EXELIXIS INC Form 10-K February 25, 2008 Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)

OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended: December 28, 2007

OR

" TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)

OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission File Number: 0-30235

EXELIXIS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or Other Jurisdiction of

Incorporation or Organization)

04-3257395 (I.R.S. Employer

Identification Number)

170 Harbor Way

P.O. Box 511

South San Francisco, CA 94083

(Address of principal executive offices, including zip code)

(650) 837-7000

(Registrant s telephone number, including area code)

Securities Registered Pursuant to Section 12(b) of the Act:

Title of Each Class Name of Each Exchange on Which Registered Common Stock \$.001 Par Value per Share The Nasdaq Stock Market LLC Securities Registered Pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes x No "

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes "No x

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K."

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

Large accelerated filer x Accelerated filer "Non-accelerated filer (Do not check if a smaller reporting company)" Smaller reporting company

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant s most recently completed second fiscal quarter: \$975,445,421 (Based on the closing sales price of the registrant s common stock on that date. Excludes an aggregate of 16,658,250 shares of the registrant s common stock held by officers, directors and affiliated stockholders. For purposes of determining whether a stockholder was an affiliate of the registrant at June 29, 2007, the registrant assumed that a stockholder was an affiliate of the registrant at June 29, 2007 if such stockholder (i) beneficially owned 10% or more of the registrant s common stock, as determined based on public filings, and/or (ii) was an executive officer or director or was affiliated with an executive officer or director of the registrant at June 29, 2007. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.)

As of February 20, 2008, there were 105,073,846 shares of the registrant s common stock outstanding.

Table of Contents

Edgar Filing: EXELIXIS INC - Form 10-K

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant s definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A, not later than April 27, 2008, in connection with the registrant s 2008 Annual Meeting of Stockholders are incorporated herein by reference into Part III of this Annual Report on Form 10-K.

EXELIXIS, INC.

FORM 10-K

INDEX

		Page	
	<u>PART I</u>		
Item 1.	Business	3	
Item 1A.	Risk Factors	22	
Item 1B.	Unresolved Staff Comments	37	
Item 2.	Properties		
Item 3.	Legal Proceedings	38	
Item 4.	Submission of Matters to a Vote of Security Holders		
	PART II		
Item 5.	Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	39	
Item 6.	Selected Financial Data	41	
Item 7.	Management s Discussion and Analysis of Financial Condition and Results of Operations	42	
Item 7A.	. Quantitative and Qualitative Disclosures About Market Risk		
Item 8.	Financial Statements and Supplementary Data		
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure		
Item 9A.	. Controls and Procedures		
Item 9B.	Other Information		
	<u>PART III</u>		
Item 10.	Directors, Executive Officers and Corporate Governance	99	
Item 11.	Executive Compensation	99	
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	99	
Item 13.	Certain Relationships and Related Transactions, and Director Independence	101	
Item 14.	Principal Accountant Fees and Services	101	
	<u>PART IV</u>		
Item 15.	Exhibits and Financial Statement Schedules	102	
	SIGNATURES	103	

PART I

Management s Discussion and Analysis of Financial Condition and Results of Some of the statements under the captions Risk Factors, Operations and Business and elsewhere in this Annual Report on Form 10-K are 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 company s 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, expect, intend, will, anticipate, plan, may should, would could, estimate, predict, potential, continue, encouraging 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 Item IA. Risk Factors as well as those discussed elsewhere in this Annual Report on Form 10-K. These and many other factors could affect our future financial and operating results. We undertake no obligation to update any forward-looking statement to reflect events after the date of this report.

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

ITEM 1. BUSINESS 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.

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, fund our operations and expand the therapeutic and commercial potential of our pipeline.

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

Compound	Principal Targets	Indication	Stage of Development
XL647*	EGFR, HER2, VEGFR2	Cancer	Phase 2
XL880	MET, VEGFR2	Cancer	Phase 2
XL820	KIT, VEGFR2, PDGFR	Cancer	Phase 2
XL184	MET, VEGFR2, RET	Cancer	Phase 1/2
XL518**	MEK	Cancer	Phase 1
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

^{*}Out-licensed to Symphony Evolution, Inc. and subject to a repurchase option as described elsewhere in this report.

** In co-development collaboration with Genentech, Inc.

In December 2007, GlaxoSmithKline exercised its option pursuant to our product development and commercialization agreement to further develop and commercialize XL880. We expect to transfer the XL880 development program to GlaxoSmithKline in the first quarter of 2008. Pursuant to the product development and commercialization agreement, GlaxoSmithKline has the option to elect to develop up to two additional compounds in our product pipeline, which may include XL820, XL184, XL281, XL844 and XL228.

In addition to the compounds identified in the table above, we have compounds in various stages of development that are being developed by our partners, such as Bristol-Myers Squibb, Daiichi Sankyo Company Limited and Wyeth Pharmaceuticals, a division of Wyeth. We also have compounds in preclinical development that we are developing internally.

Areas of Expertise

Integrated Drug Research, Discovery and Development Capabilities

We have built a multidisciplinary, integrated research and development platform that supports the complex, iterative nature of drug research, discovery and clinical development. Our platform has been designed to include all of the critical functions and expertise required to advance from gene to drug in a consistent and streamlined fashion. Our integrated approach supports advancement of candidate compounds from development candidate status to IND in less than 12 months.

Our organizational structure is designed to create a seamless and flexible research and development process. It is structured to provide one consistent set of goals and objectives to all departments within the research and development organization and to give us the flexibility to allocate and focus our diverse resources to address our most pressing needs. This organizational structure ensures that our earliest discovery activities generate data and information that inform our clinical development strategies, and enables us to apply what we learn about our drug candidates in the clinic to how we discover, assess and select new compounds for future development. We believe that this approach will allow us to align the target inhibition spectrum of a specific compound with the molecular profiles of specific cancer types and patient populations. We also believe that this strengthens our ability to select appropriate patients for clinical trials, which may allow significant efficacy to be demonstrated

Edgar Filing: EXELIXIS INC - Form 10-K

using smaller, shorter trials. Similarly, we use biological approaches to identify disease indications that give us a clear and potentially shorter path to the market, which may allow us to decrease our development times and bring drugs to market sooner.

Additionally, we are leveraging what we learn through preclinical pharmacodynamic studies to identify clinical biomarkers that can be utilized to determine early in the development process if the compound is having the expected effect on the target(s) and pathway(s) of interest and if patients are responding to it. This approach may result in an increased probability that patients receive effective therapies.

Drug Discovery

In addition to establishing an integrated research and development organizational structure, we have built an optimized drug discovery platform. We utilize a variety of high-throughput technologies to enable the rapid discovery, optimization and extensive characterization of lead compounds such that we are able to select development candidates with the best potential for further evaluation and advancement into the clinic. We have combined our ability to identify and validate novel targets with state-of-the-art drug discovery to effectively exploit both the chemical and biological sciences. In addition, we have built critical mass in all key operational areas. We believe that these human and technological resources enable us to: (1) effectively and rapidly qualify novel targets for high-throughput screening; (2) identify and optimize proprietary lead compounds; (3) develop extensive preclinical data to guide selection of patient populations, thereby maximizing the opportunity for obtaining significant clinical benefit; and (4) perform the broad range of preclinical testing required to fuel our pipeline and advance promising compounds through all stages of development. Key capabilities within drug discovery include: high-throughput screening, medicinal and combinatorial chemistry, cell biology, protein biochemistry, structural biology, pharmacology, biotherapeutics and informatics.

Translational Research

Our translational research group is focused on using the knowledge we generate in the discovery process about biological targets and the impact of our compounds on those targets to identify patient populations in which to test our compounds and methods for assessing compound activity. This includes understanding the role of specific targets in disease therapy, identifying gene mutations or gene variants that impact response to therapy and identifying biomarkers that can be used to assess drug responses early on in treatment. Key capabilities within translational research include: nonclinical development (encompassing toxicology, drug metabolism, pharmacokinetics and bioanalytics) and translational medicine.

Development

With the growth of our pipeline, we continue to invest in building our development expertise and resources. Our development group leads the development and implementation of our clinical and regulatory strategies. Working closely with the discovery and translational research groups, the development group prioritizes disease indications in which our compounds may be studied in clinical trials. The development group designs, directs, implements and oversees all areas of clinical operations, including identifying and selecting clinical investigators, recruiting study subjects to participate in our clinical trials, biostatistics, data management, drug safety evaluation, and adverse event reporting. The development group also is responsible for assuring that our development programs are conducted in compliance with all regulatory requirements. The group works closely with the cross functional project and clinical teams to facilitate the appropriate and efficient development of our diverse product pipeline. Key capabilities within development include clinical development, clinical operations, safety monitoring, biostatistics, programming and data management, regulatory strategy and program management.

Our Strategy

Our business strategy is to leverage our biological expertise and integrated drug discovery capabilities to generate a pipeline of diverse development compounds with first-in-class or best-in-class potential that fulfill unmet medical needs in the treatment of cancer and potentially other serious diseases.

Because our continued success and growth as a company depend in part on our ability to advance current and future compounds successfully in clinical development, we have committed substantial resources to build a premier clinical development organization to accommodate our expanding pipeline of compounds. We continue to build critical mass of key internal expertise and capabilities to facilitate conducting multiple clinical trial programs with speed and rigor. Specifically, our business strategy includes the following key elements:

Selectively Develop Therapeutic Products with First-In-Class or Best-In-Class Potential

We have invested and plan to continue to make significant investments in discovering and developing proprietary product candidates, particularly in the area of cancer. We have committed substantial resources to building a first-rate drug discovery effort that is integrated with our unique understanding of the biological basis of a disease. Part of our strategy is to generate a large pipeline of diverse product candidates that provides us with the flexibility to select only those compounds that have both clinical and commercial potential. In developing compounds, our strategy is to pursue a variety of clinically validated, novel and proprietary targets. These decisions are data-driven, based on stringent criteria that incorporate intrinsic potency, selectivity, preclinical efficacy and tolerability and commercial viability. Our strategy is to commit resources only to those compounds that are commercially attractive and have the potential to be first-in-class or best-in-class therapeutics.

Target Multiple Pathways

We have extensive expertise and experience in modifying gene function *in vitro* and *in vivo* as a result of our work on model organisms for the discovery of novel targets and pathways relevant to the development, progression and treatment of cancer and other diseases. We believe that the most effective therapies for cancer will target multiple pathways, simultaneously turn off growth signals, increase rates of programmed cell death and reduce the growth of blood vessels necessary to support tumor growth. Many of our first-generation anticancer product candidates in our clinical pipeline are Spectrum Selective Kinase Inhibitors, or SSKIs, that have been optimized for balanced potency, specificity, tolerability and pharmacologic parameters. These SSKIs are designed to target multiple members of a family of proteins known as receptor tyrosine kinases, or RTKs, in a concerted manner. RTKs are validated targets for drug development, as evidenced by several recent approved cancer therapies. Because interactions among multiple RTKs contribute to the development and progression of disease, SSKIs may provide more effective disease control than compounds that target only one RTK or target multiple non-related RTKs. Additionally, because SSKIs are optimized for key *in vitro* and *in vivo* parameters, these compounds may also provide improved efficacy and enhanced safety profiles compared with combinations of single-target drugs that have not been optimized for use together.

Our second-generation compounds are designed to inhibit kinases that are points of convergence in critical signaling pathways employed by growth factor receptors to transmit their aberrant signals in tumor cells. The targets of several approved therapies transmit their signals through a number of common downstream pathways, such as the RAS/RAF/MEK/ERK, PI3 kinase/AKT/mTOR, and JAK/STAT pathways. These pathways also are often mutationally activated in a wide range of tumors. Thus, inhibition of key kinase targets in these pathways may provide superior efficacy, safety and tolerability compared to conventional chemotherapy and may enable entirely new approaches to cancer therapy.

The majority of our compounds target one or more molecular pathways that control critical aspects of cancer cell growth, migration or survival. These include:

Cell Growth. In most normal adult tissues, cell growth is tightly controlled. However, cancer cells escape normal growth control and are driven to divide very rapidly. In many cases, this growth is driven by excessive activity of cellular growth factors and/or their receptors. This change in activity may result from mutations that allow the receptor to be active even when no growth factor is present or from expression of abnormally high levels of a growth factor or its receptor. This abnormal activity may also allow cancer cells to survive under conditions that would usually lead to cell death, which contributes to resistance to chemotherapy or radiation. Inhibition of growth factors or growth factor receptors is a validated approach to treating cancer, and several approved cancer therapies are designed to inhibit the activity of these proteins. Growth factor receptor, or PDGFR, the epidermal growth factor receptor, or EGFR, the human epidermal growth factor receptor 2, or HER2, the hepatocyte growth factor receptor, or IGF1R. Key kinases in signal transduction pathways downstream of growth factor receptors that promote cell growth include RAF, the MAP-ERK kinase, or MEK, the cytoplasmic tyrosine janus kinase 2, or JAK2, the phosphoinosotide-3 kinase, or PI3K, and the mammalian target of rapamycin, or mTOR.

Cell Survival. Normal cells often activate a self-destruct program known as programmed cell death or apoptosis under abnormal conditions that include the stresses that arise as a result of nutrient, oxygen or energy deprivation, for example. One of the hallmarks of tumor cells is the ability to survive under such conditions, an attribute that results from the inappropriate activation of survival signaling pathways. These pathways often become activated in tumor cells as a result of genetic alterations that result in either loss of the suppressor genes that negatively regulate such pathways or the activation of positive effectors of the pathway. Many growth factor receptors, including EGFR, HER2, MET, KIT, and IGF1R activate survival signaling pathways. Other key kinases in survival pathways include PI3K and mTOR.

Angiogenesis. Angiogenesis, the process by which new blood vessels form, is essential for the growth of tumors beyond a minimum size. In small tumors, cancer cells use existing blood vessels to get oxygen and nutrients needed for growth and to remove waste products. As tumors grow, the existing blood vessels are no longer sufficient to support the rapid pace of cancer cell growth, and continued growth and cancer cell survival requires the formation of new blood vessels. Tumor cells send out chemical signals that stimulate nearby blood vessels to grow into the tumor. In addition to providing essential oxygen and nutrients to the tumor, these new blood vessels also facilitate the migration of tumor cells into the blood system where they can travel to other parts of the body and give rise to metastatic disease. Inhibition of angiogenesis is a validated approach to treating cancer, and angiogenesis inhibitors have been approved by the U.S. Food and Drug Administration, or FDA, for the treatment of several types of cancer. RTKs that play a role in angiogenesis include the vascular endothelial growth factor receptor 2, or VEGFR2 (also known as KDR), PDGFR and MET.

Migration. Cell migration allows tumor cells to invade healthy tissue and spread to disparate parts of the body. A key target that has been shown to play a role in cell migration is MET.

Cell Cycle Regulation. In normal cells, the processes of DNA replication and cell division are tightly controlled. These processes work together to enforce cell cycle checkpoints that prevent cells with damaged DNA from progressing through the cell cycle, allowing time for the damage to be repaired. This system reduces the efficacy of a variety of cancer therapies that exert their effects through DNA damage. Inhibition of cell cycle check point proteins may increase the activity of a variety of DNA damaging agents, including radiation and some chemotherapies, and may increase the activity of these agents without increasing systemic toxicity. Cell cycle check point targets include the serine/threonine protein kinases CHK1 and CHK2.

Leverage Strategic Collaborations

We are committed to retaining a significant interest in the value of our pipeline and product candidates. Our strategy is to leverage the strength of our extensive data and the broad potential of our development compounds to establish strategic alliances that create near-term revenue, while reducing our risk of product failure and retaining long-term rights to those compounds that succeed. We have established and intend to continue pursuing commercial relationships and key partnerships with major pharmaceutical and biotechnology companies based on the strength of our biological expertise and drug discovery and development capabilities. Our collaborations to date have provided us with substantial committed funding for our research and development efforts, the potential to earn significant milestones as well as opportunities to receive significant future payments, if our collaborators successfully develop and market products that result from our collaborative work. In addition, many of our strategic relationships provide us with or permit us to obtain co-development, co-promotion or other rights to products identified or developed in such collaborative relationships as a result of our efforts.

Management of Our Financial Resources

Fiscal discipline and pragmatic allocation of our resources are key components of our corporate strategy. We believe that making significant investments in preclinical development enhances our ability to generate multiple new, high-quality INDs and to rapidly advance these new drug candidates through clinical development. We believe the return on this investment will come in the form of higher clinical success rates, funding and partnership terms that allow us to retain increasing equity in the long-term value of our pipeline. We believe that this approach will enhance the quality and growth of our pipeline while maintaining our ability to fulfill obligations to corporate partners. We seek to finance our activities through a blend of funding opportunities, including: executing under our existing partnerships, which potentially triggers substantial milestones; exploring opportunities for new partnerships for our unpartnered assets, which have the potential to bring in near-term cash and defray late-stage development costs; evaluating the suitability of third-party financing vehicles with the aim to off-load a significant portion of our near-term clinical development expense and clinical risks; and opportunistically accessing the capital markets.

Our Pipeline

We have an extensive pipeline of compounds in various stages of development that will potentially treat cancer and various metabolic and cardiovascular disorders. All of our development compounds were generated through our internal drug discovery efforts.

Cancer Program

Our cancer program currently includes the following 11 compounds in clinical development.

XL647 is a potent and balanced inhibitor of EGFR, HER2 and VEGFR2, RTKs that are implicated in driving tumor growth and vascularization (blood vessel formation). The compound has been optimized for high potency and oral bioavailability, demonstrates excellent activity in target-specific cellular functional assays and has shown sustained inhibition of target RTKs *in vivo* following a single oral dose in preclinical studies. We have completed an initial phase 1 clinical trial of XL647, and the phase 2 clinical program in patients with non-small cell lung cancer is ongoing. Preliminary data from a phase 1 trial evaluating intermittent dosing of XL647 were presented in November 2005 at the 17th EORTC-NCI-AACR International Conference on Molecular Targets and Cancer Therapeutics, or the EORTC Symposium, and at the American Society of Clinical Oncology, or ASCO, annual meeting in June 2006. Updated data were presented in November 2006 at the 18th EORTC Symposium. Data from a second phase 1 trial evaluating daily dosing of XL647 were presented in October 2007 at the 19th EORTC Symposium. A phase 2 trial of XL647 in patients with advanced non-small cell lung cancer

who have not previously been treated with chemotherapy was initiated in August 2006. Preliminary data from this trial were reported at the conference of the International Association for the Study of Lung Cancer in September 2007 and at the 19th EORTC Symposium in October 2007. A second phase 2 trial of XL647 in patients with advanced non-small cell lung cancer who have previously benefited from and then progressed on prior treatment with an EGFR inhibitor (erlotinib or gefitinib) was initiated in July 2007.

XL880 is a potent inhibitor of MET and VEGFR2, which play synergistic roles in promoting tumor growth and angiogenesis. Activation or overexpression of MET has been documented as a negative prognostic indicator in patients with various carcinomas and in patients with multiple myeloma, glioma and other solid tumors. Interim data from an ongoing phase 1 trial of XL880 were presented at the 2005 EORTC Symposium and at the 2006 ASCO Annual Meeting. Updated data were reported at the 2006 EORTC Symposium. Data from two phase 1 trials were reported at the 2007 ASCO Annual Meeting. A phase 2 clinical trial of XL880 was initiated in patients with hereditary or sporadic papillary renal cell carcinoma in June 2006, and data from this trial were reported at the 2007 EORTC Symposium. Another phase 2 trial was initiated in patients with metastatic, poorly differentiated diffuse gastric cancer in December 2006. Additionally, a phase 2 trial was initiated in head and neck cancer patients in August 2007. As described under Corporate Collaborations GlaxoSmithKline, in December 2007, GlaxoSmithKline exercised its option to further develop and commercialize XL880. We expect to transfer the XL880 development program to GlaxoSmithKline in the first quarter of 2008.

XL820 inhibits KIT as well as VEGFR2 and PDGFR, clinically validated targets implicated in a variety of human cancers. In preclinical tumor models of breast carcinoma, glioma and leukemia, the compound exhibited dose-dependent growth inhibition and has been shown to cause tumor regression. XL820 demonstrated potent activity in target-specific cellular functional assays. In biochemical and cellular assays, XL820 inhibits mutant forms of KIT that confer resistance to approved KIT inhibitors. XL820 has good oral bioavailability and has shown sustained inhibition of target RTKs *in vivo* following a single oral dose in preclinical studies. A phase 1 clinical trial of XL820 was initiated in July 2005 in patients with solid tumors for whom there are no other available therapies known to prolong survival. Preliminary data from this trial were reported by investigators at the 2006 and 2007 EORTC Symposia. A phase 2 trial was initiated in December 2007 in patients with gastrointestinal stromal tumors.

XL184 inhibits MET, RET and VEGFR2, key drivers of tumor growth and vascularization. The compelling preclinical efficacy of XL880, our first MET/VEGFR2 inhibitor, increased our interest in inhibitors of these RTKs and resulted in the discovery and development of XL184 as a distinct compound with potent activity. This SSKI has demonstrated dose-dependent tumor growth inhibition and tumor regression in a variety of tumor models, including thyroid, breast, colon, non-small cell lung cancer and glioblastoma. A phase 1 clinical trial in patients with solid tumors for whom there are no other available therapies was initiated in September 2005. Preliminary data from this study were reported by investigators at the 2006 and 2007 EORTC Symposia. A phase 1/2 trial was initiated in January 2008 in patients with non-small cell lung cancer who have failed prior therapy with erlotinib, and a phase 2 trial is planned in patients with advanced glioblastoma.

XL518 is a novel small molecule drug designed to inhibit the activity of MEK, a key component of the RAS/RAF/MEK/ERK signaling pathway. This pathway is frequently activated in human tumors and is required for transmission of growth-promoting signals from numerous receptor tyrosine kinases. Preclinical studies have demonstrated that XL518 is a potent and specific inhibitor of MEK with highly optimized pharmacokinetic and pharmacodynamic properties. XL518 exhibits oral bioavailability in multiple species and causes substantial and durable inhibition of ERK phosphorylation in xenograft tumor models. Administration of XL518 causes tumor regression in multiple xenograft models with mutationally-activated B-RAF or RAS. We filed an IND for XL518 in December 2006 and initiated a phase 1 clinical trial in May 2007. In December 2006, we entered into a worldwide co-development agreement with Genentech for the development and commercialization of XL518, as described under Corporate Collaborations Genentech.

XL281 specifically targets RAF, which is a cytoplasmic serine/threonine kinase that lies immediately downstream of RAS, and is a key component of the RAS/RAF/MEK/ERK pathway that is frequently activated in human tumors. Activating mutations in B-RAF occur in approximately 60% of melanoma patients, indicating a potentially pivotal role for deregulation of this kinase in the progression of melanoma. XL281 is a potent and highly selective inhibitor of RAF kinases, is orally bioavailable and exhibits substantial efficacy in tumor xenograft models. A phase 1 trial was initiated in April 2007.

XL019 is a selective inhibitor of the cytoplasmic tyrosine kinase JAK2. JAK2 is activated by cytokine and growth factor receptors and phosphorylates members of the STAT family of inducible transcription factors. Activation of the JAK/STAT pathway promotes cell growth and survival, and is a common feature of human tumors. JAK2 is activated by mutation in the majority of patients with polycythemia vera and essential thrombocythemia and appears to drive the inappropriate growth of blood cells in these conditions. XL019 is a potent and selective inhibitor of JAK2, with excellent pharmacodynamic properties and an encouraging safety profile in preclinical models. A phase 1 trial was initiated in patients with myelofibrosis in August 2007, and data from this study were reported at the annual meeting of the American Society of Hematology in December 2007.

XL844 potently inhibits the checkpoint kinases CHK1 and CHK2, which induce cell cycle arrest in response to a variety of DNA damaging agents. Activation of these checkpoints following DNA damage allows for DNA repair and protects tumor cells from the cytotoxic effects of chemo- and radio-therapy. XL844 abrogates these cell cycle blocks and enhances tumor cell killing by a wide variety of chemotherapeutic agents and radiation *in vitro*. XL844 displays good pharmacokinetic properties and oral bioavailability, and increases the efficacy of chemotherapeutic agents without increasing systemic toxicity in preclinical tumor models. A phase 1 trial of XL844 in patients with chronic lymphocytic leukemia was initiated in September 2005, and was closed in 2007. A phase 1 trial evaluating XL844 in combination with gemcitabine was initiated in May 2007.

XL228 potently inhibits the T315I mutant form of ABL, which is resistant to inhibition by other targeted therapies approved for chronic myelogenous leukemia. In addition, XL228 targets IGF1R, an RTK that is highly expressed and activated in a broad range of human tumors and is thought to promote tumor growth, survival and resistance to chemotherapeutic agents. XL228 exhibited efficacy in a variety of solid tumor xenograft models. We filed an IND for XL228 in August 2006. We subsequently observed formulation stability data resulting in the need for minor changes in formulation. We then initiated a phase 1 clinical trial in May of 2007 in patients with chronic myelogenous leukemia who have failed or have been intolerant to irmatinib and dasatinib therapy, and a phase 1 trial in patients with solid tumors in October 2007. Preliminary data from the trial in patients with chronic myelogenous leukemia were reported at the annual meeting of the American Society of Hematology in 2007.

XL147 selectively targets PI3K. Upregulation of PI3K activity is one of the most common characteristics of human tumor cells and can result from activation of growth factor receptors, amplification of the PI3K gene, activating mutations in the PI3K gene, downregulation of the phosphatase and tensin homolog, or PTEN, lipid phosphatase or activating mutations in RAS. Activation of PI3K results in stimulation of AKT and mTOR kinases resulting in promotion of tumor cell growth and survival. This survival signal plays a significant role in conferring resistance to chemo- and radio-therapy by inhibiting apoptotic cell death. XL147 is a potent and selective inhibitor of PI3K with excellent pharmacokinetic and pharmacodynamic properties and compelling efficacy in several preclinical xenograft models both as a single agent and in combination with chemotherapy. We filed an IND for XL147 in March 2007 and initiated a phase 1 trial in June 2007. Preliminary data from this trial were reported at the 19th EORTC Symposium in October 2007.

XL765 targets both PI3K and mTOR, key kinases in the PI3K signaling pathway. mTOR is a serine/threonine kinase that controls the protein translation machinery and hence cell growth. mTOR is activated by growth factors via PI3K and AKT, but is also activated in a PI3K independent fashion in

response to nutrient and energy levels. Thus, in some tumors targeting both PI3K and mTOR may provide additional benefit compared to selectively targeting PI3K. XL765 is a potent inhibitor of PI3K and mTOR with excellent pharmacokinetic and pharmacodynamic properties, and compelling efficacy in several preclinical xenograft models both as a single agent and in combination with chemotherapy. We filed an IND for XL765 in April 2007 and initiated a phase 1 trial in June 2007. Preliminary data from this trial were reported at the 19th EORTC Symposium in October 2007.

We currently have various compounds in preclinical development, including the following two compounds in late-stage preclinical development:

XL139 inhibits activation of Hedgehog, or HH, signaling by binding to smoothened, a key component of the signaling pathway. Genetic lesions that activate the HH pathway are key drivers of basal cell carcinoma and medulloblastoma formation in humans. In addition, activation of the HH signaling pathway via the action of the ligands SHh, IHh or DHh promotes cellular growth, and elevated ligand production and HH pathway activation is observed in a variety of human tumors including pancreatic carcinomas, small-cell lung cancer and glioblastomas. Signaling via the HH pathway is also thought to promote survival of cancer stem cells, which constitute a particularly chemo- and radio-resistant component of tumors. In preclinical models, XL139 potently inhibits HH signaling in tumors and significantly slows tumor growth. XL139 was advanced to development compound status in July 2007. As described under Corporate Collaborations Bristol-Myers Squibb 2007 Cancer Collaboration, in January 2008, Bristol-Myers Squibb exercised its option to develop and commercialize XL139, and we exercised our option to co-develop and co-commercialize XL139.

XL888 is a novel, synthetic inhibitor of HSP90, a chaperone protein that promotes the activity and stability of a range of key regulatory proteins including kinases. The activity of HSP90 is particularly prominent in tumor cells, where it promotes the activity of proteins controlling growth and survival. Natural product based inhibitors of HSP90 are currently in clinical trials and have shown encouraging signs of efficacy, but their utility is limited by poor pharmacokinetic properties and by their side effect profile. XL888 inhibits HSP90 with comparable potency to natural product-based inhibitors, but has good oral bioavailability and an improved tolerability profile in preclinical models. In multiple preclinical xenograft tumor models, XL888 exhibits substantial anti-tumor activity at well tolerated doses. XL888 was advanced to development compound status in October 2007, and we anticipate filing an IND in the second half of 2008.

We are committed to having preclinical and clinical data from our compounds presented at periodic peer review meetings.

Metabolic Program

We currently have various compounds in development that target metabolic and cardiovascular diseases. Our programs in metabolic and cardiovascular diseases originated from our acquisition of X-Ceptor Therapeutics, Inc. in October 2004. Our clinical stage compounds include:

XL652 targets the liver X receptors, or LXR, which modulate genes involved in regulation of lipid and cholesterol homeostasis. Activation of LXRα or LXRβ in foam cells in atherosclerotic plaques promotes reverse cholesterol transport and results in marked anti-atherogenic activity in multiple preclinical models of atherosclerosis. However, prototype LXR agonists also activate LXRα in the liver resulting in increased fatty acid synthesis and consequent elevations in hepatic and circulating triglyceride levels, an unacceptable side effect. XL652 is a novel LXR agonist that effectively reduces atherosclerotic plaques in preclinical models at doses that do not result in triglyceride elevations. XL652 was developed under a collaboration with Bristol-Myers Squibb, which filed the foreign equivalent of an IND for XL652 in November 2007. For more information on our LXR collaboration, see Corporate Collaborations Bristol-Myers Squibb LXR Collaboration.

XL335 targets the Farnesoid X Receptor, or FXR, which has been shown to function as a bile acid receptor regulating genes involved in lipid, cholesterol and bile acid homeostasis. We have identified proprietary, potent and selective FXR ligands (compounds that bind to a receptor) that have good oral bioavailability and drug metabolism and pharmacokinetic properties. In rodent models of dyslipidemia, these compounds lowered triglycerides by decreasing triglyceride synthesis and secretion. In addition, they improved the high-density lipoprotein (HDL)/low-density lipoprotein (LDL) ratio and are anti-atherogenic (prevent the formation of lipid deposits in the arteries) in animal models of atherosclerosis. XL335 is also effective in models of cholestasis (a condition in which bile excretion from the liver is blocked), cholesterol gallstones and liver fibrosis. These data suggest that small molecule ligands targeting FXR should function as novel therapeutic agents for treating symptoms and disease states associated with metabolic syndrome as well as certain liver disorders. In December 2005, we licensed the FXR program to Wyeth Pharmaceuticals. Wyeth Pharmaceuticals is responsible for all further preclinical and clinical development, regulatory, manufacturing and commercialization activities for the compounds. For information regarding on our collaboration with Wyeth Pharmaceuticals, see Corporate Collaborations Other Collaborations Wyeth Pharmaceuticals.

XL550 is a potent, selective, non-steroidal mineralocorticoid receptor, or MR, antagonist that is effective in animal models of hypertension and congestive heart failure. XL550 has shown excellent oral bioavailability and drug metabolism and pharmacokinetic properties in multiple preclinical models and has exhibited a significantly better pharmacokinetic and pharmacodynamic profile than existing steroid drugs. In multiple studies in various non-clinical species, XL550 shows potent anti-hypertensive action and anti-hypertrophic action on the heart, lung and kidney. In addition, XL550 shows 50-100 times greater potency vs. eplerenone in various in vivo studies related to hypertension and congestive heart failure in preclinical models. As a novel proprietary non-steroidal MR antagonist, XL550 has the potential to offer highly effective and safe therapeutic approaches for the treatment of hypertension and congestive heart failure. XL550 was licensed to Daiichi-Sankyo for development and commercialization in March 2006. See Corporate Collaborations Other Collaborations Daiichi-Sankyo.

Corporate Collaborations

We have established collaborations with major pharmaceutical and biotechnology companies based on the strength of our technologies and biological expertise to support additional development of our proprietary products. Through these collaborations, we obtain license fees, research funding, and the opportunity to receive milestone payments and royalties from research results and subsequent product development activities. Many of our collaborations have been structured strategically to provide us with access to technology that may help to advance our internal programs while at the same time enabling us to retain rights to use these technologies in different industries.

GlaxoSmithKline

In October 2002, we established a collaboration with GlaxoSmithKline to discover and develop novel therapeutics in the areas of vascular biology, inflammatory disease and oncology. The collaboration involved three agreements: (1) a Product Development and Commercialization Agreement, or PDA; (2) a Stock Purchase and Stock Issuance Agreement, or SPA; and (3) a Loan and Security Agreement, or LSA. Under the original PDA, GlaxoSmithKline paid us \$30.0 million in an upfront fee and agreed to pay up to an additional \$90.0 million in research and development funding over the first six years of the collaboration.

In January 2005, we amended the terms of the PDA, SPA and LSA. Under the amended PDA, GlaxoSmithKline selected a modified program election through which the focus of the collaboration was shifted to 12 internal programs at various stages of development (XL784, XL647, XL999, XL880, XL184, XL820, XL844, XL281, XL418, XL228 and two earlier stage oncology programs). Each program centers on compounds

that are directed against one or more targets identified in the collaboration. GlaxoSmithKline has the option to elect to develop up to three of our compounds from the programs specified in the product development and commercialization agreement. In December 2007, GlaxoSmithKline exercised its development option for XL880. GlaxoSmithKline declined to exercise its development option for XL647 in July 2007 and its development option for XL784 in January 2008. In addition, in December 2007, we discontinued the development programs for XL999 and XL418. As a result of GlaxoSmithKline s exercise of its development option for XL880, GlaxoSmithKline has the right to select from the programs up to one additional compound, or two additional compounds if it extends the specified development term. The amount of acceptance milestones that we receive from GlaxoSmithKline will depend on the number of compounds selected, the timing of the selection of the compounds and, for those acceptances made after the end of the original development term, whether GlaxoSmithKline extended the development term. 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. GlaxoSmithKline retains exclusivity rights to the 32 specified targets that are encompassed by the 12 programs through the end of the specified development term, or any extension thereof by GlaxoSmithKline. After the end of the development. We have retained rights to all compounds not encompassed by the 12 programs that are part of the collaboration with GlaxoSmithKline and may work on any targets with the exception of the 32 targets or, if applicable, a subset, subject to GlaxoSmithKline s exclusivity rights.

In May 2005, we filed the third of three INDs required by the amended PDA to achieve a \$30.0 million milestone, which we received from GlaxoSmithKline in May 2005. In May 2005, we also submitted two new development candidates to GlaxoSmithKline, thereby triggering an additional \$5.0 million milestone, which we received in May 2005. We may also receive additional development related milestones and royalties on product sales and may have certain co-promotion rights to products in North America. In addition, under the amended PDA, GlaxoSmithKline agreed to provide research funding of \$47.5 million over the remaining three-year term of the collaboration, all of which we received by the end of 2007. In connection with GlaxoSmithKline is exercise of its development option for XL880, we earned a selection milestone of \$35.0 million, all of which was retained by GlaxoSmithKline to offset the \$30.0 million milestone that GlaxoSmithKline paid to us in 2005 under the amended PDA. To date, we have received \$65.0 million in upfront and milestone payments, \$85.0 million in research and development funding and loans in the principal amount of \$85.0 million.

The terms of the amended PDA and LSA allow us to use third-party financing vehicles to fund the further clinical development of our compounds XL647, XL784 and XL999, but any such compounds developed through clinical financing vehicles continued to be subject to GlaxoSmithKline s compound selection rights. In June 2005, we entered into a transaction to fund the clinical development of XL647, XL784 and XL999 through Symphony Evolution, Inc., which is described under Corporate Collaborations Symphony Evolution. GlaxoSmithKline has declined to exercise its compound selection right with respect to XL647 and XL784, and we have discontinued development of XL999.

Pursuant to the terms of the original SPA, the amended SPA and as a result of its modified program election, GlaxoSmithKline purchased a total of three million shares of our common stock. We have no further option to sell, and GlaxoSmithKline has no further obligation to purchase, additional shares of our common stock.

Bristol-Myers Squibb

2001 Cancer Collaboration. In July 2001, we entered into a cancer collaboration agreement with Bristol-Myers Squibb. Under the terms of the collaboration, Bristol-Myers Squibb paid us a \$5.0 million upfront license fee and agreed to provide us with \$3.0 million per year in research funding for a minimum of three years. In December 2003, the cancer collaboration was extended until January 2007, at which time Bristol-Myers Squibb elected to continue the collaboration until July 2009. The goal of the extension was to increase the total number

and degree of validation of cancer targets that we will deliver to Bristol-Myers Squibb. Each company will maintain the option to obtain exclusive worldwide rights to equal numbers of validated targets arising from the collaboration. Under the terms of the extended collaboration, Bristol-Myers Squibb provided us with an upfront payment and agreed to provide increased annual research funding and milestones on certain cancer targets arising from the collaboration that progress through specified stages of validation. We will also be entitled to receive milestones on compounds in the event of successful clinical and regulatory events and royalties on commercialized products.

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

Under the collaboration agreement, Bristol-Myers Squibb paid us a nonrefundable upfront payment in the amount of \$17.5 million and was obligated to provide research and development funding of \$10.0 million per year for an initial research period of two years. On September 20, 2007, the collaboration was extended at Bristol-Myers Squibb s request through January 12, 2009. Bristol-Myers Squibb also has retained the option to further extend the collaboration by an additional year.

Under the collaboration 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 sales of any products commercialized under the collaboration. In connection with the extension of the collaboration through January 2009, Bristol-Myers Squibb is obligated to pay to us additional research funding of \$7.5 million. Bristol-Myers Squibb has the option to terminate the collaboration agreement at any time after January 2008, in which case Bristol-Myers Squibb s payment obligations would cease, its license relating to compounds that modulate LXR would terminate and revert to us, and we would receive, subject to certain terms and conditions, licenses from Bristol-Myers Squibb to research, develop and commercialize certain collaboration compounds that were discovered under the collaboration agreement. In December 2007, we received \$5.0 million for achieving a development milestone.

2007 Cancer Collaboration. In December 2006, we entered into a worldwide collaboration with Bristol-Myers Squibb, which became effective in January 2007, to discover, develop and commercialize novel targeted therapies for the treatment of cancer. We are responsible for discovery and preclinical development of small molecule drug candidates directed against mutually selected targets. In January 2007, Bristol-Myers Squibb made an upfront payment of \$60.0 million to us for which we granted Bristol-Myers Squibb the right to select up to three IND candidates from six future Exelixis compounds.

For each IND candidate selected, we are entitled to receive a \$20.0 million selection milestone from Bristol-Myers Squibb. Once selected, Bristol-Myers Squibb will lead the further development and commercialization of the selected IND candidates. In addition, we have the right to opt in to co-promote the selected IND candidates, in which case we will equally share all development costs and profits in the United States. If we opt-in, we will be responsible for 35% of all development costs related to clinical trials intended to support regulatory approval in both the United States and the rest of the world, with the remaining 65% to be paid by Bristol-Meyers Squibb. This percentage ratio was intended to approximate a 50/50 split of development and commercialization costs in the United States. If we do not opt in to co-promote the selected IND candidates, we would be entitled to receive

milestones and royalties in lieu of profits from sales in the United States. Outside of the United States, Bristol-Myers Squibb will have primary responsibility for development activities and we will be entitled to receive royalties on product sales. After exercising its co-development option, Bristol-Myers Squibb may, upon notice to us, terminate the agreement as to any product containing or comprising the selected candidate. In the event of such termination election, Bristol-Myers Squibb s license relating to such product would terminate and revert to us, and we would receive, subject to certain terms and conditions, licenses from Bristol-Myers Squibb to research, develop and commercialize certain collaboration compounds that were discovered.

In January 2008, Bristol-Myers Squibb exercised its option under the collaboration to develop and commercialize XL139. Under the terms of the collaboration agreement, the selection of XL139 by Bristol-Myers Squibb entitles us to a milestone payment of \$20.0 million, which we received in February 2008. In addition, we exercised our option under the collaboration agreement to co-develop and co-commercialize XL139 in the United States. Following the transfer of the XL139 development program, which is expected to occur in the first quarter of 2008, Bristol-Myers Squibb will lead all global activities. The parties will co-develop and co-commercialize XL139 and equally share all development costs and profits in the United States. We will be entitled to receive double-digit royalties on product sales outside of the United States.

Genentech

Cancer Collaboration. In May 2005, we established a collaboration agreement with Genentech to discover and develop therapeutics for the treatment of cancer, inflammatory diseases, and tissue growth and repair. Under the terms of the collaboration agreement, we granted to Genentech a license to certain intellectual property. Genentech paid us a nonrefundable upfront license payment and is obligated to provide research and development funding over the three-year research term, totaling \$16.0 million.

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

MEK Collaboration. In December 2006, we entered into a worldwide co-development agreement with Genentech for the development and commercialization of XL518, a small-molecule inhibitor of MEK. Genentech paid upfront and milestone payments of \$25.0 million in December 2006 and \$15.0 million in January 2007 upon signing of the co-development agreement and with the submission of an IND for XL518. We initiated a phase 1 clinical trial of XL518 in the first quarter of 2007, and enrollment in this trial is ongoing.

Under the terms of the co-development agreement, we are responsible for developing XL518 through the end of a phase 1 clinical trial, and Genentech has the option to co-develop XL518, which Genentech may exercise after receipt of certain phase 1 data from us. If Genentech exercises its option to co-develop XL518, we will be entitled to receive an opt-in payment and we will be required to grant to Genentech an exclusive worldwide revenue-bearing license to XL518. Genentech will be responsible for all further development costs of XL518 and we will share equally in the U.S. commercialization costs. On an annual basis, we are entitled to an initial equal share of U.S. profits and losses, which will decrease as sales increase, and we are also entitled to royalties on non-U.S. sales. Genentech has the right to terminate the agreement without cause at any time. If Genentech terminates the co-development agreement without cause, all licenses that were granted to Genentech under the agreement terminate and revert to us. Additionally, we would receive, subject to certain conditions, licenses from Genentech to research, develop and commercialize reverted product candidates.

Symphony Evolution

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

Pursuant to the agreements, we received an exclusive purchase option that gives us the right to acquire all of the equity of SEI, thereby allowing us to reacquire XL647, XL784 and XL999. Under our amended purchase option agreement with SEI, we cannot repurchase a single product candidate without also repurchasing the other two product candidates. The Phase 2 clinical development program for XL647 is ongoing, and GlaxoSmithKline has declined to exercise its development option for XL647. In order to retain rights to XL647 after the expiration of the purchase option period, we would be required to reacquire XL647, XL784 and XL999 from SEI s investors through the exercise of our purchase option. In December 2007, we discontinued the development of 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 amended purchase option allows us, at our sole election, to pay up to 100% of the purchase option exercise price in shares of our common stock. The purchase option is exercisable 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 at an exercise price equal to the sum of: (1) the total amount of capital invested in SEI by Holdings; and (2) an amount equal to 25% per year on such funded capital (with respect to the initial funded capital, compounded from June 9, 2005 and, with respect to the second draw amount, compounded from June 9, 2006).

Pursuant to the agreements, we issued to Holdings two five-year warrants to purchase 1.5 million shares of our common stock at \$8.90 per share. In addition, should the purchase option expire unexercised until the earlier of June 9, 2009, or the 90th day after SEI provides us with financial statements showing cash and cash equivalents of less than \$5.0 million, we are obligated to issue to Holdings an additional five-year warrant to purchase 500,000 shares of our common stock at a price per share equal to 125% of the market price of our common stock at the time of expiration of the purchase option.

Other Collaborations

Wyeth Pharmaceuticals. In December 2005, we entered into a license agreement with Wyeth Pharmaceuticals related to compounds targeting FXR, a nuclear hormone receptor implicated in a variety of metabolic and liver disorders. Under the terms of the agreement, we granted to Wyeth Pharmaceuticals an exclusive, worldwide license with respect to certain intellectual property primarily relating to compounds that modulate FXR. Wyeth Pharmaceuticals paid us a nonrefundable upfront payment in the amount of \$10.0 million and we received \$4.5 million in November 2006 for achieving a development milestone. In November 2007, Wyeth Pharmaceuticals paid us \$2.5 million for achieving a second development milestone. Wyeth Pharmaceuticals is obligated to pay additional development and commercialization milestones of up to \$140.5 million as well as royalties on sales of any products commercialized by Wyeth Pharmaceuticals under the agreement. Wyeth Pharmaceuticals will be responsible for all further preclinical and clinical development,

regulatory, manufacturing and commercialization activities for the compounds. Subject to certain terms and conditions, Wyeth Pharmaceuticals has the option to terminate the license agreement.

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

Daiichi-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. In June 2007, the parties agreed to extend the research term for an additional six months. In November 2007, the parties decided not to further extend the research term. For each product from the collaboration, we are also entitled to receive payments upon attainment of pre-specified development, regulatory and commercialization milestones. In addition, we are also entitled to receive royalties on any sales of certain products commercialized under the collaboration. Daiichi-Sankyo may terminate the agreement upon 90 days written notice in which case Daiichi-Sankyo s payment obligations would cease, its license relating to compounds that modulate MR would terminate and revert to us, and we would receive, subject to certain terms and conditions, licenses from Daiichi-Sankyo to research, develop and commercialize compounds that were discovered under the collaboration.

Manufacturing and Raw Materials

We currently do not have manufacturing capabilities necessary to enable us to produce materials for our clinical trials. Raw materials and supplies required for the production of our product candidates are generally available from multiple suppliers. However, in some instances materials are available only from one supplier. In those cases where raw materials are only available through one supplier, we manage supplies, to the extent feasible, by ordering raw materials well in advance of scheduled needs. However, clinical trial schedules may be delayed due to interruptions of raw material supplies.

Government Regulation

The following section contains some general background information regarding the regulatory environment and processes affecting our industry and is designed to illustrate in general terms the nature of our business and the potential impact of government regulations on our business. It is not intended to be comprehensive or complete. Depending on specific circumstances, the information below may or may not apply to us or any of our product candidates. In addition, the information is not necessarily a description of activities that we have undertaken in the past or will undertake in the future. The regulatory context in which we operate is complex and constantly changing.

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our products.

The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

preclinical laboratory and animal tests;

submission of an IND, which must become effective before clinical trials may begin;

adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug candidate for its intended use;

pre-approval inspection of manufacturing facilities and selected clinical investigators; and

FDA approval of a new drug application (NDA), or NDA supplement, for an approval of a new indication if the product is already approved for another indication.

The testing and approval process requires substantial time, effort and financial resources.

Prior to commencing the first clinical trial with a product candidate, we must submit an IND to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Our submission of an IND may not result in FDA authorization to commence a clinical trial. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development, and the FDA must grant permission for each clinical trial to start and continue. Further, an independent institutional review board for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center. Regulatory authorities or an institutional review board or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

For purposes of NDA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

Phase 1 Studies are initially conducted in a limited patient population to test the product candidate for safety, dosage tolerance, absorption, metabolism, distribution and excretion in healthy humans or patients.

Phase 2 Studies are conducted with groups of patients afflicted with a specified disease in order to provide enough data to evaluate the preliminary efficacy, optimal dosages and expanded evidence of safety. Multiple phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive phase 3 clinical trials. In some cases, a sponsor may decide to run what is referred to as a phase 2b evaluation, which is a second, confirmatory phase 2 trial that could, if positive, serve as a pivotal trial in the approval of a product candidate.

Phase 3 When phase 2 evaluations demonstrate that a dosage range of the product is effective and has an acceptable safety profile, phase 3 trials are undertaken in large patient populations to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety in an expanded patient population at multiple clinical trial sites.

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called phase 4 studies may be made a condition to be satisfied after a drug receives approval. The results of phase 4 studies can confirm the effectiveness of a product candidate and can provide important safety information to augment the FDA s voluntary adverse drug reaction reporting system. The results of product development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA, or as part of an NDA supplement. The FDA may deny approval of an NDA or NDA supplement if the applicable regulatory criteria are not satisfied, or it may require additional clinical data and/or an additional pivotal phase 3 clinical trial. Even if such data are submitted, the FDA may ultimately decide that the NDA or NDA supplement does not satisfy the criteria for approval. Once issued, the FDA may withdraw product approval if ongoing regulatory standards are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

Edgar Filing: EXELIXIS INC - Form 10-K

Satisfaction of FDA requirements or similar requirements of state, local and foreign regulatory agencies typically takes several years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease. Government regulation may delay or prevent marketing of product candidates or new diseases for a considerable period of time and impose costly procedures upon our activities. The FDA or any other regulatory agency may not grant approvals for new indications for our product candidates on a timely basis, if at all. Success in early stage clinical trials does not ensure success in later stage clinical trials. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Even if a product candidate receives regulatory approval, the approval may be significantly limited to specific disease states, patient populations and dosages. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

Any products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the drug. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. We cannot be certain that we or our present or future suppliers will be able to comply with the good manufacturing practices regulations and other FDA regulatory requirements. If our present or future suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, require us to recall a drug from distribution, or withdraw approval of the NDA for that drug.

The FDA closely regulates the marketing and promotion of drugs. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available drugs for uses that are not described in the product s labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer s communications on the subject of off-label use.

The FDA s policies may change and additional government regulations may be enacted which could prevent or delay regulatory approval of our product candidates or approval of new diseases for our product candidates. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

Competition

There are many companies focused on the development of small molecules and antibodies for diseases including cancer and metabolic and cardiovascular disorders. Our potential competitors include major pharmaceutical and biotechnology companies. Many of our potential competitors have significantly more financial, technical and other resources than we do, which may allow them to have a competitive advantage. Any products that we may develop or discover are likely to be in highly competitive markets. Many of our competitors may succeed in developing products that may render our products and those of our collaborators obsolete or noncompetitive.

We believe that our ability to successfully compete will depend on, among other things:

efficacy, safety and reliability of our product candidates;

timing and scope of regulatory approval;

the speed at which we develop product candidates;

our ability to complete preclinical testing and clinical development and obtaining regulatory approvals for product candidates;

our ability to manufacture and sell commercial quantities of a product to the market;

obtaining reimbursement for product use in approved indications;

product acceptance by physicians and other health care providers;

quality and breadth of our technology;

skills of our employees and our ability to recruit and retain skilled employees;

protection of our intellectual property; and

availability of substantial capital resources to fund development and commercialization activities. Research and Development Expenses

Research and development expenses consist primarily of personnel expenses, laboratory supplies, consulting and facilities costs. Research and development expenses were \$225.4 million for the year ended December 31, 2007, compared to \$185.5 million for 2006 and \$141.1 million for 2005.

Revenues from Significant Collaborators

In 2007, we derived 35%, 24%, 16% and 10% of our revenues from Bristol-Myers Squibb, GlaxoSmithKline, Genentech and Daiichi-Sankyo, respectively.

Proprietary Rights

We have obtained licenses from various parties that give us rights to technologies that we deem to be necessary or desirable for our research and development. These licenses (both exclusive and non-exclusive) may require us to pay royalties as well as upfront and milestone payments.

Patents extend for varying periods according to the date of patent filing or grant and the legal term of patents in the various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country.

While trade secret protection is an essential element of our business and we have taken security measures to protect our proprietary information and trade secrets, we cannot give assurance that our unpatented proprietary technology will afford us significant commercial protection. We seek to protect our trade secrets by entering into confidentiality agreements with third parties, employees and consultants. Our employees and consultants are also required to sign agreements obligating them to assign to us their interests in intellectual property arising from their work for us. All employees sign an agreement not to engage in any conflicting employment or activity during their employment with us and not to disclose or misuse our confidential information. However, it is possible that these agreements may be breached or invalidated, and if so, there may not be an adequate corrective remedy available. Accordingly, we cannot ensure that employees, consultants or third parties will not breach the confidentiality provisions in our contracts, infringe or misappropriate our trade secrets and other proprietary rights or that measures we are

Edgar Filing: EXELIXIS INC - Form 10-K

taking to protect our proprietary rights will be adequate.

In the future, third parties may file claims asserting that our technologies or products infringe on their intellectual property. We cannot predict whether third parties will assert such claims against us or against the

licensors of technology licensed to us, or whether those claims will harm our business. If we are forced to defend ourselves against such claims, whether they are with or without merit and whether they are resolved in favor of, or against, our licensors or us, we may face costly litigation and the diversion of management s attention and resources. As a result of such disputes, we may have to develop costly non-infringing technology or enter into licensing agreements. These agreements, if necessary, may be unavailable on terms acceptable to us, or at all.

Employees

As of December 31, 2007, we had 735 full-time employees worldwide, 241 of whom hold Ph.D. and/or M.D. degrees, most of whom were engaged in full-time research and development activities. We plan to hire additional staff and to expand our internal development efforts. Our success will depend upon our ability to attract and retain qualified employees. We face competition in this regard from other companies in the biotechnology, pharmaceutical and high technology industries, as well as research and academic institutions. None of our employees are represented by a labor union, and we consider our employee relations to be good.

Available Information

We were incorporated in Delaware in November 1994 as Exelixis Pharmaceuticals, Inc., and we changed our name to Exelixis, Inc. in February 2000.

We maintain a site on the worldwide web at www.exelixis.com; however, information found on our website is not incorporated by reference into this report. We make available free of charge on or through our website our SEC filings, including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Further, copies of our filings with the SEC are available at the SEC s Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains a site on the worldwide web that contains reports, proxy and information statements and other information regarding our filings at www.sec.gov.

ITEM 1A. RISK FACTORS

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

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 December 31, 2007, we had \$299.5 million in cash and cash equivalents and short-term and long-term marketable securities, which included investments held by SEI of \$30.9 million and restricted cash and investments of \$7.2 million. We anticipate that our current cash and cash equivalents, short-term and long-term marketable securities, investments held by SEI and other funding that we expect to receive from collaborators, which assumes a moderate level of business development activity, will enable us to maintain our operations for a period of at least 12 months following the filing date of this report. However, our future capital requirements will be substantial and will depend on many factors that may require us to 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. In order to retain rights to XL647 after the expiration of the purchase option period, we would be required to reacquire XL647, XL784 and XL999 from SEI s investors through the exercise of our exclusive purchase option, which is described elsewhere in this report. We cannot 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 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 price for the compounds licensed to SEI increases over time;

whether and when GlaxoSmithKline selects at clinical proof-of-concept for further development and commercialization any additional product candidates Under the amended PDA, any milestone payments relating to product candidates remaining under the PDA must be used to pay down our loan with GlaxoSmithKline as long as the loan is outstanding. The amount of milestone payments that we receive from GlaxoSmithKline will depend on the number of compounds selected, the timing of the selection of the compounds and, for those acceptances made after the end of the original development

term, whether GlaxoSmithKline extended the development term. As of December 31, 2007, the aggregate principal and interest outstanding under our GlaxoSmithKline loan was \$98.6 million. In December 2007, GlaxoSmithKline exercised its option to further develop and commercialize XL880. As XL880 was the first compound selected by GlaxoSmithKline under the PDA, 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 PDA and was not used to pay down the loan. An additional \$1.0 million from the first commercialization milestone for any product candidate selected by GlaxoSmithKline will also be offset against the 2005 milestone;

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

future clinical trial results;

our need to expand our product and clinical development efforts;

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

the cost and timing of regulatory approvals;

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

the effect of competing technological and market developments;

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

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

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

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

Edgar Filing: EXELIXIS INC - Form 10-K

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 LSA, which, as amended, contains financial covenants pursuant to which our working capital (the amount by which our current assets exceed our current liabilities as defined by the agreement) must not be less than \$25.0 million and our cash and investments (total cash, cash equivalents and investments as defined by the agreement, which excludes restricted cash) must not be less than \$50.0 million. As of December 31, 2007, our working capital was \$150.9 million and our cash and investments were \$292.3 million. If we were to default on the financial covenants under the LSA, GlaxoSmithKline may, among other

remedies, declare immediately due and payable all obligations under the LSA. Outstanding borrowings and accrued interest under the loan and security agreement totaled \$98.6 million at December 31, 2007.

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 \$86.4 million for the year ended December 31, 2007. As of that date, we had an accumulated deficit of \$791.7 million. Our losses for the year ended December 31, 2007 were partially offset by nonrecurring gains on the sale of our plant trait business and the sale of 80.1 % of our ownership interest in our German subsidiary, Artemis Pharmaceuticals, GmbH, or Artemis. We also expect the losses attributed to our noncontrolling interest will decline in 2008, which will increase our net losses as compared to 2007. 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 Artemis, our only revenues to date are license revenues and revenues under contracts with our partners. In December 2007, we sold 80.1% of our ownership interest in Artemis, and will not recognize revenue associated with Artemis in future periods. The amount of our net losses will depend, in part, on the rate of growth, if any, in our license and contract revenues and on the level of our expenses. These losses have had and will continue to have an adverse effect on our stockholders equity and working capital. Our research and development expenditures and general and administrative expenses have exceeded our revenues to date, and we expect to spend significant additional amounts to fund research and development in order to enhance our technologies and undertake product development. We currently have numerous product candidates in various stages of clinical development and we anticipate filing additional IND applications for additional product candidates within the next 12 months. As a result, we expect 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, 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.

Risks Related to Development of Product Candidates

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

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

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

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

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

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

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

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

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

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

Edgar Filing: EXELIXIS INC - Form 10-K

the number of patients that ultimately participate in the clinical trial;

the duration of patient follow-up that is appropriate in view of the results;

the number of clinical sites included in the trials; and

the length of time required to enroll suitable patient subjects.

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

Risks Related to Our Relationships with Third Parties

Disagreements between SEI and us regarding the development of our product candidates XL647 and XL784 may 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 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 is scheduled to expire in October 2008 but became subject to earlier termination at the discretion of GlaxoSmithKline starting in 2005. Our agreements with Bristol-Myers Squibb, Genentech, Daiichi-Sanko and Wyeth Pharmaceuticals 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.

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 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 production of such product and 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. In addition, even if third-party payors provide some coverage or reimbursement for our products, the availability of such coverage or reimbursement for prescription drugs under private health insurance and managed care plans often varies based on the type of contract or plan purchased.

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

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

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

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

The biotechnology industry is highly fragmented and is characterized by rapid technological change. In particular, the area of kinase-targeted therapies is a rapidly evolving and competitive field. We face, and will continue to face, intense competition from biotechnology and pharmaceutical companies, as well as academic research institutions, clinical reference laboratories and government agencies that are pursuing research activities similar to ours. Some of our competitors have entered into collaborations with leading companies within our target markets, including some of our existing collaborators. In addition, significant delays in the development of our product candidates could allow our competitors to bring products to market before us, which would impair our ability to commercialize our product candidates. Our future success will depend upon our ability to maintain a competitive position with respect to technological advances. Any products that are developed through our

technologies will compete in highly competitive markets. Further, our competitors may be more effective at using their technologies to develop commercial products. Many of the organizations competing with us have greater capital resources, larger research and development staff and facilities, more experience in obtaining regulatory approvals and more extensive product manufacturing and marketing capabilities. As a result, our competitors may be able to more easily develop technologies and products that would render our technologies and products, and those of our collaborators, obsolete and noncompetitive. In addition, there may be product candidates of which we are not aware at an earlier stage of development that may compete with our product candidates.

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

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

Risks Related to Our Intellectual Property

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

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

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties (for example, the patent owner has failed to work the invention in that country or the third party has patented improvements). In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. Compulsory licensing of life-saving drugs is also becoming increasingly popular in developing countries either through direct legislation or international initiatives. Such compulsory licenses could be extended to include some of our product candidates, which could limit our potential revenue opportunities. Moreover, the

legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patent and other intellectual property protection, which makes it difficult to stop infringement. We rely on trade secret protection for our confidential and proprietary information. We have taken security measures to protect our proprietary information and trade secrets, but these measures may not provide adequate protection. While we seek to protect our proprietary information by entering into confidentiality agreements with employees, collaborators and consultants, we cannot assure you that our proprietary information will not be disclosed, or that we can meaningfully protect our trade secrets. In addition, our competitors may independently develop substantially equivalent proprietary information or may otherwise gain access to our trade secrets.

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

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

Third parties may accuse us of employing their proprietary technology without authorization. In addition, third parties may obtain patents that relate to our technologies and claim that use of such technologies infringes on their patents. Regardless of their merit, such claims could require us to incur substantial costs, including the diversion of management and technical personnel, in defending ourselves against any such claims or enforcing our patents. In the event that a successful claim of infringement is brought against us, we may be required to pay damages and obtain one or more licenses from third parties. We may not be able to obtain these licenses at a reasonable cost, or at all. Defense of any lawsuit or failure to obtain any of these licenses could adversely affect our ability to develop and commercialize products.

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

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

Risks Related to Employees, Growth and Location

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

We are highly dependent upon the principal members of our management and scientific staff, the loss of whose services might adversely impact the achievement of our objectives and the continuation of existing collaborations. Also, we do not currently have sufficient clinical development personnel to fully execute our business plan. Recruiting and retaining qualified clinical and scientific personnel will be critical to support

activities related to advancing our clinical and preclinical development programs, and supporting our collaborative arrangements and our internal proprietary research and development efforts. Competition is intense for experienced clinical personnel, and we may be unable to retain or recruit clinical personnel with the expertise or experience necessary to allow us to pursue collaborations, develop our products and core technologies or expand our operations to the extent otherwise possible. Further, all of our employees are employed at will and, therefore, may leave our employment at any time.

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

We work with scientific and clinical advisors and collaborators at academic and other institutions that assist us in our research and development efforts. These advisors and collaborators are not our employees and may have other commitments that limit their availability to us. Although these advisors and collaborators generally agree not to do competing work, if a conflict of interest between their work for us and their work for another entity arises, we may lose their services. In such a circumstance, we may lose work performed by them, and our development efforts with respect to the matters on which they were working maybe significantly delayed or otherwise adversely affected. In addition, although our advisors and collaborators sign agreements not to disclose our confidential information, it is possible that valuable proprietary knowledge may become publicly known through them.

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

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

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

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

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

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

respect to our proprietary and confidential information, including research or clinical data, or that results in damage to our research and development equipment and assets could have a material adverse impact on our business, operating results and financial condition.

Risks Related to Environmental and Product Liability

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

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

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 product sapproved for marketing. On occasion, juries have awarded large judgments in class action lawsuits for claims based on drugs that had unanticipated side effects. In addition, the pharmaceutical and biotechnology industries, in general, have been subject to significant medical malpractice litigation. A successful product liability claim or series of claims brought against us could harm our reputation and business and would decrease our cash reserves.

Risks Related to Our Common Stock

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

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

recognition of upfront licensing or other fees;

payments of non-refundable upfront or licensing fees to third parties;

acceptance of our technologies and platforms;

the success rate of our discovery efforts leading to milestone payments and royalties;

the introduction of new technologies or products by our competitors;

the timing and willingness of collaborators to commercialize our products;

our ability to enter into new collaborative relationships;

the termination or non-renewal of existing collaborations;

the timing and amount of expenses incurred for clinical development and manufacturing of our product candidates;

the impairment of acquired goodwill and other assets; and

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

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

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;

Edgar Filing: EXELIXIS INC - Form 10-K

the announcement of new products by us or our competitors;

quarterly variations in our or our competitors results of operations;

conflicts or litigation with our collaborators;

litigation, including intellectual property infringement and product liability lawsuits, involving us;

failure to achieve operating results projected by securities analysts;

changes in earnings estimates or recommendations by securities analysts;

financing transactions;

developments in the biotechnology or pharmaceutical industry;

sales of large blocks of our common stock or sales of our common stock by our executive officers, directors and significant stockholders;

departures of key personnel or board members;

developments concerning current or future collaborations;

FDA or international regulatory actions;

third-party reimbursement policies;

acquisitions of other companies or technologies;

disposition of any of our subsidiaries, technologies or compounds; and

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

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

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

Edgar Filing: EXELIXIS INC - Form 10-K

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 1B. UNRESOLVED STAFF COMMENTS Not applicable.

ITEM 2. PROPERTIES

We currently lease an aggregate of 347,212 square feet of office and laboratory facilities. In California, we currently lease 329,352 square feet in our South San Francisco and San Diego locations. The South San Francisco location, which currently is comprised of five buildings totaling 296,027 square feet, is covered by three lease agreements. The first two leases covering three buildings for a total of 179,964 square feet expire

Table of Contents

Edgar Filing: EXELIXIS INC - Form 10-K

in 2017, with two five-year options to extend their respective terms prior to expiration. The third lease covering two buildings for a total of 116,063 square feet expires in 2018. In addition, we entered into a fourth lease agreement

related to our South San Francisco location to lease an additional 66,000 square feet that is estimated to commence in May 2008 and expires in 2015. Under the terms of this lease, we have the right to rent all of the remaining 62,393 rentable square feet of the building. This expansion right expires on December 31, 2008. If we exercise our right to lease the entire building, we will have the option to extend the lease for an additional ten years. In our San Diego location, we lease 33,325 square feet under a month-to-month lease, with a nine-month termination notice.

In Portland, Oregon, we lease 17,860 square feet of office and laboratory space. The lease expires in February 2009 but we may terminate it earlier effective March 2008. In addition, we lease a 15-acre farm in Woodburn, Oregon. Greenhouse capacity at the farm currently totals 50,000 square feet. We previously owned the farm but sold it to Agrigentics, Inc., a wholly-owned subsidiary of The Dow Chemical Company, in September 2007. We are leasing the farm in connection with a contract research agreement between us and Agrigentics, and the lease expires upon termination or expiration of the contract research agreement.

In Guilford, Connecticut, we lease 3,000 square feet of office space. The lease commenced in January 2008 and it expires in April 2009.

We believe that our leased facilities have sufficient space to accommodate our current needs and also provide for the expansion of our operations for the near term.

ITEM 3. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings. We may from time to time become a party to various legal proceedings arising in the ordinary course of business.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS None.

PART II

ITEM 5. MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock has traded on the Nasdaq Global Select Market (formerly the Nasdaq National Market) under the symbol EXEL since April 11, 2000. The following table sets forth, for the periods indicated, the high and low intraday sales prices for our common stock as reported by the Nasdaq Global Select Market:

	Commo Pri	
	High	Low
Quarter ended December 31, 2007	\$ 12.29	\$ 7.82
Quarter ended September 30, 2007	\$ 12.37	\$ 9.40
Quarter ended June 30, 2007	\$ 12.77	\$ 9.92
Quarter ended March 31, 2007	\$ 11.74	\$ 8.67
Quarter ended December 31, 2006	\$ 10.65	\$ 7.81
Quarter ended September 30, 2006	\$ 10.24	\$ 7.53
Quarter ended June 30, 2006	\$ 12.49	\$ 9.00
Quarter ended March 31, 2006	\$ 12.21	\$ 9.22

On February 20, 2008, the last reported sale price on the Nasdaq Global Select Market for our common stock was \$6.26 per share.

Holders

As of February 20, 2008, there were approximately 638 stockholders of record of our common stock.

Dividends

Since inception, we have not paid dividends on our common stock. We currently intend to retain all future earnings, if any, for use in our business and currently do not plan to pay any cash dividends in the foreseeable future. Any future determination to pay dividends will be at the discretion of our Board of Directors.

Performance Graph

This performance graph shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities under that Section and shall not be deemed to be incorporated by reference into any filing of the company under the Securities Act of 1933, as amended.

The following graph compares, for the five year period ended December 31, 2007, the cumulative total stockholder return for our common stock, the Nasdaq Stock Market (U.S. companies) Index, or the Nasdaq Market Index, and the Nasdaq Biotech Index. The graph assumes that \$100 was invested on December 31, 2002 in each of the common stock of the company, the Nasdaq Market Index and the Nasdaq Biotech Index and the Nasdaq Biotech Index and the Nasdaq Biotech Index and the Stock price performance on the following graph is not necessarily indicative of future stock price performance.

	12/31/02	03/31/03	06/30/03	09/30/03	12/31/03	03/31/04	06/30/04
Exelixis, Inc.	100	83	86	89	88	107	126
Nasdaq Market Index	100	100	122	134	150	149	153
Nasdaq Biotech Index	100	103	135	145	146	157	153
	09/30/04	12/31/04	03/31/05	06/30/05	09/30/05	12/31/05	03/31/06
Exelixis, Inc.	101	119	85	93	96	118	150
Nasdaq Market Index	142	163	150	154	161	165	175
Nasdaq Biotech Index	144	155	131	139	158	159	169
	06/30/06	09/30/06	12/31/06	03/31/07	06/30/07	09/30/07	12/31/07
Exelixis, Inc.	126	109	113	124	151	132	108
Nasdaq Market Index	163	169	181	181	195	202	199
Nasdaq Biotech Index	150	152	161	156	162	172	168

ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial information has been derived from our audited consolidated financial statements. The financial information as of December 31, 2007 and 2006 and for each of the three years in the period ended December 31, 2007 are derived from audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. The following Selected Financial Data should be read in conjunction with Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations and Item 8. Financial Statements and Supplementary Data included elsewhere in this Annual Report on Form 10-K. The historical results are not necessarily indicative of the results of operations to be expected in the future.

	2007	2006	Ended Decembe 2005 ds, except per sl	2004	2003
Consolidated Statement of Operations Data:					
Total revenues	\$ 113,470	\$ 98,670	\$ 75,961	\$ 52,857	\$ 51,540
Operating expenses:					
Research and development(1)	225,375	185,481	141,135	137,724	127,622
General and administrative(2)	44,940	39,123	27,731	20,905	18,586
Amortization of intangible assets	202	820	1,086	779	666
Restructuring charge				2,275	925
Acquired in-process research and development				26,376	
Total operating expenses	270,517	225,424	169,952	188,059	147,799
Loss from operations	(157,047)	(126,754)	(93,991)	(135,202)	(96,259)
Total other income (expense)(3)	46,025	3,565	(819)	(2,043)	1,140
Loss from continuing operations before income taxes and					
noncontrolling interest in Symphony Evolution, Inc.	(111,022)	(123,189)	(94,810)	(137,245)	(95,119)
Benefit from income taxes					345
Loss from continuing operations before noncontrolling interest in					
Symphony Evolution, Inc.	(111,022)	(123,189)	(94,810)	(137,245)	(94,774)
Loss attributed to noncontrolling interest in Symphony Evolution,			())		())
Inc.	24,641	21,697	10,406		
Net loss	\$ (86,381)	\$ (101,492)	\$ (84,404)	\$ (137,245)	\$ (94,774)
Net loss per share, basic and diluted	\$ (0.87)	\$ (1.17)	\$ (1.07)	\$ (1.89)	\$ (1.45)
Shares used in computing basic and diluted net loss per share	99,147	86,602	78,810	72,504	65,387

(1) Amounts for 2007 and 2006 include \$11.6 million and \$11.2 million in employee stock-based compensation, respectively, under Statement of Financial Accounting Standards No. 123 (revised 2004), Shared-Based Payment (SFAS 123R).

(2) Amounts for 2007 and 2006 include \$7.3 million and \$6.3 million in employee stock-based compensation, respectively, under SFAS 123R.

(3) In September 2007, we sold our plant trait business and, as a result, we recognized a gain of \$18.8 million in other income. In November 2007, we sold 80.1% of our German subsidiary, Artemis Pharmaceuticals GmbH, and, as a result, we recognized a gain of \$18.1 million in other income.

			December 31,		
	2007	2006	2005	2004	2003
			(In thousands)		
Consolidated Balance Sheet Data:					

Table of Contents

Edgar Filing: EXELIXIS INC - Form 10-K

Cash and cash equivalents, marketable securities, investments held					
by Symphony Evolution, Inc. and restricted cash and investments	\$ 299,530	\$ 263,180	\$ 210,499	\$ 171,223	\$ 241,930
Working capital	150,898	150,814	86,463	89,597	179,595
Total assets	412,120	395,417	332,712	291,340	357,794
Long-term obligations, less current portion	130,671	128,565	121,333	144,491	102,411
Accumulated deficit	(791,650)	(705,269)	(603,777)	(519,373)	(382,128)
Total stockholders equity	72,081	52,540	33,543	50,671	161,482

ITEM 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS 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.

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, fund our operations and expand the therapeutic and commercial potential of our pipeline.

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

Compound	Principal Targets	Indication	Stage of Development
XL647*	EGFR, HER2, VEGFR2	Cancer	Phase 2
XL880	MET, VEGFR2	Cancer	Phase 2
XL820	KIT, VEGFR2, PDGFR	Cancer	Phase 2
XL184	MET, VEGFR2, RET	Cancer	Phase 1/2
XL518**	MEK	Cancer	Phase 1
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

Out-licensed to Symphony Evolution, Inc. and subject to a repurchase option as described elsewhere in this report.

** In co-development collaboration with Genentech, Inc.

In December 2007, GlaxoSmithKline exercised its option pursuant to our product development and commercialization agreement to further develop and commercialize XL880. We expect to transfer the XL880 development program to GlaxoSmithKline in the first quarter of 2008. Pursuant to the product development and commercialization agreement, GlaxoSmithKline has the option to elect to develop up to two additional compounds in our product pipeline, which may include XL820, XL184, XL281, XL844 and XL228.

In addition to the compounds identified in the table above, we have compounds in various stages of development that are being developed by our partners, such as Bristol-Myers Squibb, Daiichi Sankyo Company Limited and Wyeth Pharmaceuticals, a division of Wyeth. We also have compounds in preclinical development that we are developing internally.

2007 Dispositions

In 2007, we completed the disposition of certain of our non-core assets, as described more fully below.

Sale of Plant Trait Business

On September 4, 2007, we entered into an asset purchase and license agreement, or APA, with Agrigenetics, Inc., a wholly-owned subsidiary of The Dow Chemical Company, or Agrigenetics. Under the terms of the APA, we sold to Agrigenetics a major portion of our assets used for crop trait discovery, including a facility, and granted to Agrigenetics licenses to certain other related assets and intellectual property. As consideration for these assets and licenses, Agrigenetics paid us \$18.0 million and is obligated to pay an additional \$4.5 million upon the first anniversary of the closing date for the transaction. Under the APA, we have agreed to indemnify Agrigenetics and its affiliates up to a specified amount if they incur damages due to any infringement or alleged infringement of certain patents.

Concurrently with the execution of the APA, we also entered into a contract research agreement, or the CRA, with Agrigenetics. Agrigenetics has agreed to pay us up to \$24.7 million in research and development funding over the term of the CRA. The research funding will cover employee costs, facilities expenses and capital expenditures. After September 4, 2007, the closing date for the transaction, the research and development funding to be received over the term of the CRA will be recognized as a reduction to expenses incurred by us in connection with our performance under the CRA. In order for us to perform our obligations under the CRA, we are leasing at no cost the facility that Agrigenetics acquired under the APA. We are also entitled to receive additional payments of up to \$13.5 million from Agrigenetics if we achieve the development of up to three designated assets during the term of the CRA. If development of any of the three designated assets is completed, the related payment will be treated as additional proceeds from the sale of our plant trait business.

The term of the CRA is five years, unless earlier terminated. Agrigenetics may terminate the CRA if we fail to complete the development of any of the three designated assets within our respective specified research periods or if we fail to cure a material breach within specified time periods. Following our development and transfer to Agrigenetics of the second designated asset, either party may terminate the CRA upon expiration of a specified notice period. In the event that the CRA is terminated prior to the end of the term, we will receive less than the maximum amount of research and development funding described above.

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

Sale of Interest in Artemis Pharmaceuticals GmbH

On November 20, 2007, we entered into a share sale and transfer agreement with Taconic Farms, Inc., or Taconic, pursuant to which Taconic acquired from us, for \$19.8 million in cash, 80.1% of the outstanding share capital in our wholly-owned subsidiary, Artemis Pharmaceuticals GmbH, or Artemis, located in Cologne, Germany. Artemis activities are directed toward providing transgenic mouse generation services, tools and related licenses to the industrial and academic community.

We also entered into a shareholders agreement and approved amended articles of association of Artemis that govern the relationship between us and Taconic as shareholders of Artemis, particularly with respect to matters of corporate governance and the transfer of our respective ownership interests. The shareholders agreement provides that we may require Taconic to purchase our remaining 19.9% interest in Artemis between 2010 and 2015 or in the event of a change in control of Taconic, and that Taconic may require us to sell our 19.9% interest to Taconic between 2013 and 2015 or in the event of a change in control of Exelixis, in each case subject to certain conditions set forth in the shareholders agreement. The amended articles of association provide for the establishment of a shareholders committee, in which we participate based on our 19.9% ownership, to assist in the management of Artemis.

The sale of 80.1% of Artemis was accounted for as a sale of a business. We recognized a gain of \$18.1 million, net of \$1.6 million in transaction costs. The gain primarily consists of cash received of \$19.8 million, plus \$2.5 million relating to the elimination of the cumulative foreign currency translation adjustment and the elimination of net liabilities, less \$0.3 million of intangible assets (acquired patents) and derecognition of \$2.3 million of goodwill. As we believe we have significant influence over the operations of Artemis through our rights under the shareholders agreement and the amended articles, we will account for our remaining 19.9% equity interest in Artemis under the equity method of accounting. We will subsequently adjust our investment balance to recognize our share of future Artemis earnings or losses after the November 20, 2007 closing date. As of December 31, 2007, the carrying value of our investment in Artemis was approximately \$30,000.

Artemis revenues and net income (loss) after the effect of all intercompany eliminations are as follows (in thousands):

	Fo	For the Year Ended			
		December 31			
	2007(1)	2006	2005		
Revenues	\$ 11,234	\$ 7,920	\$ 5,773		
Net income (loss)	\$ 1,210	\$ (1,036)	\$ (619)		

(1) The revenues and net income for the year ended December 31, 2007 only include revenues through November 20, 2007, the closing date for the transaction.

Certain Factors That May Affect Our Business

Industry-wide Factors

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

Company-specific Factors

Our financial performance is driven by many factors, including:

Clinical Trials. We currently have multiple compounds in clinical development and expect to continue to advance more compounds into clinical trials. Our compounds may fail to show adequate safety or

efficacy in clinical testing. Furthermore, predicting the timing of the initiation or completion of clinical trials is exceedingly difficult and our trials may be delayed due to many factors, including factors outside of our control. The future development path of each of our compounds depends upon the results of each stage of clinical development. 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 December 31, 2007, we had \$299.5 million in cash and cash equivalents and short-term and long-term marketable securities, which included investments held by SEI of \$30.9 million and restricted cash and investments of \$7.2 million. We anticipate that our current cash and cash equivalents, short-term and long-term marketable securities, investments held by SEI and other funding that we expect to receive from collaborators, which assumes a moderate level of business development activity, will enable us to maintain our operations for a period of at least 12 months following the filing date of this report. However, our future capital requirements will be substantial and depend on many factors, including the timing of key events in our agreements with GlaxoSmithKline and SEI that may require us to use available capital significantly earlier than we currently anticipate. We will have to obtain additional funding in order to support our plans for the aggressive development of our broad clinical and preclinical pipelines. Our minimum liquidity needs are also determined by certain financial covenants contained in our loan and security agreement with GlaxoSmithKline, which require us to maintain working capital of at least \$25.0 million and cash and investments of at least \$50.0 million. Our ability to raise additional funds may be severely impaired if any of our product candidates fails to show adequate safety or efficacy in clinical testing.

Reliance on Partners. We currently have no pharmaceutical products that have received marketing approval, and we have generated no revenues from the sale of such products. We do not expect to generate product revenues from the sale of pharmaceutical products in the near term and expect that all of our near term revenues, such as research and development funding and milestone and royalty revenues, will be generated from 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 to elect to develop up to three of our compounds from the programs specified in the product development and commercialization agreement. In December 2007, GlaxoSmithKline exercised its development option for XL880. As a result of GlaxoSmithKline s exercise of this option, GlaxoSmithKline has the right to select from the identified programs up to one additional compound, which may include XL820, XL184, XL281, XL844 or XL228, or up to two additional compounds if it extends the specified development term. The amount of acceptance milestones that we receive from GlaxoSmithKline will depend on the number of compounds selected, the timing of the selection of the compounds and, for those acceptances made after the end of the original development term, whether GlaxoSmithKline extended the development term. Any future delays in obtaining clinical proof-of-concept for compounds subject to GlaxoSmithKline s election rights may decrease the size of any GlaxoSmithKline milestone payments and negatively affect our financial position. If GlaxoSmithKline selects a second compound prior to the end of the development term under the product development and commercialization agreement in October 2008, the amount of the selection milestone for the second compound would be at least \$55.0 million. Under our product development and commercialization agreement, any milestone payments relating to product candidates remaining under the agreement must be used to pay down our loan with GlaxoSmithKline as long as the loan is outstanding. See Liquidity and Capital Resources Cash Requirements.

Symphony Evolution, Inc. In 2005, we licensed three of our compounds, XL647, XL784 and XL999, to SEI in return for an \$80.0 million investment for the clinical development of these compounds. We have an exclusive purchase option to acquire all of the equity of SEI, thereby allowing us to reacquire

XL647, XL784 and XL999 at our sole discretion. We cannot repurchase a single product candidate without also repurchasing the other two product candidates. The purchase 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 price for the compounds licensed to SEI increases over time. The phase 2 clinical development program for XL647 is ongoing, and GlaxoSmithKline has declined to exercise its development option for XL647. In order to retain rights to XL647 after the expiration of the purchase option period, we would be required to reacquire XL647, XL784 and XL999 from SEI s investors through the exercise of our exclusive purchase option. In December 2007, we discontinued the development of 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. In order to repurchase the compounds, we would need to raise additional funds to cover the purchase price or issue to SEI s investors a substantial number of shares of our common stock.

Critical Accounting Estimates

Our consolidated financial statements and related notes are prepared in accordance with U.S. generally accepted accounting principles, or GAAP, which requires us to make judgments, estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses and related disclosure of contingent assets and liabilities. We have based our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for 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. We believe the following critical accounting policies reflect the more significant estimates and assumptions used in the preparation of our consolidated financial statements:

Revenue Recognition

Most of our revenues are generated from the terms of our research and licensing arrangements. These research and licensing arrangements may include up-front non-refundable payments. Although these up-front payments are generally non-refundable, under GAAP we defer the revenues under these arrangements and recognize the revenues on a straight-line basis over our expected period of continuing involvement, generally the research term specified in the agreements. Our research and license arrangements may also include milestone payments. Although these milestone payments are generally non-refundable once the milestone is achieved, we recognize the milestone revenues on a straight-line basis over the research term of the arrangement. This typically results in a portion of the milestone being recognized on the date the milestone is achieved, with the balance being recognized over the remaining research term of the agreement. It is our understanding that there is diversity in practice on the recognition of milestone revenue. Other companies have adopted an alternative acceptable milestone revenue recognition policy whereby the full milestone fee is recognized upon completion of the milestone. If we had adopted such a policy, our revenues recorded to date would have increased and our deferred revenues would have decreased by a material amount compared to total revenue recognized. In certain

situations, we may receive milestone payments after the end of our period of continued involvement. In such circumstances, we would recognize 100% of the milestone revenue when the milestone is achieved.

Some of our research and licensing arrangements have multiple deliverables in order to meet our customer 's needs. For example, the arrangements may include a combination of up-front fees, license payments, research and development services, milestone payments and future royalties. Multiple element revenue agreements are evaluated under Emerging Issues Task Force No. 00-21, Revenue Arrangements with Multiple Deliverables, or EITF 00-21, to determine whether the delivered item has value to the customer on a stand-alone basis and whether objective and reliable evidence of the fair value of the undelivered item exists. Deliverables in an arrangement that do not meet the separation criteria in EITF 00-21 are treated as one unit of accounting for purposes of revenue recognition. Generally, the revenue recognition guidance applicable to the final deliverable is followed for the combined unit of accounting. For certain arrangements, the period of time over which certain deliverables will be provided is not contractually defined. Accordingly, management is required to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. For example, we recognized revenue of approximately \$27.9 million in 2007 related to arrangements for which the period of time over which the research and development will be performed was not contractually defined. For this arrangement, if the research and development were delayed, the amount of revenue recognized in future periods could be reduced. To date, there has not been a change in an estimate or assumption that had a material impact on our revenue recognition.

Goodwill and Intangible Impairment

As of December 31, 2007, our consolidated balance sheet included \$63.7 million of goodwill and other intangible assets. Under GAAP, we evaluate goodwill for impairment on an annual basis and on an interim basis if events or changes in circumstances between annual impairment tests indicate that the asset might be impaired. We will also evaluate other intangible assets for impairment when impairment indicators are identified.

The impairment tests for goodwill are performed at the reporting unit level and require us to perform a two-step impairment test. Our reporting units have been determined to be consistent with our operating segments. In the first step, we compare the fair value of our reporting units to their respective carrying values. If the fair value of the reporting unit exceeds the carrying value of the net assets assigned to that unit, goodwill is not impaired and we are not required to perform further testing. If the carrying value of the net assets assigned to the reporting unit exceeds the fair value of the reporting unit, we perform the second step of the impairment test in order to determine the implied fair value of the reporting unit s goodwill. If the carrying value of a reporting unit s goodwill exceeds its fair value, then we record an impairment loss equal to the difference.

Clinical Trial Accruals

Substantial portions of our preclinical studies and all of our clinical trials have been performed by third-party contract research organizations, or CROs, and other vendors. We accrue expenses for preclinical studies performed by our vendors based on certain estimates over the term of the service period and adjust our estimates as required. We accrue costs for clinical trial activities performed by CROs based upon the estimated amount of work completed on each study. For clinical trial expenses, the significant factors used in estimating accruals include the number of patients enrolled, the number of active clinical sites, and the duration for which the patients will be enrolled in the study. We monitor patient enrollment levels and related activities to the extent possible through internal reviews, correspondence with CROs and review of contractual terms. We base our estimates on the best information available at the time. However, additional information may become available to us which will allow us to make a more accurate estimate in future periods. In this event, we may be required to record adjustments to research and development expenses in future periods when the actual level of activity becomes more certain, such increases or decreases in cost are generally considered to be changes in estimates and will be reflected in research and development expenses in the period first known. For example, during the quarter

ended December 31, 2007, we recorded a reduction of \$2.6 million to our accrued clinical trial liabilities and research and development expenses related to our phase 2 clinical trial for XL784.

Stock Option Valuation

Effective January 1, 2006, we adopted the fair value recognition provisions of Statement of Financial Accounting Standards No. 123 (revised 2004), Shared-Based Payment (SFAS 123R). Under this standard, our estimate of compensation expense requires us to determine the appropriate fair value model and a number of complex and subjective assumptions including our stock price volatility, employee exercise patterns, future forfeitures and related tax effects. The most significant assumptions are our estimates of the expected volatility and the expected term of the award. We have limited historical information available to support the underlying estimates of certain assumptions required to value stock options. The value of a stock option is derived from its potential for appreciation. The more volatile the stock, the more valuable the option becomes because of the greater possibility of significant changes in stock price. Because there is a market for options on our common stock, we have considered implied volatilities as well as our historical realized volatilities when developing an estimate of expected volatility. The expected option term also has a significant effect on the value of the option. The longer the term, the more time the option holder has to allow the stock price to increase without a cash investment and thus, the more valuable the option. Further, lengthier option terms provide more opportunity to exploit market highs. However, empirical data shows that employees, for a variety of reasons, typically do not wait until the end of the contractual term of a nontransferable option to exercise. Accordingly, companies are required to estimate the expected term of the option for input to an option-pricing model. As required under the accounting rules, we review our valuation assumptions at each grant date and, as a result, from time to time we will likely change the valuation assumptions we use to value stock based awards granted in future periods. The assumptions used in calculating the fair value of share-based payment awards represent management s best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our stock-based compensation expense could be materially different in the future. In addition, we are required to estimate the expected forfeiture rate and recognize expense only for those shares expected to vest. If our actual forfeiture rate is materially different from our estimate, the stock-based compensation expense could be significantly different from what we have recorded in the current period. As of December 31, 2007, \$45.9 million of total unrecognized compensation expense related to stock options is expected to be recognized over a weighted-average period of 2.7 years. See Note 10 to the Consolidated Financial Statements for a further discussion on stock-based compensation.

Fiscal Year Convention

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

Results of Operations Comparison of Years Ended December 31, 2007, 2006 and 2005

Revenues

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

	Year Ended December 31,		
	2007	2006	2005
Contract revenues:			
Research and development services	\$ 50.4	\$46.3	\$46.7
Milestones	18.0	15.6	9.0
Delivery of compounds under chemistry collaborations	0.7	0.5	
License revenues:			
Ratable recognition of upfront payments, including premiums paid on equity purchases	44.4	36.3	20.3
Total revenues	\$ 113.5	\$ 98.7	\$ 76.0
Dollar increase	\$ 14.8	\$ 22.7	
Percentage increase	15%	30%	

The increase in revenues from research and development services from 2006 to 2007 was primarily the result of increases in research and development services of \$3.4 million attributable to Artemis, \$1.5 million from our agreement with Agrigenetics and \$1.2 million from our agreement with Daiichi-Sankyo. These increases were partially offset by decreases in research and development services of \$1.0 million from our one of our Bristol-Myers Squibb collaborations and \$0.9 million from our collaboration with Renessen LLC.

The decrease in research and development services from 2005 to 2006 was primarily a result of the conclusion of our Genoptera collaboration in June 2005, which included a one-time termination fee related to research and development services totaling \$13.4 million. This decrease was partially offset by increases in research and development services of \$9.2 million from Bristol-Myers Squibb, \$2.1 million attributable to customers of Artemis and \$1.2 million from Genentech.

The increase in milestone revenues from 2006 to 2007 was primarily due to \$4.9 million in revenues associated with a milestone achieved under our co-development collaboration with Genentech relating to XL518 and \$3.3 million in revenues associated with a milestone achieved under one of our collaborations with Bristol-Myers Squibb. These increases were partially offset by \$4.0 million in revenues in 2006 associated with a milestone achieved under achieved under our collaboration with Helsinn Healthcare S.A, or Helsinn, and \$2.0 million in revenues associated with a milestone achieved under our collaboration with Wyeth Pharmaceuticals in 2006.

The increase in milestone revenues from 2005 to 2006 was driven primarily by achieving and recognizing as revenue milestones of \$4.5 million under our collaboration with Wyeth Pharmaceuticals and a \$4.0 million milestone under our collaboration with Helsinn and \$1.2 million in revenues associated with achieving two milestones under one of our collaborations with Bristol-Myers Squibb. This increase was partially offset by a decrease of \$2.7 million in milestone revenues related to the conclusion of our Genoptera collaboration in June 2005.

The revenues from the delivery of compounds in 2007 approximates that of 2006. The increase in revenues from 2005 to 2006 from the delivery of compounds of \$0.5 million was related to the delivery of compounds under our chemistry collaboration agreement with Bayer CropScience.

The increase from 2006 to 2007 in the amortization of upfront payments, including premiums paid on equity purchases, was driven primarily by upfront payments from the oncology collaboration we entered into with Bristol-Myers Squibb in December 2006, resulting in increased revenues of \$14.6 million, and our co-development collaboration with Genentech relating to XL518, resulting in increased revenues of \$8.1 million. These increases were partially offset by the completion of amortizing upfront payments from Wyeth Pharmaceuticals, resulting in decreased revenues of \$9.7 million, and from Daiichi-Sankyo, resulting in decreased revenues of \$4.6 million.

The increase from 2005 to 2006 in the amortization of upfront payments, including premiums paid on equity purchases, was driven primarily by upfront payments from Daiichi-Sankyo, resulting in increased revenues of \$12.3 million, Wyeth Pharmaceuticals, resulting in increased revenues of \$9.4 million, and Bristol-Myers Squibb, resulting in increased revenues of \$5.6 million. These increases were partially offset by a decrease of \$7.8 million related to the conclusion of our Genoptera collaboration in June 2005, which included acceleration of upfront payments, and by a decrease of \$4.0 million related to the conclusion of our collaboration with Helsinn.

Prior to the closing of the sale of 80.1% of the share capital of Artemis on November 20, 2007, we had included \$11.2 million, \$7.9 million and \$5.8 million of revenues attributable to Artemis for 2007, 2006 and 2005, respectively, within our consolidated total revenues. As a result of the sale, Artemis financial results will no longer be consolidated into our consolidated financial statements.

The following table sets forth the revenue recognized as a percentage of total revenue from customers that exceeded 10% or more of total revenues during the years ended December 31, 2007, 2006 and 2005:

Collaborator	2007	2006	2005
Bristol-Myers Squibb	35%	22%	7%
GlaxoSmithKline	24%	28%	37%
Genentech	16%	6%	4%
Daiichi-Sankyo	10%	15%	1%
Wyeth Pharmaceuticals	2%	14%	0%
Genoptera	0%	0%	32%

Research and Development Expenses

Total research and development expenses were as follows (dollar amounts are presented in millions):

	Year H	Year Ended December 31,			
	2007	2006	2005		
Research and development expenses(1)	\$ 225.4	\$ 185.5	\$141.1		
Dollar increase	\$ 39.9	\$ 44.3			
Percentage increase	22%	31%			

(1) Amounts for 2007 and 2006 include \$11.6 million and \$11.2 million, respectively, in employee stock-based compensation under SFAS 123R.

Research and development expenses consist primarily of personnel expenses, clinical trials and consulting, laboratory supplies and facility costs. The change in 2007 compared to 2006 resulted primarily from the following:

Clinical Trials and Consulting Clinical trials and consulting expense, which includes services performed by third-party contract research organizations and other vendors, increased by \$16.0 million, or 34%, primarily due to an increase in activities associated with advancing our clinical and preclinical development programs. During 2007, these activities included phase 2 clinical trial activities for XL784, XL880,

XL647 and XL820 and phase 1 clinical trial activity for XL999, XL844, XL228, XL281, XL518, XL184, XL418, XL147, XL765 and XL019, as well as preclinical activity for XL443 and XL139, which were partially offset by a decrease in phase 2 clinical trial activity for XL999 during 2007.

Personnel Personnel expense, which includes salaries, bonuses, related fringe benefits, recruiting and relocation costs, increased by \$13.9 million, or 24%, primarily due to the expanded workforce supporting drug development operations to advance our clinical and preclinical development programs.

Lab Supplies Lab supplies expense increased by \$5.2 million, or 30%, primarily due to an increase in our drug discovery activities and drug development activities.

The change in 2006 compared to 2005 in research and development expenses resulted primarily from the following:

Clinical Trials and Consulting Clinical trials and consulting expense, which includes services performed by third-party contract research organizations and other vendors, increased by \$21.3 million, or 85%, primarily due to an increase in activities associated with advancing our clinical and preclinical development programs. During 2006, these activities included phase 2 clinical trial activity for XL999, XL784, XL880 and XL647 and phase 1 clinical trial activity for XL844, XL820 and XL184 as well as pre-clinical activity for XL228, XL281, XL418, XL518, XL147, XL765 and XL019.

Employee Stock-Based Compensation Employee stock-based compensation expense increased by \$11.2 million due to our adoption of SFAS 123R effective January 1, 2006.

Personnel Personnel expense, which includes salaries, bonuses, related fringe benefits, recruiting and relocation costs, increased by \$9.2 million, or 19%, primarily due to the expanded workforce supporting drug development operations to advance our clinical and preclinical development programs.

Lab Supplies Lab supplies expense increased by \$1.3 million, or 9%, primarily due to an increase in our development activities related to our phase 1 and phase 2 clinical trials.

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

We currently do not have reliable estimates of total costs for a particular drug candidate to reach the market. Our potential therapeutic products are subject to a lengthy and uncertain regulatory process that may involve unanticipated additional clinical trials and may not result in receipt of 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 were as follows (dollar amounts are presented in millions):

	Year E	nded Decem	ıber 31,
	2007	2006	2005
General and administrative expenses(1)	\$ 44.9	\$ 39.1	\$ 27.7

Dollar increase	\$ 5.8	\$ 11.4	
Percentage increase	15%	41%	

(1) Amounts for 2007 and 2006 include \$7.3 million and \$6.3 million, respectively, in employee stock-based compensation under SFAS 123R.

General and administrative expenses consist primarily of personnel expenses to support our general operating activities, facility costs and professional expenses, such as legal and accounting fees. The increase in 2007 from 2006 resulted primarily from an increases in personnel expenses of \$3.9 million and increases in employee and nonemployee stock-based compensation expense of \$2.1 million. The increases in personnel expenses and stock-based compensation expense were primarily to support our expanding operations. The increase in 2006 from 2005 resulted primarily from increases in employee stock-based compensation expense of \$6.3 million due to our adoption of SFAS 123R, personnel expenses of \$3.4 million and consulting expenses of \$2.5 million, which were partially offset by a decrease in legal and accounting expenses of \$1.2 million.

Amortization of Intangible Assets

Total amortization of intangible assets were as follows (dollar amounts are presented in millions):

	Year E	Year Ended December 31,			
	2007	2006	2005		
Amortization of intangible assets	\$ 0.2	\$ 0.8	\$ 1.1		
Dollar decrease	\$ (0.6)	\$ (0.3)			
Percentage decrease	(75%)	(24%)			

Intangible assets resulted from our acquisitions of X-Ceptor, Genomica, Artemis and Agritope (renamed Exelixis Plant Sciences). These assets are amortized over specified time periods. The decrease in amortization of intangible assets expense in 2007 compared to 2006 was due to the completion of the amortization of the assembled workforce related to our acquisition of X-Ceptor Therapeutics and the developed technology related to our acquisition of Artemis. In addition, amortization of intangible assets expense decreased as a result of our transaction in September 2007 with Agrigenetics in which we sold \$2.1 million of acquired patents and our transaction in November 2007 in which we sold 80.1% of the share capital of Artemis, which included \$0.3 million of acquired patents.

The decrease in amortization of intangibles expense in 2006 as compared to 2005 was due to the developed technology intangible asset related to our acquisition of Artemis in 2001 becoming fully amortized in October 2006.

Total Other Income (Expense)

Total other income (expense) were as follows (dollar amounts are presented in millions):

	Year l	Year Ended December 31,			
	2007	2006	2005		
Total other income (expense)	\$ 46.0	\$ 3.6	\$ (0.8)		
Dollar increase	\$ 42.5	\$ 4.4			

The increase in total other income for 2007 compared to 2006 was primarily due to the gain on the sale of our plant trait business and the gain on sale of 80.1% of the share capital of Artemis and an increase in interest income as a result of higher cash and investment balances and higher average interest rates.

In September 2007, we sold our plant trait business to Agrigenetics, and, as a result, we recognized a gain of \$18.8 million in total other income. The gain of \$18.8 million primarily consists of a purchase price of \$22.5 million, less \$2.4 million in net book value of tangible and intangible assets and the derecognition of \$1.4 million of goodwill.

As a result of the sale of 80.1% of the share capital of Artemis, we recognized a gain of \$18.1 million in total other income. This gain primarily consists of cash received of \$19.8 million, plus \$2.5 million relating to the

elimination of cumulative foreign currency translation adjustments and the elimination of net liabilities, less \$0.3 million of intangible assets (acquired patents) and the derecognition of \$2.3 million of goodwill.

The increase in total other income for 2006 compared to 2005 was primarily due to a decrease in interest expense as a result of a decrease in the principal balance of our debt from the repayment of our \$30.0 million convertible note to PDL BioPharma, Inc. in May 2006 as well as higher average interest yields on our investments.

Noncontrolling Interest in Symphony Evolution, Inc.

Pursuant to the agreements that we entered into with SEI and certain other parties in June 2005, we consolidate SEI s financial condition and results of operations in accordance with FIN 46R. Accordingly, we have deducted the losses attributable to the noncontrolling interest (SEI s losses) from our net loss in the consolidated statement of operations and we have also reduced the noncontrolling interest holders ownership interest in SEI in the consolidated balance sheet by SEI s losses. The noncontrolling interest holders ownership in the consolidated balance sheet by SEI s losses are in excess of the noncontrolling interest holders ownership, SEI s losses will no longer be deducted from our net losses. For the years ended December 31, 2007, 2006 and 2005, the losses attributed to the noncontrolling interest holders were \$24.6 million, \$21.7 million and \$10.4 million, respectively.

The increase in 2007 from 2006 in the losses attributed to the noncontrolling interest holders is related to increased development expenses associated with XL784 and XL647, which were partially offset by a decrease in development expenses associated with XL999. The increase in 2006 from 2005 in the losses attributed to the noncontrolling interest holders is related to increased development expenses associated with XL999, XL784 and XL647.

Income Taxes

We have incurred net losses since inception and, consequently, have not recorded any U.S. federal or state income taxes. As of December 31, 2007, we had federal and California net operating loss carryforwards of \$655.0 million and \$357.0 million, respectively. As of December 31, 2007, we had federal and California research and development credit carryforwards of \$46.4 million and \$15.8 million, respectively. If not utilized, the net operating loss and credit carryforwards expire at various dates, which began in 2008.

Under the Internal Revenue Code and similar state provisions, certain substantial changes in our ownership could result in an annual limitation on the amount of net operating loss and credit carryforwards that can be utilized in future years to offset future taxable income. Annual limitations may result in the expiration of net operating loss and credit carryforwards before they are used.

Liquidity and Capital Resources

Sources and Uses of Cash

The following table summarizes our cash flow activities for the years ended December 31, 2007, 2006 and 2005 (dollar amounts are presented in thousands):

	Year Ended December 31,		
	2007	2006	2005
Net loss	\$ (86,381)	\$ (101,492)	\$ (84,404)
Adjustments to reconcile net loss to net cash used in operating activities	(29,126)	13,598	8,121
Changes in operating assets and liabilities	46,768	42,555	29,922
Net cash used in operating activities	(68,739)	(45,339)	(46,361)
Net cash used in investing activities	(3,019)	(21,701)	(40,648)
Net cash provided by financing activities	84,248	109,344	100,933
Effect of foreign exchange rates on cash and cash equivalents	(402)	(263)	(137)
Net increase in cash and cash equivalents	12,088	42,041	13,787
Cash and cash equivalents, at beginning of year	123,369	81,328	67,541
Cash and cash equivalents, at end of year	\$ 135,457	\$ 123,369	\$ 81,328

To date, we have financed our operations primarily through the sale of equity, payments and loans from collaborators, equipment financing facilities and interest income. We have also financed certain of our research and development activities under our agreements with SEI. In August 2005, we received net proceeds, after underwriting fees and offering expenses, of \$49.6 million from the sale of 6.5 million shares of our common stock under a shelf registration statement. In October 2006, we received net proceeds, after underwriting fees and offering expenses, of \$90.5 million from the sale of 11.5 million shares of our common stock under a shelf registration statement. In September 2007, we received net proceeds, after underwriting fees and offering expenses, of \$71.9 million from the sale of 7.0 million shares of our common stock under a shelf registration statement. As of December 31, 2007, we had \$299.5 million in cash and cash equivalents and marketable securities, which included restricted cash and investments of \$7.2 million and investments held by SEI of \$30.9 million. In addition, as of December 31, 2007, approximately \$34.2 million of cash and cash equivalents and marketable securities serve as collateral for bank lines of credit.

Operating Activities

Our operating activities used cash of \$68.7 million for the year ended December 31, 2007, compared to \$45.3 million for 2006 and \$46.4 million for 2005. Cash used in operating activities during 2007 related primarily to our loss from operations of \$157.0 million, partially offset by non-cash charges totaling \$31.3 million relating to stock-based compensation and depreciation and amortization. In addition, cash used in operating activities was reduced by \$49.9 million as the result of decreases in accounts receivable and increases in accounts payable, other accrued expenses, other long term liabilities and deferred revenue. Cash used in operating activities during 2006 related primarily to funding net losses, losses attributed to the noncontrolling interest and receivables. These uses of cash were partially offset by changes in deferred revenues, accrued expenses and non-cash charges related to stock-based compensation expense recognized due to our adoption of SFAS 123R and depreciation and amortization. Cash used in operating activities during 2005 related primarily to funding net losses attributed to the noncontrolling interest evenues from collaborators and non-cash charges related to depreciation and amortization. As of December 31, 2007, we had received cash payments from collaborators relating to \$64.1 million in short-term deferred revenue that we expect to recognize as revenue during 2008.

The increase of \$23.4 million in cash used in our operating activities from 2006 as compared to 2007 was primarily driven by an increase in our loss from operations. This increase in the loss from operations was primarily driven by an increase in research and development expenses. This increase to cash used was partially offset by increases in accrued expenses, due to increased clinical trial activity, and a decrease in receivables. The decrease of \$1.0 million in cash used in our operating activities from 2005 as compared to 2006 was primarily driven by increases in deferred revenues, accrued expenses, increased clinical trial activity and non-cash charges related to stock-based compensation expense recognized due to our adoption of SFAS 123R. These decreases to cash used were partially offset by increases in our net losses, losses attributed to the noncontrolling interest and receivables due to a milestone achieved under a collaboration agreement. While cash used in operating activities is primarily driven by our net loss, operating cash flows differ from our net loss as a result of differences in the timing of cash receipts and earnings recognition, expenses related to the noncontrolling interest and non-cash charges. We expect to use cash for operating activities for at least the next several years as we continue to incur net losses associated with our research and development activities, including manufacturing and development expenses for compounds in preclinical and clinical studies.

Investing Activities

Our investing activities used cash of \$3.0 million for the year ended December 31, 2007, compared to \$21.7 million for 2006 and \$40.6 million for 2005.

Cash used in investing activities for 2007 was primarily driven by net purchases of marketable securities of \$47.5 million and purchases of property and equipment of \$17.4 million. Most of the cash invested in marketable securities and investments was generated by a common stock offering in 2007 and payments received from collaborators. These uses of cash were partially offset by net proceeds of \$35.3 million from the sale of our plant trait business and Artemis. The proceeds provided by maturities of our marketable securities and the sale of investments by SEI were used to fund our operations. We expect to continue to make significant investments in property and equipment to support our expanding operations.

Cash used in investing activities for 2006 was primarily driven by purchases of marketable securities of \$91.7 million, purchases of investments held by SEI of \$42.3 million and purchases of property and equipment of \$11.6 million. Most of the cash invested in marketable securities and investments was generated by a common stock offering in 2006 and a second capital draw by our consolidated entity SEI in 2006. These uses of cash were partially offset by proceeds of \$99.6 million from the maturities of marketable securities and \$21.3 million from the sales of investments held by SEI. The proceeds provided by maturities of our marketable securities and the sale of investments by SEI were used to fund our operations.

Cash used in investing activities for 2005 was primarily driven by the purchases of marketable securities of \$109.4 million, purchases of investments held by SEI of \$40.7 million and purchases of property and equipment of \$14.4 million. Most of the cash invested in marketable securities and investments was generated by a common stock offering in 2005 and the first capital draw by our consolidated entity SEI in 2005. These uses of cash were partially offset by proceeds of \$113.6 million from the maturities of marketable securities and \$6.6 million from the sales of investments held by SEI. The proceeds provided by maturities of our marketable securities and the sale of investments by SEI were used to fund our operations.

Financing Activities

Our financing activities provided cash of \$84.2 million for the year ended December 31, 2007, compared to \$109.3 million for 2006 and \$100.9 million for 2005. Cash provided by our financing activities for 2007 was primarily due to net proceeds of \$71.9 million received through the sale of our common stock and \$12.6 million of proceeds from note payable and bank obligations. These increases were partially offset by \$12.1 million of principal payments on notes payable and bank obligations.

Cash provided by our financing activities for 2006 was primarily due to net proceeds of \$90.5 million received through the sale of our common stock, a \$40.0 million capital draw by SEI and the related funding by preferred shareholders of SEI and \$14.8 million of proceeds from note payable and bank obligations. These increases were partially offset by \$41.9 million of principal payments on notes payable and bank obligations, which included the repayment of \$30.0 million convertible promissory note to PDL BioPharma.

Cash provided by our financing activities for 2005 was primarily driven by net proceeds of \$37.0 million associated with the purchase and funding of the noncontrolling interest by preferred shareholders of SEI and net proceeds of \$49.6 million received through the sale of our common stock. In addition, we received \$11.1 million in cash from the purchase of 1.0 million shares of our common stock by GlaxoSmithKline, which included a \$2.2 million premium.

We finance property and equipment purchases through equipment financing facilities, such as 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, merger and acquisition expenses and other general corporate purposes. During 2008, we have the ability to draw up to an additional \$30.0 million on an equipment line of credit. Over the next several years, we are required to make certain payments on notes, bank obligations and loans from collaborators.

Cash Requirements

We have incurred net losses since inception, including a net loss of \$86.4 million for the year ended December 31, 2007, and we expect to incur substantial losses for at least the next several years as we continue our research and development activities, including manufacturing and development expenses for compounds in preclinical and clinical studies. We anticipate that our current cash and cash equivalents, short-term and long-term marketable securities, investments held by SEI and other funding that we expect to receive from collaborators, which assumes a moderate level of business development activity, will enable us to maintain our operations for a period of at least 12 months following the filing date of this report. However, our future capital requirements will be substantial and will depend on many factors that may require us to use available capital resources significantly sooner 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. In order to retain rights to XL647 after the expiration of the purchase option period, we would be required to reacquire XL647, XL784 and XL999 from SEI s investors through the exercise of our exclusive purchase option, which is described elsewhere in this report. We cannot 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 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 price for the compounds licensed to SEI increases over time;

whether and when GlaxoSmithKline selects at clinical proof-of-concept for further development and commercialization any additional product candidates Under the amended PDA, any milestone payments relating to product candidates remaining under the PDA must be used to pay down our loan with GlaxoSmithKline as long as the loan is outstanding. The amount of milestone payments that we receive from GlaxoSmithKline will depend on the number of compounds selected, the timing of the selection of the compounds and, for those acceptances made after the end of the original development

term, whether GlaxoSmithKline extended the development term. As of December 31, 2007, the aggregate principal and interest outstanding under our GlaxoSmithKline loan was \$98.6 million. In December 2007, GlaxoSmithKline exercised its option to further develop and commercialize XL880. As XL880 was the first compound selected by GlaxoSmithKline under the PDA, 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 PDA and was not used to pay down the loan. An additional \$1.0 million from the first commercialization milestone for any product candidate selected by GlaxoSmithKline will also be offset against the 2005 milestone;

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

future clinical trial results;

our need to expand our product and clinical development efforts;

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

the cost and timing of regulatory approvals;

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

the effect of competing technological and market developments;

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

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

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

In addition, we will have to obtain additional funding in order to stay in compliance with financial covenants contained in our collaboration with GlaxoSmithKline. Our loan and security agreement with GlaxoSmithKline dated October 28, 2002, as amended, contains financial covenants pursuant to which our working capital must not be less than \$25.0 million and our cash and investments must not be less than \$50.0 million. If we were to default on the financial covenants under the loan and security agreement, GlaxoSmithKline may, among other remedies, declare immediately due and payable all outstanding obligations thereunder.

If our capital resources are insufficient to meet future capital requirements, we will have to raise additional funds. We may seek to raise funds through the sale of equity or debt securities or through external borrowings. In addition, we may enter into strategic partnerships for the

Edgar Filing: EXELIXIS INC - Form 10-K

development and commercialization of our compounds. We currently have shelf registration statements on file with the SEC that allow 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 leases, notes payable and licensing agreements. The following chart details our contractual obligations (in thousands):

	Payments Due by Period				
		Less than	1-3	4-5	After 5
Contractual Obligations	Total	1 year	Years	years	years
Notes payable and bank obligations	\$ 36,514	\$ 15,767	\$ 17,814	\$ 2,933	\$
Licensing agreements	1,543	1,291	247	5	
Convertible loans(1)	98,583		65,065	33,518	
Operating leases	172,016	16,600	34,857	36,712	83,847
Total contractual cash obligations	\$ 308,656	\$ 33,658	\$ 117,983	\$ 73,168	\$ 83,847

 Includes interest payable on the convertible loans of \$13.6 million. The debt and interest payable can be repaid in cash or common stock at our election. This obligation is described in further detail in Note 8 of the notes to our consolidated financial statements.
In January 2008, Bristol-Myers Squibb exercised its option to develop and commercialize compound XL139. In addition, we exercised our

option under the collaboration agreement to co-develop and co-commercialize XL139 in the United States. Due to our election to co-develop and co-commercialize XL139, we will be required to pay 35% of the worldwide development expenses. See Note 3 of the Notes to the Consolidated Financial Statements for further information concerning this collaboration.

Recent Accounting Pronouncements

In September 2006, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 157, Fair Value Measurements (SFAS 157). SFAS 157 provides guidance for using fair value to measure certain assets and liabilities. It also responds to investors requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS 157 applies whenever other standards require (or permit) assets or liabilities to be measured at fair value, and does not expand the use of fair value in any new circumstances. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and is required to be adopted by us in the first quarter of fiscal 2008. We do not believe the effect that the adoption of SFAS 157 will be material to our consolidated results of operations and financial condition.

In June 2007, the FASB also ratified EITF 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities (EITF 07-3). EITF 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed. EITF 07-3 is effective, on a prospective basis, for fiscal years beginning after December 15, 2007 and will be adopted by us in the first quarter of fiscal 2008. We do not expect the adoption of EITF 07-3 to have a material effect on our consolidated results of operations and financial condition.

In December 2007, the FASB issued SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements an amendment of Accounting Research Bulletin No. 51 (SFAS 160). SFAS 160 establishes accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income attributable to the parent and to the noncontrolling interest, changes in a parent s ownership interest and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. SFAS 160 also establishes disclosure requirements that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS 160 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and will be adopted by us in the first

quarter of fiscal 2009. We are currently evaluating the potential impact, if any, of the adoption of SFAS 160 on our consolidated results of operations and financial condition.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements (as defined by applicable SEC regulations) that are reasonably likely to have a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources, except warrants and stock options. Our off-balance sheet arrangements are described in further detail in Notes 9 and 10 of the notes to our consolidated financial statements.

5	n
J	9

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio and our long-term debt. At December 31, 2007 and 2006, we had cash and cash equivalents, marketable securities, investments held by SEI and restricted cash and investments of \$299.5 million and \$263.2 million, respectively. Our marketable securities and investments are subject to interest rate risk, and our interest income may fluctuate due to changes in U.S. interest rates. By policy, we limit our investments to money market instruments, debt securities of U.S. government agencies and debt obligations of U.S. corporations. These securities are generally classified as available-for-sale and consequently are recorded on the balance sheet at fair value with unrealized gains or losses reported as a separate component of accumulated other comprehensive income (loss), net of estimated income taxes. We manage market risk through diversification requirements mandated by our investment policy, which limits the amount of our portfolio that can be invested in a single issuer. We manage credit risk by limiting our purchases to high-quality issuers. Through our money managers, we maintain risk management control systems to monitor interest rate risk. The risk management control systems use analytical techniques, including sensitivity analysis. At December 31, 2007 and 2006, we had debt outstanding of \$121.5 million and \$121.7 million, respectively. Our payment commitments associated with these debt instruments are fixed during the corresponding terms and are comprised of interest payments, principal payments or a combination thereof. The fair value of our debt will fluctuate with movements of interest rates, increasing in periods of declining rates of interest, and declining in periods of increasing rates of interest.

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 December 31, 2007 and 2006. As of December 31, 2007 and 2006, a decrease in the interest rates of one percentage point would have had a net adverse change in the fair value of interest rate sensitive assets and liabilities of \$1.4 million and \$2.4 million, respectively. We have assumed that the changes occur immediately and uniformly to each category of instrument containing interest rate risks. Significant variations in market interest rates could produce changes in the timing of repayments due to available prepayment options. The fair value of such instruments could be affected and, therefore, actual results might differ from our estimate.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA EXELIXIS, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	Page
Report of Independent Registered Public Accounting Firm	62
Consolidated Balance Sheets	63
Consolidated Statements of Operations	64
Consolidated Statements of Stockholders Equity	65
Consolidated Statements of Cash Flows	66
Notes to Consolidated Financial Statements	67

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Exelixis, Inc.

We have audited the accompanying consolidated balance sheets of Exelixis, Inc. as of December 28, 2007 and December 29, 2006, and the related consolidated statements of operations, stockholders equity and cash flows for each of the three fiscal years in the period ended December 28, 2007. These financial statements are the responsibility of Exelixis, Inc. s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Exelixis, Inc. at December 28, 2007 and December 29, 2006, and the consolidated results of its operations and its cash flows for each of the three fiscal years in the period ended December 28, 2007, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 1 to the consolidated financial statements, in 2006 Exelixis, Inc. changed its method of accounting of stock-based compensation in accordance with guidance provided in Statement of Financial Accounting Standards No. 123(R), Share-Based Payment.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Exelixis, Inc. s internal control over financial reporting as of December 28, 2007, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 13, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California

February 13, 2008

EXELIXIS, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except share data)

		ber 31,
ASSETS	2007	2006
Current assets:		
Cash and cash equivalents	\$ 135,457	\$ 123,369
Marketable securities	105,157	55,516
Investments held by Symphony Evolution, Inc.	30,935	55,087
Other receivables	6,087	22,197
Prepaid expenses and other current assets	6,151	6,082
Total current assets	283,783	262,251
Restricted cash and investments	7,238	9,635
Long-term marketable securities	20,747	19,573
Property and equipment, net	34,664	32,294
Goodwill	63,684	67,364
Other intangibles, net	05,084	2,605
Other assets	2,004	1,695
Total assets	\$ 412,120	\$ 395,417
	\$ 412,120	\$ 575,417
LIABILITIES, NONCONTROLLING INTEREST AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 9,288	\$ 3,699
Accrued clinical trial liabilities	21,651	12,209
Other accrued liabilities	7,594	7,018
Accrued compensation and benefits	14,480	11,456
Current portion of notes payable and bank obligations	15,767	13,579
Deferred revenue	64,105	63,476
Total current liabilities	132,885	111,437
Notes payable and bank obligations	20,747	23,074
Convertible loans	85,000	85,000
Other long-term liabilities	24,924	20,491
Deferred revenue	63,053	64,804
Total liabilities	326,609	304,806
Noncontrolling interest in Symphony Evolution, Inc.	13,430	38,071
Commitments (Note 12)	15,450	50,071
Stockholders equity:		
Preferred stock, \$0.001 par value, 10,000,000 shares authorized and no shares issued		
Common stock, \$0.001 par value; 200,000,000 shares authorized; issued and outstanding: 104,744,732 and		
95,990,148 shares at December 31, 2007 and 2006, respectively	105	96
Additional paid-in-capital	863,127	756,568
Accumulated other comprehensive income	499	1,145
Accumulated deficit	(791,650)	(705,269
Total stockholders equity	72,081	52,540

Edgar Filing: EXELIXIS INC - Form 10-K

Total liabilities, noncontrolling interest and stockholders equity

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

\$ 412,120 \$ 395,417

EXELIXIS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

	Yea1 2007	: 31, 2005	
Revenues:			
Contract	\$ 69,023	\$ 62,414	\$ 55,715
License	44,447	36,256	20,246
Total revenues	113,470	98,670	75,961
Operating expenses:			
Research and development	225,375	185,481	141,135
General and administrative	44,940	39,123	27,731
Amortization of intangible assets	202	820	1,086
Total operating expenses	270,517	225,424	169,952
Loss from operations	(157,047)	(126,754)	(93,991)
Other income (expense):			
Interest income and other, net	13,055	8,546	5,371
Interest expense	(3,966)	(4,981)	(6,190)
Gain on sale of businesses	36,936		
Total other income (expense)	46,025	3,565	(819)
Loss before noncontrolling interest in Symphony Evolution, Inc.	(111,022)	(123,189)	(94,810)
Loss attributed to noncontrolling interest in Symphony Evolution, Inc.	24,641	21,697	10,406
Net loss	\$ (86,381)	\$ (101,492)	\$ (84,404)
Net loss per share, basic and diluted	\$ (0.87)	\$ (1.17)	\$ (1.07)
Shares used in computing basic and diluted loss per share amounts	99,147	86,602	78,810

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

EXELIXIS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

(in thousands, except share data)

	Common Stock Shares	S	mmon tock nount	Additional Paid-in Capital	(Comp	imulated)ther orehensive ocome	Accumulated Deficit		Total tockholders Equity	
Balance at December 31, 2004	74,995,484	\$	75	\$ 569,345	\$	624	\$	(519,373)	\$ 50,671	
Net loss								(84,404)	(84,404)	
Decrease in unrealized loss on										
available-for-sale securities						63			63	
Change in accumulated translation adjustment						286			286	
Comprehensive loss									(84,055)	
Issuance of common stock under stock plans	909,238			5,505					5,505	
Issuance of common stock, net of offering costs	6,500,000		8	49,608					49,616	
Issuance of common stock under the GlaxoSmithKline collaboration	1,000,000		1	8.853					8,854	
Issuance of warrants to Symphony Evolution	1,000,000		1	0,055					0,054	
Holdings, Inc.				2,842					2,842	
Stock-based compensation expense				110					110	
Balance at December 31, 2005	83,404,722		84	636,263		973		(603,777)	33,543	
Net loss								(101,492)	(101,492)	
Decrease in unrealized loss on										
available-for-sale securities						405			405	
Change in accumulated translation adjustment, net						(233)			(233)	
Comprehensive loss									(101,320)	
Issuance of common stock under stock plans	1,013,998			8,145					8,145	
Issuance of common stock, net of offering costs	11,500,000		12	90,482					90,494	
Issuance of warrants to Symphony Evolution										
Holdings, Inc.				3,984					3,984	
Exercise of Warrant	71,428			81					81	
Stock-based compensation expense				17,613					17,613	
Balance at December 31, 2006	95,990,148		96	756,568		1,145		(705,269)	52,540	
Net loss	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		20	100,000		1,110		(86,381)	(86, 381)	
Change in unrealized gains on								((,,	
available-for-sale securities						542			542	
Change in cumulative translation adjustment						(1,188)			(1,188)	
Comprehensive loss									(87,027)	
Issuance of common stock under stock plans	1,754,584		2	14,508					14,510	
Issuance of common stock, net of offering costs	7,000,000		7	71,883					71,890	
Stock-based compensation expense				20,168					20,168	
Balance at December 31, 2007	104,744,732	\$	105	\$ 863,127	\$	499	\$	(791,650)	\$ 72,081	

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

EXELIXIS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Year 2007	Ended Decembe 2006	mber 31, 2005	
Cash flows from operating activities:				
Net loss	\$ (86,381)	\$ (101,492)	\$ (84,404)	
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	11,130	16,090	16,669	
Loss attributed to noncontrolling interest	(24,641)	(21,697)	(10,406)	
Stock-based compensation expense	20,168	17,613	110	
Amortization of intangibles	202	820	1,086	
Gain on sale of plant trait business and Artemis Pharmaceuticals	(36,936)			
Loss on the sale of equipment	165	18	60	
Other	786	754	602	
Changes in assets and liabilities:				
Other receivables	17,698	(15,090)	(2,801)	
Prepaid expenses and other current assets	(2,965)	(645)	(1,103)	
Other assets	(175)	644	(1,022)	
Accounts payable and other accrued expenses	23,658	12,164	355	
Other long-term liabilities	4,433	6,015	6,479	
Deferred revenue	4,119	39,467	28,014	
Net cash used in operating activities	(68,739)	(45,339)	(46,361)	
Cash flows from investing activities:				
Purchases of investments held by Symphony Evolution, Inc.	(2,280)	(42,338)	(40,681)	
Proceeds on sale of investments held by Symphony Evolution, Inc.	26,433	21,290	6,642	
Purchases of property and equipment	(17,399)	(11,610)	(14,357)	
Proceeds from sale of equipment		10	186	
Proceeds on sale of plant trait business	18,000			
Proceeds on sale of Artemis Pharmaceuticals, net	17,309			
Change in restricted cash and investments	2,396	3,048	3,358	
Proceeds from maturities of marketable securities	156,339	99,641	113,598	
Purchases of marketable securities	(203,817)	(91,742)	(109,394)	
Net cash used in investing activities	(3,019)	(21,701)	(40,648)	
Cash flows from financing activities:		00.100		
Proceeds from the issuance of common stock, net of offering costs	71,890	90,482	58,468	
Proceeds from exercise of stock options and warrants	8,301	3,275	1,773	
Proceeds from employee stock purchase plan	3,567	2,783	2,199	
Payments on capital lease obligations		(98)	(1,931)	
Proceeds from notes payable and bank obligations	12,632	14,791	12,725	
Principal payments on notes payable and bank obligations	(12,142)	(41,889)	(9,301)	
Proceeds from purchase of noncontrolling interest by preferred shareholders in Symphony Evolution, Inc., net of fees		40,000	37,000	
Net cash provided by financing activities	84,248	109,344	100,933	
Effect of foreign exchange rates on cash and cash equivalents	(402)	(263)	(137)	

Edgar Filing: EXELIXIS INC - Form 10-K

Net increase in cash and cash equivalents		088		42,041	13,787
Cash and cash equivalents, at beginning of year	123	369		81,328	67,541
Cash and cash equivalents, at end of year	\$ 135	457	\$ 1	123,369	\$ 81,328
Supplemental cash flow disclosure:					
Cash paid for interest	\$	597	\$	2,634	\$ 2,747
Warrants issued in conjunction with the Symphony Evolution, Inc. financing				3,984	2,842
	• • • •				

The accompany notes are an integral part of these consolidated financial statements

EXELIXIS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization

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

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 Artemis Pharmaceuticals GmbH, our German subsidiary, is an operating segment. Selected segment information is provided in Note 2 of the Notes to the Consolidated Financial Statements.

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

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States (GAAP) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ significantly from those estimates.

Cash and Investments

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

Investments held by Symphony Evolution, Inc. consist of investments in money market funds. As of December 31, 2007 and 2006, we had investments held by Symphony Evolution, Inc. of \$30.9 million and \$55.1 million, respectively.

All marketable securities are classified as available-for-sale and are carried at fair value. We view our available-for-sale portfolio as available for use in current operations. Accordingly, we have classified certain

EXELIXIS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

The following summarizes available-for-sale securities included in cash and cash equivalents, short-term and long-term marketable securities and restricted cash and investments as of December 31, 2007 and 2006 (in thousands):

December 31, 2007

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	\$ 79,360	\$	\$	\$ 79,360
Commercial paper	68,816	21	(12)	68,825
Corporate bonds	68,614	471	(12)	69,073
U.S. Government agency securities	51,977	32	(1)	52,008
Total	\$ 268,767	\$ 524	\$ (25)	\$ 269,266

		Gross	Gross	
	Amortized Cost	Unrealized Gains	l Unrealized Losses	Fair Value
As reported:				
Cash equivalents	\$ 136,124	\$ 16	\$ (12)	\$ 136,128
Marketable securities	104,658	508	(13)	105,153
Long-term marketable securities	20,747			20,747
Restricted cash and investments	7,238			7,238
Total	\$ 268,767	\$ 524	\$ (25)	\$ 269,266

December 31, 2006

		Gross	Gross	
	Amortized	Unrealized	Unrealized	Fair
	Cost	Gains	Losses	Value
Money market funds	\$ 79,745	\$	\$	\$ 79,745
Commercial paper	102,969	24	(25)	102,968
Corporate bonds	6,115		(2)	6,113
U.S. Government agency securities	21,776		(41)	21,735

Edgar Filing: EXELIXIS INC - Form 10-K							
Total		\$ 210,605	\$	24	\$	(68)	\$ 210,561
Total		\$ 210,605	\$	24	\$	(68)	\$ 210,561

EXELIXIS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	Amortized Cost	Unre	ross ealized ains	Unr	ross ealized osses	Fair Value
As reported:						
Cash equivalents	\$ 125,826	\$	24	\$	(13)	\$ 125,837
Marketable securities	55,571				(55)	55,516
Long-term marketable securities	19,573					19,573
Restricted cash and investments	9,635					9,635
Total	\$ 210,605	\$	24	\$	(68)	\$ 210,561

The following is a summary of the amortized cost and estimated fair value of marketable securities at December 31, 2007 by contractual maturity (in thousands):

	Amortized Cost	Fair Value
Mature in less than one year	\$ 213,656	\$ 213,692
Mature in one to three years	55,111	55,574
Total	\$ 268,767	\$ 269,266

The following is a summary of the estimated fair value and aggregate unrealized losses of marketable securities at December 31, 2007 and 2006 by continuous unrealized loss position (in thousands):

December 31, 2007

	Less than	Less than 12 months		12 months or		er
	Fair Value		alized oss	Fair Value	Unrea Lo:	
Commercial Paper	\$ 39,919	\$	(12)	\$	\$	
Corporate bonds	12,195		(5)	4,003		(7)
U.S. Government agency securities				1,499		(1)
Total	\$ 52,114	\$	(17)	\$ 5,502	\$	(8)

December 31, 2006

	Less than	Less than 12 months		12 month	is or longer
	Fair	Unre	alized	Fair	Unrealized
	Value	L	OSS	Value	Loss
Commercial Paper	\$ 47,027	\$	(25)	\$	\$
Corporate bonds	1,571		(2)	4,043	

Edgar Filing: EXELIXIS INC - Form 10-K

U.S. Government agency securities	13,524	(41)	6,274	
Total	\$ 62,122	\$ (68)	\$ 10,317	\$

As of December 31, 2007, unrealized losses were primarily due to changes in interest rates. Based on the scheduled maturities of our marketable securities we concluded that some of the unrealized losses in our investment securities are other-than-temporary. Accordingly, we recorded a non-cash impairment charge of \$30,000 and \$0.1 million in interest income and other, net, during the years ended December 31, 2007 and 2006, respectively, in order to write down the carrying value of these securities to estimated fair value.

EXELIXIS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Property and Equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over the following estimated useful lives:

Equipment and furniture	5 years
Computer equipment and software	3 years
Leasehold improvements	Shorter of lease life or 7 years

Repairs and maintenance costs are charged to expense as incurred.

Intangible Assets

Goodwill amounts have been recorded as the excess purchase price over tangible assets, liabilities and intangible assets acquired based on their estimated fair value, by applying the purchase method. Under GAAP, we evaluate goodwill for impairment on an annual basis and on an interim basis if events or changes in circumstances between annual impairment tests indicate that the asset might be impaired. When evaluating goodwill for impairment we must determine the reporting units that exist within Exelixis. We determined that our reporting units are consistent with our operating segments. We have allocated goodwill to our reporting units based on the relative fair value of the reporting units. We also evaluate other intangible assets for impairment when impairment indicators are identified.

Other intangible assets have been amortized using the straight-line method over the following estimated useful lives:

Developed technology	5 years
Patents/core technology	15 years
Assembled workforce	2 years
Long-lived Assets	

The carrying value of our long-lived assets is reviewed for impairment whenever events or changes in circumstances indicate that the asset may not be recoverable. An impairment loss would be recognized when estimated future cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount. Long-lived assets include property and equipment and identified intangible assets.

Fair Value of Financial Instruments

The carrying amounts of certain of our financial instruments, including cash and cash equivalents and marketable securities, approximate fair value due to their short maturities. We have estimated the fair value of our long-term debt instruments using the net present value of the payments discounted at an interest rate that is consistent with our current borrowing rate for similar long-term debt. We have outstanding balances associated with our \$85.0 million convertible loan with GlaxoSmithKline and our equipment lines of credit of \$10.9 million and \$21.9 million as of December 31, 2007. These items are described in further detail in Note 8 of the Notes to the Consolidated Financial Statements. We estimated the fair value of our convertible loan with GlaxoSmithKline to be \$73.4 million and \$71.4 million as of December 31, 2007 and 2006, respectively. We

EXELIXIS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

estimated the fair value of our first equipment line of credit to be \$10.4 million and \$14.4 million as of December 31, 2007 and 2006, respectively, and our second line of credit, respectively, to be \$20.2 million and \$11.2 million as of December 31, 2007 and 2006.

Concentration of Credit Risk

Financial instruments that potentially subject us to concentrations of credit risk are primarily cash and cash equivalents, accounts receivable and investments in marketable securities. Cash equivalents and marketable securities consist of money market funds, taxable commercial paper, corporate bonds with high credit quality and U.S. government agency obligations. Investments held by Symphony Evolution, Inc. consist of investments in money market funds. All cash and cash equivalents, marketable securities and investments held by Symphony Evolution, Inc. are maintained with financial institutions that management believes are creditworthy. Other receivables are typically unsecured and are concentrated in the pharmaceutical and biotechnology industries. Accordingly, we may be exposed to credit risk generally associated with pharmaceutical and biotechnology companies. We have incurred no bad debt expense since inception.

The following table sets forth revenues recognized under our collaboration agreements that exceed 10% of total revenues during the years ending December 31, 2007, 2006 and 2005:

Collaborator	2007	2006	2005
Bristol-Myers Squibb	35%	22%	7%
GlaxoSmithKline	24%	28%	37%
Genentech	16%	6%	4%
Daiichi-Sankyo	10%	15%	1%
Wyeth Pharmaceuticals	2%	14%	0%
Genoptera	0%	0%	32%
Revenue Recognition			

License, research commitment and other non-refundable payments received in connection with research collaboration agreements are deferred and recognized on a straight-line basis over the period of continuing involvement, generally the research term specified in the agreement. Contract research revenues are recognized as services are performed pursuant to the terms of the agreements. Any amounts received in advance of performance are recorded as deferred revenue. Payments are not refundable if research is not successful.

We enter into corporate collaborations under which we may obtain up-front license fees, research funding, and contingent milestone payments and royalties. We evaluate whether the delivered elements under these arrangements have value to our collaboration partner on a stand-alone basis and whether objective and reliable evidence of fair value of the undelivered item exists. Deliverables that do not meet these criteria are not evaluated separately for the purpose of revenue recognition. For a combined unit of accounting, non-refundable up-front fees and milestones are recognized in a manner consistent with the final deliverable, which is generally ratably over the research period.

Milestone payments are non-refundable and recognized as revenues over the period of the research arrangement. This typically results in a portion of the milestone being recognized at the date the milestone is achieved, which portion is equal to the applicable percentage of the research term that has elapsed at the date the milestone is achieved, and the balance being recognized over the remaining research term of the agreement. In

EXELIXIS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

certain situations, we may receive milestone payments after the end of our period of continued involvement. In such circumstances, we would recognize 100% of the milestone revenue when the milestone is achieved.

Revenues from chemistry collaborations were generally recognized upon the delivery of accepted compounds.

Research and Development Expenses

Research and development costs are expensed as incurred and include costs associated with research performed pursuant to collaborative agreements. Research and development costs consist of direct and indirect internal costs related to specific projects as well as fees paid to other entities that conduct certain research activities on our behalf.

Substantial portions of our preclinical studies and all of our clinical trials have been performed by third-party contract research organizations (CROs) and other vendors. We accrue expenses for preclinical studies performed by our vendors based on certain estimates over the term of the service period and adjust our estimates as required. We accrue costs for clinical trial activities performed by CROs based upon the estimated amount of work completed on each study. For clinical trial expenses, the significant factors used in estimating accruals include the number of patients enrolled, the number of active clinical sites, and the duration for which the patients will be enrolled in the study. We monitor patient enrollment levels and related activities to the extent possible through internal reviews, correspondence with CROs and review of contractual terms. We base our estimates on the best information available at the time. However, additional information may become available to us which will allow us to make a more accurate estimate in future periods. In this event, we may be required to record adjustments to research and development expenses in future periods when the actual level of activity becomes more certain, such increases or decreases in cost are generally considered to be changes in estimates and will be reflected in research and development expenses in the period first known. For example, during the quarter ended December 31, 2007, we recorded a reduction of \$2.6 million to our accrued clinical trial liabilities and research and development expenses related to our XL784 clinical trial.

Net Loss Per Share

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

The following table sets forth potential shares of common stock that are not included in the computation of diluted net loss per share because to do so would be antidilutive for the years ended December 31:

	2007	2006	2005
Options to purchase common stock	20,718,661	17,210,626	13,157,431
Conversion of loans	11,315,160	10,769,781	13,920,556
Warrants	1,500,000	1,500,000	821,148
	33,533,821	29,480,407	27,899,135

EXELIXIS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In addition, if we decide to exercise our option to repurchase our product candidates XL784, XL647 and XL999 from Symphony Evolution, we may issue a substantial number of shares in satisfaction of the purchase price. The Symphony Evolution transaction is described in further detail in Note 4 of the Notes to the Consolidated Financial Statements.

Foreign Currency Translation

Exelixis subsidiary located in Germany operated using the local currency as the functional currency. Accordingly, all assets and liabilities of this subsidiary were translated using exchange rates in effect at the end of the period, and revenues and expenses were translated using average exchange rates for the period. The resulting translation adjustments are presented as a separate component of accumulated other comprehensive income. In November 2007, we sold 80.1% of our subsidiary located in Germany and as a result we removed from accumulated other comprehensive income the cumulative translation adjustment of \$1.0 million and reported this as part of the gain on the sale of the subsidiary in 2007.

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 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 provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, (SFAS 123). Stock-based compensation expense for all stock-based compensation awards granted after January 1, 2006 is based on the grant date fair value estimated using the Black-Scholes option pricing model.

We have limited historical information available to support the underlying estimates of certain assumptions required to value stock options. Because there is a market for options on our common stock, we have considered implied volatilities as well as our historical realized volatilities when developing an estimate of expected volatility. The expected option term also has a significant effect on the value of the option. The longer the term, the more time the option holder has to allow the stock price to increase without a cash investment and thus, the more valuable the option. However, empirical data shows that employees, for a variety of reasons, typically do not wait until the end of the contractual term of a nontransferable option to exercise. Accordingly, companies are required to estimate the expected term of the option for input to an option-pricing model. We estimate the term using historical data and peer data. We recognize compensation expense on a straight-line basis over the requisite service period. We have elected to use the simplified method to calculate the beginning pool of excess tax benefits as described in FASB FSP 123(R)-3.

Prior to the adoption of SFAS 123R, we recognized stock-based compensation expense in accordance with Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees (APB 25). Accordingly, no compensation expense is recognized in our financial statements for the stock options granted to employees, which had an exercise price equal to the fair value of the underlying common stock on the date of grant. We have employee and director stock option plans that are more fully described in Note 10 of the Notes to the Consolidated Financial Statements.

EXELIXIS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 cumulative translation adjustments, not reflected in the consolidated statement of operations.

Comprehensive loss is as follows (in thousands):

	Year Ended December 31,		
	2007	2006	2005
Net loss	\$ (86,381)	\$ (101,492)	\$ (84,404)
Increase in net unrealized gains on available-for-sale securities	514	331	63
Reclassification for unrealized losses on marketable securities recognized in earnings	28	74	
(Decrease) increase in cumulative translation adjustment	(162)	(233)	286
Reclassification adjustment for the cumulative translation adjustment upon the sale of Artemis			
Pharmaceuticals	(1,026)		
Comprehensive loss	\$ (87,027)	\$ (101,320)	\$ (84,055)

The components of accumulated other comprehensive income are as follows (in thousands):

	December 31,		
	2007	2006	2005
Unrealized gains (losses) on available-for-sale securities	\$ 499	\$ (44)	\$ (449)
Cumulative translation adjustment		1,189	1,422
Accumulated other comprehensive income	\$ 499	\$ 1,145	\$ 973

Recent Accounting Pronouncements

In September 2006, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 157, Fair Value Measurements (SFAS 157). SFAS 157 provides guidance for using fair value to measure certain assets and liabilities. It also responds to investors requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS 157 applies whenever other standards require (or permit) assets or liabilities to be measured at fair value, and does not expand the use of fair value in any new circumstances. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and is required to be adopted by us in the first quarter of fiscal 2008. We do not believe the effect that the adoption of SFAS 157 will be material to our consolidated results of operations and financial condition.

In June 2007, the FASB also ratified EITF 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities (EITF 07-3). EITF 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed. EITF 07-3 is effective, on a prospective basis, for fiscal years beginning after December 15, 2007 and will be adopted by us in the first quarter of fiscal 2008. We do not expect the adoption of EITF 07-3 to have a material effect on our consolidated results of operations and financial condition.

Edgar Filing: EXELIXIS INC - Form 10-K

EXELIXIS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In December 2007, the FASB issued SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements an amendment of Accounting Research Bulletin No. 51 (SFAS 160). SFAS 160 establishes accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income attributable to the parent and to the noncontrolling interest, changes in a parent s ownership interest and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. SFAS 160 also establishes disclosure requirements that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS 160 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and will be adopted by us in the first quarter of fiscal 2009. We are currently evaluating the potential impact, if any, of the adoption of SFAS 160 on our consolidated results of operations and financial condition.

NOTE 2. DISPOSITIONS

Sale of Plant Trait Business

On September 4, 2007 (the Closing Date), we entered into an asset purchase and license agreement (the APA) with the Dow Chemical Company (Dow). Under the terms of the APA, we sold to Dow a major portion of our assets used for crop trait discovery, including a facility, and granted to Dow licenses to certain other related assets and intellectual property. As consideration for these assets and licenses, Dow paid us \$18.0 million and is obligated to pay an additional \$4.5 million upon the first anniversary of the Closing Date. Under the APA, we have agreed to indemnify Dow and its affiliates up to a specified amount if they incur damages due to any infringement or alleged infringement of certain patents.

Concurrently with the execution of the APA, we also entered into a contract research agreement (the CRA) with Dow. Dow has agreed to pay up to a maximum of \$24.7 million in research and development funding over the term of the CRA. The research funding will cover employee costs, facilities expenses and capital expenditures. After the Closing Date, the research and development funding to be received over the term of the CRA will be recognized as a reduction to expenses incurred by Exelixis in connection with its performance under the CRA. In order for us to perform our obligations under the CRA, we will lease at no cost the facility that Dow acquired under the APA. We are also entitled to receive additional payments of up to a maximum of \$13.5 million from Dow if we achieve the development of up to three designated assets during the term of the CRA. If development of any of the three designated assets is completed, the related payment will be treated as additional proceeds from the sale of our plant trait business.

The term of the CRA is five years, unless earlier terminated. Dow may terminate the CRA if we fail to complete the development of any of the three designated assets within our respective specified research periods or if we fail to cure a material breach within specified time periods. Following our development and transfer to Dow of the second designated asset, either party may terminate the CRA upon expiration of a specified notice period. In the event that the CRA is terminated prior to the end of the term, we will receive less than the maximum amount of research and development funding described above.

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

EXELIXIS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Artemis Pharmaceuticals

On November 20, 2007 (the Closing Date), we entered into a share sale and transfer agreement with Taconic Farms, Inc. (Taconic), pursuant to which Taconic acquired from Exelixis, for \$19.8 million in cash, 80.1% of the outstanding share capital in our wholly-owned subsidiary, Artemis Pharmaceuticals GmbH (Artemis), located in Cologne, Germany. Artemis activities are directed toward providing transgenic mouse generation services, tools and related licenses to the industrial and academic community.

We also entered into a Shareholders Agreement and amended articles of association that govern the relationship between Exelixis and Taconic as shareholders of Artemis, particularly with respect to matters of corporate governance and the transfer of their respective ownership interests. The Shareholders Agreement provides that we may require Taconic to purchase our remaining 19.9% interest in Artemis (the Minority Interest) between 2010 and 2015 or in the event of a change in control of Taconic, and that Taconic may require us to sell our Minority Interest to Taconic between 2013 and 2015 or in the event of a change in control of Exelixis, in each case subject to certain conditions set forth in the shareholders agreement. The amended articles of association provide for the establishment of a shareholders committee, in which we participate based on our 19.9% ownership, to assist in the management of Artemis.

The sale of 80.1% of Artemis was accounted for as a sale of a business. We recognized a gain of \$18.1 million, net of \$1.6 million in transaction costs. The gain primarily consists of cash received of \$19.8 million, plus \$2.5 million relating to the elimination of the cumulative foreign currency translation adjustment and the elimination of net liabilities, less \$0.3 million of intangible assets (acquired patents) and derecognition of \$2.3 million of goodwill. As we believe we have significant influence over the operations of Artemis through our rights under the Shareholders Agreement and the amended articles of association, we will account for our remaining 19.9% equity interest in Artemis under the equity method of accounting. We will subsequently adjust our investment balance to recognize our share of future Artemis earnings or losses after the Closing Date. As of December 31, 2007, the carrying value of our investment in Artemis was approximately \$30,000.

Artemis revenues and net income (loss) after the effect of all intercompany eliminations are as follows (in thousands):

	Fo	For the Year Ended		
		December 31		
	2007 (1)	2006	2005	
Revenues	\$ 11,234	\$ 7,920	\$ 5,773	
Net income (loss)	\$ 1,210	\$ (1,036)	\$ (619)	

(1) The revenues and net income for the year ended December 31, 2007 only include revenues through November 20, 2007, the Closing Date. **NOTE 3. RESEARCH AND COLLABORATION AGREEMENTS**

Bristol-Myers Squibb

2001 Cancer Collaboration

In July 2001, we entered into a cancer collaboration agreement with Bristol-Myers Squibb. Under the terms of the collaboration, Bristol-Myers Squibb paid Exelixis a \$5.0 million upfront license fee and agreed to provide Exelixis with \$3.0 million per year in research funding for a minimum of three years. In December 2003, the

EXELIXIS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

cancer collaboration was extended until January 2007, at which time Bristol-Myers Squibb elected to continue the collaboration until July 2009. The goal of the extension is to increase the total number and degree of validation of cancer targets that we will deliver to Bristol-Myers Squibb. Each company will maintain the option to obtain exclusive worldwide rights to equal numbers of validated targets arising from the collaboration. Under the terms of the extended collaboration, Bristol-Myers Squibb provided us with an upfront payment and will provide increased annual research funding and milestones on certain cancer targets arising from the collaboration that progress through specified stages of validation. We will also be entitled to receive milestones on compounds in the event of successful clinical and regulatory events and royalties on commercialized products.

LXR Collaboration

In December 2005, Exelixis entered into a collaboration agreement with Bristol-Myers Squibb, for the discovery, development and commercialization of novel therapies targeted against Liver X Receptor (LXR), a nuclear hormone receptor implicated in a variety of cardiovascular and metabolic disorders. This agreement became effective in January 2006, at which time Exelixis granted 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 sales/marketing activities for the selected drug candidate and we do not have rights to reacquire such drug candidates.

Under the LXR collaboration agreement, Bristol-Myers Squibb paid Exelixis a nonrefundable upfront payment in the amount of \$17.5 million and is obligated to provide research and development funding of \$10.0 million per year for an initial research period of two years. 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.

In September 2007, Bristol-Myers Squibb exercised its existing option to extend the LXR collaboration research period for an additional one-year term, through January 2009. Under the terms of the extension, Bristol-Myers Squibb is obligated to provide Exelixis research and development funding of \$7.5 million during the extension period. In addition, the LXR collaboration agreement was amended to grant Bristol-Myers Squibb an option to extend the research period for an additional one-year term, which would be through January 2010. In December 2007, we received \$5.0 million for achieving a development milestone.

2007 Cancer Collaboration

In December 2006, Exelixis entered into a worldwide collaboration with Bristol-Myers Squibb Company, which became effective in January 2007, to collaborate in the discovery, development and commercialization of novel targeted therapies for the treatment of cancer. Exelixis is responsible for discovery and preclinical development of small molecule drug candidates directed against mutually selected targets. In January 2007, Bristol-Myers Squibb made an upfront payment of \$60.0 million to Exelixis for which we granted Bristol-Myers Squibb the right to select up to three IND candidates from six future Exelixis compounds. We are recognizing the upfront payment as revenue over the estimated four-year research term.

EXELIXIS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

For each IND candidate selected Exelixis is entitled to receive a \$20.0 million selection milestone from Bristol-Myers Squibb. Once selected, Bristol-Myers Squibb will lead the further development and commercialization of the selected IND candidates. In addition, we have the right to opt in to co-promote the selected IND candidates, in which case we will equally share all development costs and profits in the United States. If we opt-in, we will be responsible for 35% of all development costs related to clinical trials intended to support regulatory approval in both the United States and the rest of the world, with the remaining 65% to be paid by Bristol-Myers Squibb. This percentage ratio was intended to approximate a 50/50 split of development and commercialization costs in the United States. If we do not opt in to co-promote the selected IND candidates, we could be entitled to receive milestones and royalties in lieu of profits from sales in the United States. Outside of the United States, Bristol-Myers Squibb will have primary responsibility for development activities and we will be entitled to receive royalties on product sales. After exercising its co-development option, Bristol-Myers Squibb may, upon notice to us, terminate the agreement as to any product containing or comprising the selected candidate. In the event of such termination election, Bristol-Myers Squibb s license relating to such product would terminate and revert to Exelixis, and we would receive, subject to certain terms and conditions, licenses from Bristol-Myers Squibb to research, develop and commercialize certain collaboration compounds that were discovered.

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

Genentech

2005 Collaboration

In May 2005, Exelixis and Genentech, Inc. (Genentech) established a collaboration to discover and develop therapeutics for the treatment of cancer, inflammatory diseases, and tissue growth and repair. Under the terms of the agreement, we granted to Genentech a license to certain intellectual property. Genentech paid us a nonrefundable upfront license payment and is obligated to provide research and development funding over the three-year research term, totaling \$16.0 million. The upfront license payment and the research and development funding are being recognized as revenue over the research term.

Under the agreement, Genentech will have primary responsibility in the field of cancer for research and development activities as well as rights for commercialization of any products to which we have no contractual reacquisition rights. In the fields of inflammatory disease and in the field of tissue growth and repair, we will initially have primary responsibility for research activities and after the expiration of the research term, we will have the option to elect to share a portion of the costs and profits associated with the development, manufacturing and commercialization of products in one of these fields. The research term under the agreement is three years and may be extended upon mutual consent for one-year terms. For all products under the agreement that are not elected as cost or profit sharing products, we may receive milestone and royalty payments.

MEK Collaboration

In December 2006, Exelixis entered into a worldwide co-development agreement with Genentech for the development and commercialization of XL518, a small-molecule inhibitor of MEK. Genentech paid upfront and

milestone payments of \$25.0 million in December 2006 and \$15.0 million in January 2007 upon signing of the

EXELIXIS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

agreement and with the submission of an IND for XL518. We expect to recognize the upfront and milestone payments as revenue over the estimated research term of three years.

Under the terms of the agreement, we are responsible for developing XL518 through the end of a phase 1 clinical study at which point Genentech has the option to co-develop XL518. If Genentech exercises its option to co-develop XL518 we will be entitled to receive an opt-in payment and we will be required to grant to Genentech an exclusive worldwide revenue-bearing license to XL518. Genentech will be responsible for all further development and development costs of XL518 and we will share equally in the U.S. commercialization costs. On an annual basis we are entitled to an initial equal share of U.S. profits and losses, which will decrease as sales increase, and we are also entitled to royalties on non-U.S. sales. Genentech has the right to terminate the agreement without cause at any time. If Genentech terminates the co-development agreement without cause, all licenses that were granted to Genentech under the agreement terminate and revert to us. Additionally, we would receive, subject to certain conditions, licenses from Genentech to research, develop and commercialize reverted product candidates.

Daiichi Sankyo Company Limited

In March 2006, Exelixis and Daiichi Sankyo Company Limited entered into a collaboration agreement for the discovery, development and commercialization of novel therapies targeted against 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 Daiichi-Sankyo an exclusive, worldwide license to certain intellectual property primarily relating to compounds that modulate MR. After completion of the research term, Daiichi-Sankyo will be responsible for all further preclinical and clinical development, regulatory, manufacturing and commercialization activities for the compounds and we do not have rights to reacquire such compounds.

Daiichi-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 through June 2007. The upfront payment and research and development funding will be recognized as revenue over the initial 15-month research term, which commenced on April 1, 2006. During June 2007, our collaboration agreement with Daiichi-Sankyo was amended to extend the research term by six months over which Daiichi-Sankyo is required to provide \$1.5 million in research and development funding. In November 2007, the parties decided not to further extend the research term. For each product from the collaboration, we are also entitled to receive payments upon attainment of pre-specified development, regulatory and commercialization milestones. In addition, we are also entitled to receive royalties on any sales of certain products commercialized under the collaboration. Daiichi-Sankyo may terminate the agreement upon 90 days written notice in which case Daiichi-Sankyo s payment obligations will cease, its license relating to compounds that modulate MR will terminate and revert to us, and we will receive, subject to certain terms and conditions, licenses from Daiichi-Sankyo to research, develop and commercialize compounds that were discovered under the agreement.

Wyeth Pharmaceuticals

In December 2005, Exelixis and Wyeth Pharmaceuticals, a division of Wyeth, entered into a license agreement related to compounds targeting Farnesoid X Receptor (FXR), a nuclear hormone receptor implicated in a variety of metabolic and liver disorders. Under the terms of the agreement, we have granted to Wyeth Pharmaceuticals an exclusive, worldwide license with respect to certain intellectual property primarily relating to compounds that modulate FXR. Wyeth Pharmaceuticals paid us a nonrefundable upfront payment in the amount of \$10.0 million and we received \$4.5 million in November 2006 and \$2.5 million in November 2007

EXELIXIS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

for achieving development milestones. Wyeth Pharmaceuticals is obligated to pay additional development and commercialization milestones of up to \$140.5 million, as well as royalties on sales of any products commercialized by Wyeth Pharmaceuticals under the agreement. Substantially all the upfront and November 2006 milestone payments were recognized as revenue in 2006. In addition, the November 2007 milestone payment was recognized as revenue when the development milestone was achieved. Wyeth Pharmaceuticals will be responsible for all further preclinical and clinical development, regulatory, manufacturing and commercialization activities for the compounds.

Helsinn Healthcare

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

In May 2006, we supplied Helsinn with certain clinical trial materials in order for Helsinn to maintain enrollment in the phase 3 clinical trial for XL119. Helsinn s acceptance of the clinical trial materials triggered a \$4.0 million milestone payment, which was received and recognized as revenue in June 2006. In November 2006, Helsinn discontinued the XL119 phase 3 clinical trial program.

Bayer

In May 1998, Exelixis entered into a six-year research collaboration agreement with Bayer Corporation (Bayer) to identify novel screening targets for the development of new pesticides for use in crop protection. We received a \$1.2 million license fee upon execution of the agreement that was recognized as revenue over the term of the agreement.

In December 1999, we expanded our relationship with Bayer by forming a joint venture in the form of a new limited liability company, Genoptera LLC (Genoptera). Under the terms of the Genoptera operating agreement, Bayer provided 100% of the capital necessary to fund the operations of Genoptera and had the ability to control the entity with a 60% ownership interest and we owned the other 40% interest in Genoptera and we reported our investment in Genoptera using the equity method of accounting. Bayer s initial capital contributions to Genoptera were \$10.0 million in January 2000 and another \$10.0 million in January 2001. Bayer also contributed cash to Genoptera in amounts necessary to fund its ongoing operating expenses. Genoptera incurred losses since inception. Since the carrying value of the investment remained at zero and we had no obligation to fund future losses, we did not record any equity method losses for Genoptera.

In January 2000, Exelixis, Bayer and Genoptera entered into an exclusive eight-year research collaboration agreement, which superseded the 1998 agreement discussed above. We were required to provide Genoptera with expanded research services focused on developing insecticides and nematicides for crop protection. Under the terms of the collaboration agreement, Genoptera paid us a \$10.0 million license fee and a \$10.0 million research commitment fee, which we received in January 2000 and January 2001, respectively. Additionally, Genoptera was required to pay us \$10.0 million in annual research funding.

In March 2005, Exelixis, Bayer and Genoptera agreed to amend the terms of the collaboration agreement, dated January 1, 2000, among Exelixis, Bayer and Genoptera. The amended agreement provided for an early termination of the research term and required Bayer to acquire our 40% ownership interest in Genoptera, which

EXELIXIS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

was acquired in December 2005. The amended agreement also required Bayer to pay us an early termination fee of \$10.9 million, which was paid in April 2005.

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

GlaxoSmithKline

In October 2002, Exelixis and SmithKlineBeecham Corporation, which does business as GlaxoSmithKline, established a collaboration to discover and develop novel therapeutics in the areas of vascular biology, inflammatory disease and oncology. The collaboration involved three agreements: (i) a Product Development and Commercialization Agreement (PDA); (ii) a Stock Purchase and Stock Issuance Agreement (SPA); and (iii) a Loan and Security Agreement (LSA). Under the original PDA, GlaxoSmithKline paid us \$30.0 million in an upfront fee and \$10.0 million in annual research funding, and agreed to pay a minimum of an additional \$80.0 million in research and development funding over the first six years of the collaboration.

Under the original SPA, GlaxoSmithKline purchased 2.0 million shares of our common stock in a private placement at a purchase price of \$7.00 per share, which represented a premium of approximately 100% to the stock price on the effective date of the agreements. We received cash proceeds of approximately \$14.0 million for the purchase of these shares in November 2002. The upfront fee and the premium portion of the equity purchase have been deferred and are being recognized as revenue over the development term. Under the terms of the SPA, we had the option to sell additional common shares to GlaxoSmithKline in the future, as described below.

Under the original LSA, GlaxoSmithKline provided a loan facility of up to \$85.0 million for use in our efforts under the collaboration, and we borrowed \$25.0 million under that agreement in December 2002, an additional \$30.0 million in December 2003, and the remaining \$30.0 million in December 2004. All loan amounts bear interest at a rate of 4.0% per annum and are secured by the intellectual property, technology and equipment created or utilized pursuant to the collaboration. Principal and accrued interest becomes due in installments, beginning on the first anniversary of the later of the: (a) completion of the development term; or (b) the end of any extension period. Repayment of all or any of the amounts advanced to us under this agreement may, at our election, be in the form of our common stock at fair market value, subject to certain conditions.

In January 2005, we amended the terms of our collaboration with GlaxoSmithKline. Under the amended PDA, GlaxoSmithKline selected a modified program election through which the focus of the collaboration is shifted to 12 internal programs at various stages of development (XL784, XL647, XL999, XL880, XL184, XL820, XL844, XL281, XL418, XL228 and two earlier stage oncology programs). Each program centers on compounds that are directed against one or more targets identified in the collaboration. Under the modified program, GlaxoSmithKline has the right to select from these programs up to two compounds, or three compounds if GlaxoSmithKline extends the specified development term. The amount of acceptance milestones that we receive from GlaxoSmithKline will depend on the number of compounds selected, the timing of the selection of the compounds and, for those acceptances made after the end of the original development term, whether GlaxoSmithKline extended the development term. GlaxoSmithKline retains exclusivity rights to the 32 specified targets that are encompassed by the 12 programs through the end of the specified development term, or any extension thereof by GlaxoSmithKline. After the end of the development term or any extension, GlaxoSmithKline retains exclusivity rights to a subset of these targets based on the compounds that they have

EXELIXIS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

selected for development. We have retained rights to all compounds not encompassed by the 12 programs that are part of the collaboration with GlaxoSmithKline and may work on any targets with the exception of the 32 targets or, if applicable, a subset, subject to GlaxoSmithKline s exclusivity rights.

In May 2005, we filed the third of three INDs required by the amended PDA to achieve a \$30.0 million milestone, which we received from GlaxoSmithKline in May 2005. The revenue from this milestone is being recognized over the term of the amended PDA on a straight-line basis from January 2005 to November 2010. In return for the new \$30.0 million milestone, GlaxoSmithKline will receive a \$30.0 million credit and a specified reduction against the first acceptance milestone as well as a temporary reduction in the royalty rate it owes us on net sales of products developed under the collaboration. In May 2005, we submitted two new development candidates to GlaxoSmithKline, thereby triggering an additional \$5.0 million milestone, which we received in May 2005. We may also receive additional development related milestones and royalties on product sales and have certain co-promotion rights to products in North America. In addition, under the amended PDA, GlaxoSmithKline agreed to provide research funding of \$47.5 million over the remaining three-year term of the collaboration, all of which we have received by the end of 2007.

The terms of the amended PDA allow us to use third-party financing vehicles to fund the further clinical development of our compounds XL784, XL647 and XL999 but any such compounds developed through clinical financing vehicles continue to be subject to GlaxoSmithKline s compound selection rights. In June 2005, we entered into a transaction to fund the clinical development of XL784, XL647 and XL999 through Symphony Evolution, a third-party financing vehicle. This is described in further detail in Note 4 of the Notes to the Consolidated Financial Statements. During 2007, XL647 and XL784 data packages were presented to GlaxoSmithKline for selection for further development and commercialization, and GlaxoSmithKline elected not to select either compound for further development. We have discontinued development of XL999.

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

In December 2007, GlaxoSmithKline exercised its option under the original PDA to exclusively license XL880 for further development and commercialization. XL880 is a small molecule compound currently being evaluated in phase 2 trials in patients with papillary renal cell carcinoma, gastric cancer and head and neck cancer. Upon antitrust clearance, GlaxoSmithKline s selection of XL880 entitles us to the first selection milestone of \$35.0 million under the terms of the original PDA. Under the terms of the amended PDA, the first selection milestone is to be reduced by up to \$36.0 million as a result of a new \$30.0 million milestone that GlaxoSmithKline paid to us in 2005, as described above. As a result, we will not receive a payment or recognize any revenues related to the first selection milestone that was achieved. We are also entitled to receive specific development and commercialization milestones and double-digit royalties on product sales if the compound is approved for marketing and commercialized and we will have certain co-promotion rights to XL880 in North America.

NOTE 4. SYMPHONY EVOLUTION

On June 9, 2005 (the Closing Date), we entered into a series of related agreements providing for the financing of the clinical development of XL784, XL647 and XL999 (the Programs). Pursuant to the agreements, Symphony Evolution, Inc. (SEI) invested \$80.0 million to fund the clinical development of these Programs and we have licensed to SEI our intellectual property rights related to these Programs. SEI is a wholly

EXELIXIS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

owned subsidiary of Symphony Evolution Holdings LLC (Holdings), which provided \$40.0 million in funding to SEI at closing, and an additional \$40.0 million in June 2006. We continue to be primarily responsible for the development of the Programs in accordance with specified development plans and related development budgets.

In accordance with FIN 46R, we have determined that SEI is a variable interest entity for which we are the primary beneficiary. As a result, we will include the financial condition and results of operations of SEI in our consolidated financial statements. Accordingly, we have deducted the losses attributable to the noncontrolling interest in SEI from our net loss in the consolidated statement of operations and we have also reduced the noncontrolling interest holders ownership interest in SEI in the consolidated balance sheet by SEI s losses. The noncontrolling interest holders ownership, SEI s losses will no longer be deducted from our net losses. For the years ended December 31, 2007, 2006 and 2005, the losses attributed to the noncontrolling interest holders ownership interest holders were \$24.6 million, \$21.7 million and \$10.4 million, respectively. We also reduced the noncontrolling interest holders ownership interest in SEI in the consolidated balance sheet by: (i) a \$3.0 million structuring fee that we incurred in connection with the closing of the SEI transaction, (ii) a \$2.8 million value assigned to the warrants that were issued to Holdings in June 2006.

Pursuant to the agreements, we have received an exclusive purchase option (the Purchase Option) that gives us the right to acquire all of the equity of SEI, thereby allowing us to reacquire all of the Programs. The Purchase Option was amended in December 2006 to allow us, at our election, to pay up to 100% of the purchase option exercise price in shares of our common stock. Under the original terms of the purchase option, we were only entitled to pay up to 33% of the purchase option exercise price in shares. This Purchase Option is exercisable at any time, until the earlier of June 9, 2009 or the 90th day after the date that SEI provides us with financial statements showing cash and cash equivalents of less than \$5.0 million at an exercise price equal to the sum of: (i) the total amount of capital invested in SEI by Holdings and (ii) an amount equal to 25% per year on such funded capital (with respect to the initial funded capital, compounded from the Closing Date and, with respect to the second draw amount, compounded from the second draw date). The Purchase Option exercise price may be paid in cash, our common stock or in a combination of cash and our common stock, at our sole discretion.

Pursuant to the agreements, we issued to Holdings a five-year warrant to purchase 750,000 shares of our common stock at \$8.90 per share in June 2005. We issued an additional five-year warrant to purchase 750,000 shares of our common stock at \$8.90 per share in connection with the additional \$40.0 million in funding in June 2006. In addition, if the Purchase Option expires unexercised at June 9, 2009, we are obligated to issue to Holdings an additional warrant to purchase 500,000 shares of our common stock at a price per share equal to 125% of the market price of our common stock at the time of expiration of the Purchase Option, with a five-year term. The warrants issued upon closing were assigned a value of \$2.8 million and the warrants issued in June 2006 were assigned a value of \$4.0 million in accordance with the Black-Scholes option valuation methodology and we recorded these values as a reduction to the noncontrolling interest in SEI. Pursuant to the agreements, we have no further obligation beyond the items described above and we have no obligation to the creditors of SEI as a result of our involvement with SEI.

The Programs were subject to our collaboration with GlaxoSmithKline, and GlaxoSmithKline had the option to select at proof-of-concept for further development one or more of the Programs licensed to SEI, in which case we would have been required to repurchase the Programs through the exercise of our Purchase Option. During 2007, XL647 and XL784 data packages were presented to GlaxoSmithKline for selection for further development and commercialization, and GlaxoSmithKline elected not to select either compound for further development. In December 2007, we discontinued the development of XL999.

EXELIXIS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 5. RELATED PARTY TRANSACTIONS

For the year ended, December 31, 2005, we recognized revenues of \$24.0 million under a collaboration agreement with Bayer through our joint venture with Genoptera. The \$24.0 million recognized was primarily related to the recognition of \$21.1 million in revenues from the acceleration of upfront payments, milestones and a termination payment associated with the termination of our Genoptera collaboration.

NOTE 6. PROPERTY AND EQUIPMENT

Property and equipment consists of the following (in thousands):

	Decem	ber 31,
	2007	2006
Laboratory equipment	\$ 66,974	\$ 63,490
Computer equipment and software	21,027	17,890
Furniture and fixtures	4,577	5,182
Leasehold improvements	22,593	21,817
Construction-in-progress	2,357	1,264
	117,528	109,643
Less accumulated depreciation and amortization	(82,864)	(77,349)
	\$ 34,664	\$ 32,294

For the years ended December 31, 2007, 2006 and 2005, we recorded depreciation expense of \$13.7 million, \$15.3 million and \$13.9 million, respectively.

NOTE 7. GOODWILL AND OTHER ACQUIRED INTANGIBLES

Our annual goodwill impairment test date is performed at the beginning of the fourth quarter of every year. Following this approach, we monitor asset-carrying values as of October 1 and on an interim basis if events or changes in circumstances occur we assess whether there is a potential impairment and complete the measurement of impairment, if required. To date, our annual impairment tests have not resulted in impairment of recorded goodwill. Intangible asset components listed below have been amortized using the straight-line method over the assets estimated useful life.

As part of our business disposals in 2007, we sold the technology, patents and core technology related to these businesses. As a result, at December 31, 2007 we had no recorded intangible assets, apart from goodwill. The components of our intangible assets as of December 31, 2006 were as follows (in thousands):

		December 31, 2006		
	Gross			
	Carrying	Accumulated		
	Amount	Amortization	Net	
Developed technology	\$ 1,240	\$ (1,240)	\$	
Patents and core technology	4,323	(1,718)	2,605	

Edgar Filing: EXELIXIS INC - Form 10-K

Assembled workforce	1,100	(1,100)	
Total	\$ 6,663	\$ (4,058)	\$ 2,605

EXELIXIS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

NOTE 8. DEBT

Our debt consists of the following (in thousands):

	Decem	December 31,	
	2007	2006	
GlaxoSmithKline convertible loans	\$ 85,000	\$ 85,000	
Bank equipment lines of credit	36,514	36,653	