Sawochka Hooper, Esq.

Cooley Godward Kronish LLP

Five Palo Alto Square

3000 El Camino Real

Palo Alto, CA 94306-2155

(650) 843-5000

Approximate date of commencement of proposed sale to the public:

From time to time after the effective date of this Registration Statement.

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If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. ☒ x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐ "

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐ "

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐ "

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒ x

Accelerated filer ☐ "

Non-accelerated filer ☐ "

Smaller reporting company ☐ "

(Do not check if a smaller reporting company)

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered	Offering Price Per Unit	Proposed Maximum	Amount of Registration Fee (1)
			Proposed Maximum Aggregate Offering Price	
Common Stock, par value \$0.001 per share (2)	1,000,000	\$6.37	\$6,370,000	\$251

- (1) Calculated in accordance with Rule 457(c) of the Securities Act. The price per share and aggregate offering price are based on the average of the high and low prices of the registrant's common stock on September 23, 2008, as reported on The Nasdaq Global Select Market. All filing fees payable in connection with the registration of the 1,000,000 shares being registered hereby were previously paid in connection with the filing of the original registration statement.
- (2) Includes shares of common stock issuable upon the exercise of warrants issued pursuant to a facility agreement dated as of June 4, 2008 between the registrant and the lenders identified therein. Pursuant to Rule 416 under the Securities Act, this Registration Statement also includes such additional shares as may hereafter be offered or issued to prevent dilution resulting from stock splits, stock dividends, recapitalizations or certain other capital adjustments.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act, or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PROSPECTUS

Subject to Completion

Preliminary Prospectus dated September 26, 2008

1,000,000 Shares

EXELIXIS, INC.

Common Stock

This prospectus relates to the offer and sale of up to 1,000,000 shares of our common stock by the selling security holders listed on page 21, including their transferees, pledgees or donees or their respective successors, which includes shares of our common stock issuable upon the exercise of warrants issued pursuant to a facility agreement dated as of June 4, 2008 between us and the lenders identified therein. We are registering these shares on behalf of the selling security holders, to be offered and sold by them from time to time.

We will not receive any proceeds from any resale of the shares of common stock being offered by this prospectus. The selling security holders may sell the shares of common stock described in this prospectus in a number of different ways and at varying prices. We provide more information about how the selling security holders may sell their shares of common stock in the section entitled **Plan of Distribution** on page 24. We will not be paying any underwriting discounts or commissions in this offering.

Our common stock is traded on The Nasdaq Global Select Market under the trading symbol **EXEL**. On September 23, 2008, the last reported sale price of our common stock was \$6.16 per share.

Investing in our securities involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading Risk Factors beginning on page 3 before you decide whether to invest in shares of our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this Prospectus is _____, 2008

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This prospectus is part of a registration statement on Form S-1 that we filed with the Securities and Exchange Commission using the shelf registration process. Under this process, selling security holders may from time to time, in one or more offerings, sell the securities described in this prospectus.

You should rely only on the information contained in or incorporated by reference into this prospectus (as supplemented and amended). We have not authorized anyone to provide you with different information. This document may only be used where it is legal to sell these securities. You should not assume that the information contained in this prospectus is accurate as of any date other than its date regardless of the time of delivery of the prospectus or any sale of the securities described in this prospectus.

This prospectus and the information incorporated herein by reference includes trademarks, service marks and trade names owned by us or others. All trademarks, service marks and trade names included or incorporated by reference into this prospectus or any applicable prospectus supplement are the property of their respective owners.

We urge you to read carefully this prospectus, together with the information incorporated herein by reference as described under the heading Where You Can Find More Information, before deciding whether to invest in any of the securities being offered.

References in this prospectus to Exelixis, we, us and our refer to Exelixis, Inc., a Delaware corporation, and its subsidiaries. Our principal executive offices are located at 249 East Grand Ave, P.O. Box 511, South San Francisco, CA 94083-0511 and our telephone number is (650) 837-7000. Our web site address is <http://www.exelixis.com>. The information contained in, or that can be accessed through, our web site is not part of this prospectus.

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This summary may not contain all the information that may be important to you. You should read the entire prospectus, including the financial data and related notes, risk factors and other information incorporated by reference in this prospectus (as supplemented and amended), before making an investment decision.

Company Overview

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

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

To date, we have filed 14 investigational new drug applications, or INDs. We believe that our deep pool of drug candidates will enable us to continue to file multiple new INDs each year for the foreseeable future. As our compounds advance into clinical development, we expect to generate a critical mass of data that will help us to understand the full clinical and commercial potential of our product candidates. In addition to guiding the potential commercialization of our innovative therapies, these data may contribute to the understanding of disease and help improve treatment outcomes.

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

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

* Pursuant to our product development and commercialization agreement with GlaxoSmithKline, GlaxoSmithKline has the option to develop two compounds in our product pipeline. GlaxoSmithKline previously selected XL880 and will be able to choose one additional compound from among XL820, XL184, XL281, XL844 and XL228. On June 27, 2008 we announced that our six year collaboration with GlaxoSmithKline will conclude on October 27, 2008, as scheduled. On July 28, 2008, we announced that proof-of-concept for XL184 had been achieved under our collaboration with GlaxoSmithKline and that we submitted the corresponding data report to GlaxoSmithKline. We anticipate a decision from GlaxoSmithKline by late October 2008.

** Out-licensed to Symphony Evolution, Inc. and subject to a repurchase option as described more fully in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007, incorporated herein by reference.

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

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

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

* We will continue to be responsible for the phase 1 clinical trial until the point that a maximum tolerated dose, or MTD, is determined. After MTD is achieved, Genentech will be responsible for completing the phase 1 clinical trial and subsequent clinical development. Though not represented in the tables above, we also have compounds in preclinical development that we are developing internally.

The Offering

The selling security holders named in this prospectus may offer up to 1,000,000 shares of our common stock, which includes shares of our common stock issuable upon the exercise of warrants issued pursuant to a facility agreement dated as of June 4, 2008, or the Facility Agreement, between us and Deerfield Private Design Fund, L.P., Deerfield Private Design International, L.P., Deerfield Partners, L.P. and Deerfield International Limited, which we collectively refer to as the Deerfield Entities. Our common stock currently is listed on the Nasdaq Global Select Market under the symbol EXEL. Shares of common stock that may be offered in this offering, when issued and paid for, will be fully paid and non-assessable. We will not receive any of the proceeds of sales by the selling security holders of any of the securities covered by this prospectus.

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RISK FACTORS

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

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

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

We will need to raise additional capital to:

fund our operations and clinical trials;

continue our research and development efforts; and

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

As of June 30, 2008, we had \$189.8 million in cash and cash equivalents and short-term and long-term marketable securities, which included investments held by Symphony Evolution, Inc., or SEI, of \$22.4 million and restricted cash and investments of \$5.7 million. We anticipate that our current cash and cash equivalents, short-term and long-term marketable securities, investments held by SEI, funds available under the Facility Agreement with the Deerfield Entities, and other funding that we expect to receive from collaborators, which assumes a moderate level of business development activity, will enable us to maintain our operations for a period of at least 12 months following the filing date of the registration statement of which this prospectus is a part. However, our future capital requirements will be substantial and will depend on many factors that may require us to use available capital resources significantly earlier than we currently anticipate. These factors include:

the timing and progress of the clinical development of our product candidate XL647, which is out-licensed to SEI. The phase 2 clinical development program for XL647 is ongoing, and GlaxoSmithKline has declined to exercise its development option for XL647. We are in discussions with potential partners and with SEI regarding the future clinical development of XL647 and related funding. The initiation of a previously announced proposed phase 2 clinical trial comparing XL647 with doublet chemotherapy as a first-line treatment in non-small cell lung cancer remains dependent on the outcome of these discussions. In order to retain rights to XL647 after the expiration of the purchase option period, our agreements with SEI require us to reacquire XL647, XL784 and XL999 from SEI's investors through the exercise of our exclusive purchase option, as described more fully in our Annual Report on Form 10-K for the fiscal year ended December 28, 2007, incorporated herein by reference. We do not have the right to repurchase a single product candidate without also repurchasing the other two product candidates. In December 2007, we discontinued the development program for XL999, and, in January 2008, GlaxoSmithKline declined to exercise its option to further develop and commercialize XL784. We do not intend to invest further in the development of XL784, but will seek a partner with which to take the compound forward, which would also require us to repurchase all three compounds from SEI's investors. The purchase option price, which may be paid in cash and/or shares of our common stock, at our sole discretion, would be equal to the sum of (1) the total amount of capital invested in SEI by its investors (\$80.0 million) and (2) an amount equal to 25% per year on such funded capital, compounded from the time of funding. As a result, the purchase option price for the compounds licensed to SEI increases over time;

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whether and when GlaxoSmithKline selects for further development and commercialization any additional product candidate Under the amended product development and commercialization agreement between us and GlaxoSmithKline, any milestone payments relating to product candidates remaining under the product development and commercialization agreement must be used to pay down our loan with GlaxoSmithKline as long as the loan is outstanding. As of June 30, 2008, the aggregate principal and interest outstanding under our GlaxoSmithKline loan was \$100.3 million. We have submitted the data report for XL184 to GlaxoSmithKline and anticipate a decision by GlaxoSmithKline regarding XL184 by late October 2008. If GlaxoSmithKline selects XL184, we would earn a \$55.0 million selection milestone. If GlaxoSmithKline does not select XL184, then GlaxoSmithKline will have the right to select one of XL281, XL228, XL820 or XL844. If GlaxoSmithKline selects one of these compounds, we potentially would be entitled to a selection milestone of \$27.5 million, which would not be payable unless and until GlaxoSmithKline takes the compound to proof-of-concept. In December 2007, GlaxoSmithKline exercised its option to further develop and commercialize XL880. As XL880 was the first compound selected by GlaxoSmithKline under the product development and commercialization agreement, the entire \$35.0 million selection milestone for XL880 was retained by GlaxoSmithKline to offset a milestone payment that GlaxoSmithKline paid to us in 2005 in connection with the amendment of the product development and commercialization agreement and was not used to pay down the loan;

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

the level of payments received under existing collaboration agreements, licensing agreements and other arrangements as well as our ability to enter into new collaboration agreements, licensing agreements and other arrangements that provide additional payments;

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

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

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

future clinical trial results;

our need to expand our product and clinical development efforts;

our ability to share the costs of our clinical development efforts with third parties;

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the cost and timing of regulatory approvals;

the cost of clinical and research supplies of our product candidates;

the effect of competing technological and market developments;

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

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

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

One or more of these factors or changes to our current operating plan may require us to use available capital resources significantly earlier than we anticipate. If our capital resources are insufficient to meet future capital requirements, we will have to raise additional funds. We may be unable to raise sufficient additional capital when we need it, on favorable terms or at all. The sale of equity or convertible debt securities in the future may be dilutive to our existing stockholders, and debt-financing arrangements may require us to pledge certain assets and enter into covenants that would restrict certain business activities or our ability to incur further indebtedness and may contain other terms that are unfavorable to our stockholders or us. If we are unable to obtain adequate funds on reasonable terms, we may be required to curtail operations significantly or obtain funds by entering into financing, supply or collaboration agreements on unattractive terms. If we raise additional funds through collaboration arrangements with third parties, it will be necessary to relinquish some rights to our technologies or product candidates, or we may be required to grant licenses on terms that are unfavorable to us.

In addition, we will have to obtain additional funding in order to stay in compliance with financial covenants contained in agreements with third parties. For example, as part of our collaboration with GlaxoSmithKline, we entered into the loan and security agreement, which, as amended, contains financial covenants pursuant to which our working capital (the amount by which our current assets exceed our current liabilities as defined by the agreement, which excludes restricted cash and deferred revenue, but includes amounts available for borrowing under the Facility Agreement) must not be less than \$25.0 million and our cash and investments (total cash, cash equivalents and investments as defined by the agreement, which excludes restricted cash) must not be less than \$50.0 million. As of June 30, 2008, our working capital was \$253.4 million (including \$150 million available for borrowing under the Facility Agreement) and our cash and investments were \$184.2 million. If we were to default on the financial covenants under the loan and security agreement, GlaxoSmithKline may, among other remedies, declare immediately due and payable all obligations under the loan and security agreement. Outstanding borrowings and accrued interest under the loan and security agreement totaled \$100.3 million at June 30, 2008. Principal and accrued interest under the loan becomes due in three annual installments beginning on October 27, 2009. We are also required to maintain certain cash balances in order to access the Deerfield Facility.

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

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

We have incurred net losses since inception, including a net loss of \$45.1 million for the three-month period ended June 30, 2008 and \$86.4 million for the six-month period ended June 30, 2008. As of that date, we had an accumulated deficit of \$878.0 million. We expect our losses in 2008 to increase as compared to 2007 and anticipate negative operating cash flow for the foreseeable future. We have not yet completed the development, including obtaining regulatory approval, of any of our pharmaceutical product candidates and, consequently, have not generated revenues from the sale of pharmaceutical products. Except for revenues associated with the transgenic mouse business of our former German subsidiary, Artemis Pharmaceuticals, GmbH, or Artemis, our

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only revenues to date are license revenues and revenues under contracts with our partners. In December 2007, we sold 80.1% of our ownership interest in Artemis, and will not recognize revenue associated with Artemis in future periods. The amount of our net losses will depend, in part, on the rate of growth, if any, in our license and contract revenues and on the level of our expenses. These losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Our research and development expenditures and general and administrative expenses have exceeded our revenues to date, and we expect to spend significant additional amounts to fund research and development in order to enhance our technologies and undertake product development. We currently have numerous product candidates in various stages of clinical development and we anticipate filing additional IND applications for additional product candidates within the next 12 months. As a result, we expect to continue to incur substantial operating expenses, and, consequently, we will need to generate significant additional revenues to achieve profitability. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do increase our revenues and achieve profitability, we may not be able to maintain or increase profitability.

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

We have licensed to SEI our intellectual property rights, including commercialization rights, to our product candidates XL647, XL784 and XL999 in exchange for SEI's investment of \$80.0 million to advance the clinical development of XL647, XL784 and XL999. In exchange for this investment and for five-year warrants to purchase shares of our common stock, we received an exclusive purchase option to acquire all of the equity of SEI, thereby allowing us to reacquire the product candidates, including any associated intellectual property rights and commercialization rights. Under our amended purchase option agreement with SEI, we cannot repurchase a single product candidate without also repurchasing the other two product candidates. We may, at our sole discretion, exercise our purchase option at any time until the earlier of June 9, 2009 or the 90th day after the date on which SEI provides us with financial statements showing cash and cash equivalents of less than \$5.0 million. The purchase option exercise price, which may be paid in cash and/or shares of our common stock, at our sole discretion, is equal to the sum of: (1) the total amount of capital invested in SEI by its investors and (2) an amount equal to 25% per year on such funded capital, compounded from the time of funding. The option exercise price may be paid in cash and/or shares of our common stock, at our sole discretion.

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

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Risks Related to Development of Product Candidates

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

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

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

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

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

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

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

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

We have limited experience in conducting clinical trials and may not be able to rapidly or effectively continue the further development of our compounds or meet current or future requirements identified based on our discussions with the United States Food and Drug Administration, or 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.

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Risks Related to Our Relationships with Third Parties

Disagreements between SEI and us regarding the development of our product candidates XL647 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, XL784 and XL999, in exchange for SEI's investment of \$80.0 million to advance the clinical development of these three compounds. We are responsible for development in accordance with a specified development plan and related development budget. Our development activities are supervised by SEI's development committee, which is comprised of an equal number of representatives from Exelixis and SEI. If the development committee cannot resolve a particular development issue, the issue will be referred to the chief executive officers of Exelixis and SEI. Any disagreements between SEI and us regarding a development decision may cause significant delays in the development and commercialization of XL647 as well as lead to development decisions that do not reflect our interests. In addition, disagreements may impair our attempts to find a partner to develop XL784. Any such delays or development decisions not in our interest could negatively affect the value of XL647 and XL784. In December 2007, we discontinued our development program for XL999 following observation of cardiac adverse events in the clinical program.

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

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

If any of these agreements is not renewed or is terminated early, whether unilaterally or by mutual agreement, or if we are unable to enter into new collaboration agreements on commercially acceptable terms, our revenues and product development efforts could suffer. Our collaboration with GlaxoSmithKline will conclude in October 2008. Our agreements with Bristol-Myers Squibb, Genentech, Daiichi-Sanko and Wyeth Pharmaceuticals contain early termination provisions. In addition, from time to time we review and assess certain aspects of our collaborations, partnerships and agreements and may amend or terminate, either by mutual agreement or pursuant to any applicable early termination provisions, such collaborations, partnerships or agreements if we deem them to be no longer in our economic or strategic interests. We may not be able to enter into new collaboration agreements on similar or superior financial terms to offset the loss of revenue from the termination or expiration of any of our existing arrangements, and the timing of new collaboration agreements may have a material adverse effect on our ability to continue to successfully meet our objectives.

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

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

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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

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

Materials necessary to manufacture some of our compounds currently under development may not be available on commercially reasonable terms, or at all, which may delay our development and commercialization of these compounds.

Some of the materials necessary for the manufacture of our compounds under development may, from time to time, be available either in limited quantities, or from a limited number of manufacturers, or both. Our contract manufacturers need to obtain these materials for our clinical trials and, potentially, for commercial distribution when and if we obtain marketing approval for these compounds. Suppliers may not sell us these materials at the time we need them or on commercially reasonable terms. If we are unable to obtain the materials needed to conduct our clinical trials, product testing and potential regulatory approval could be delayed, adversely affecting our ability to develop the product candidates. Similarly, if we are unable to obtain critical manufacturing materials after regulatory approval has been obtained for a product candidate, the commercial launch of that product candidate could be delayed or there could be a shortage in supply, which could materially affect our ability to generate revenues from that product candidate. If suppliers increase the price of manufacturing materials, the price for one or more of our products may increase, which may make our products less competitive in the marketplace. If it becomes necessary to change suppliers for any of these materials or if any of our suppliers experience a shutdown or disruption at the facilities used to produce these materials, due to technical, regulatory or other reasons, it could harm our ability to manufacture our products.

Risks Related to Regulatory Approval of Our Product Candidates

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

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

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production of such product and may impose ongoing requirements for post-approval studies, including additional research and development and clinical trials. These agencies also may impose various civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval.

Risks Related to Commercialization of Products

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

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

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

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

potential advantages over alternative treatments;

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

relative convenience and ease of administration;

the strength of marketing and distribution support; and

sufficient third-party coverage or reimbursement.

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

We have no experience as a company in the sales, marketing and distribution of pharmaceutical products and do not currently have a sales and marketing organization. Developing a sales and marketing force would be expensive and time-consuming, could delay any product launch, and we may never be able to develop this capacity. To the extent that we enter into arrangements with third parties to provide sales, marketing and distribution services, our product revenues are likely to be lower than if we market and sell any products that we develop ourselves. If we are unable to establish adequate sales, marketing and distribution capabilities, independently or with others, we may not be able to generate product revenues.

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

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

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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.

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

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

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

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

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

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

To date, our product candidates have been manufactured in small quantities for preclinical and clinical trials. If any of these product candidates are approved by the FDA or other regulatory agencies for commercial sale, we will need to 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

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additional validation studies, which the FDA must review and approve. If we are unable to successfully increase the manufacturing capacity for a product candidate, the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in supply. Our product candidates require precise, high-quality manufacturing. The failure to achieve and maintain these high manufacturing standards, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously hurt our business.

Risks Related to Our Intellectual Property

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

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

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

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

Our commercial success depends in part upon our ability to avoid infringing patents and proprietary rights of third parties and not to breach any licenses that we have entered into with regard to our technologies. Other parties have filed, and in the future are likely to file, patent applications covering genes and gene fragments,

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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 t