

GENTEX CORP  
Form 5  
January 31, 2008

**FORM 5**

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

OMB APPROVAL

OMB Number: 3235-0362  
Expires: January 31, 2005  
Estimated average burden hours per response... 1.0

Check this box if no longer subject to Section 16. Form 4 or Form 5 obligations may continue. See Instruction 1(b).  
Form 3 Holdings Reported Form 4 Transactions Reported

**ANNUAL STATEMENT OF CHANGES IN BENEFICIAL OWNERSHIP OF SECURITIES**

Filed pursuant to Section 16(a) of the Securities Exchange Act of 1934, Section 17(a) of the Public Utility Holding Company Act of 1935 or Section 30(h) of the Investment Company Act of 1940

1. Name and Address of Reporting Person \*  
LA GRAND KENNETH L

(Last) (First) (Middle)

845 BARKENTINE DRIVE

(Street)

HOLLAND, MI 49424

(City) (State) (Zip)

2. Issuer Name and Ticker or Trading Symbol  
GENTEX CORP [GNTX]

3. Statement for Issuer's Fiscal Year Ended (Month/Day/Year)  
12/31/2007

4. If Amendment, Date Original Filed(Month/Day/Year)

5. Relationship of Reporting Person(s) to Issuer

(Check all applicable)

Director  10% Owner  
 Officer (give title below)  Other (specify below)

6. Individual or Joint/Group Reporting

(check applicable line)

Form Filed by One Reporting Person  
 Form Filed by More than One Reporting Person

**Table I - Non-Derivative Securities Acquired, Disposed of, or Beneficially Owned**

1. Title of Security (Instr. 3)	2. Transaction Date (Month/Day/Year)	2A. Deemed Execution Date, if any (Month/Day/Year)	3. Transaction Code (Instr. 8)	4. Securities Acquired (A) or Disposed of (D) (Instr. 3, 4 and 5)	5. Amount of Securities Beneficially Owned at end of Issuer's Fiscal Year (Instr. 3 and 4)	6. Ownership Form: Direct (D) or Indirect (I) (Instr. 4)	7. Nature of Indirect Beneficial Ownership (Instr. 4)
				(A) Amount or (D) Price			
COMMON STOCK	11/26/2007	11/26/2007	G	12,440 D \$ 19.13	339,935 <sup>(1)</sup>	I	BY TRUST
COMMON STOCK	11/27/2007	11/27/2007	G	3,000 D \$ 18.74	336,935	I	BY TRUST

Reminder: Report on a separate line for each class of securities beneficially owned directly or indirectly.

**Persons who respond to the collection of information contained in this form are not required to respond unless the form displays a currently valid OMB control number.**

SEC 2270 (9-02)

Edgar Filing: GENTEX CORP - Form 5

**Table II - Derivative Securities Acquired, Disposed of, or Beneficially Owned**  
(e.g., puts, calls, warrants, options, convertible securities)

1. Title of Derivative Security (Instr. 3)	2. Conversion or Exercise Price of Derivative Security	3. Transaction Date (Month/Day/Year)	3A. Deemed Execution Date, if any (Month/Day/Year)	4. Transaction Code (Instr. 8)	5. Number of Derivative Securities Acquired (A) or Disposed of (D) (Instr. 3, 4, and 5)	6. Date Exercisable and Expiration Date (Month/Day/Year)	7. Title and Amount of Underlying Securities (Instr. 3 and 4)	8. Price of Derivative Security (Instr. 5)	9. Price of Underlying Security (Instr. 6)
					(A) (D)	Date Exercisable Expiration Date	Title	Amount or Number of Shares	

## Reporting Owners

Reporting Owner Name / Address	Relationships			
	Director	10% Owner	Officer	Other
LA GRAND KENNETH L 845 BARKENTINE DRIVE HOLLAND, MI 49424	X			

## Signatures

/s/Ken LaGrand 01/31/2008  
 \*\*Signature of Reporting Person Date

## Explanation of Responses:

- \* If the form is filed by more than one reporting person, see Instruction 4(b)(v).
- \*\* Intentional misstatements or omissions of facts constitute Federal Criminal Violations. See 18 U.S.C. 1001 and 15 U.S.C. 78ff(a).

(1) 50,500 SHARES INDIRECTLY HELD IN THE "JOAN M. LA GRAND TRUST"

Note: File three copies of this Form, one of which must be manually signed. If space provided is insufficient, see Instruction 6 for procedure. Potential persons who are to respond to the collection of information contained in this form are not required to respond unless the form displays a currently valid OMB number. Reduction of our workforce by approximately 40%, or 270 employees. While we will continue to maintain an integrated research and development organization, the reduction in our workforce was weighted towards our drug discovery group. We have maintained capabilities in all aspects of drug discovery and expect to continue to generate novel investigational new drug application-, or IND-, ready compounds, although fewer on a yearly basis for the foreseeable future than we have generated historically. We have retained the ability to meet all of our obligations to existing partners. Further, and as a result of our retained research capabilities and our numerous unpartnered clinical and preclinical compounds, we expect that our ongoing and planned future business development discussions will be unaffected by the restructuring. We believe that the restructuring increases our financial strength and positions us for longer-term sustainable growth.

### Our Pipeline

#### Overview

## Edgar Filing: GENTEX CORP - Form 5

We have an extensive pipeline of compounds in various stages of development that will potentially treat cancer and various metabolic, cardiovascular and inflammatory disorders. All of our development compounds were generated through our internal drug discovery efforts, although we are developing certain of these compounds in collaboration with partners and have out-licensed others. We are focusing our development efforts on our lead clinical compounds, XL184, XL147 and XL765. These drug candidates are the most advanced in our pipeline, and we believe that they have the greatest near-term therapeutic and commercial potential. As a result, we are dedicating the majority of our resources to aggressively advance these drug candidates through development towards commercialization.

**Table of Contents**

The following table sets forth compounds that we are developing independently or are co-developing with a partner:

Compound	Partner	Principal Targets	Indication	Stage of Development
XL184	Bristol-Myers Squibb	MET, VEGFR2, RET	Cancer	Phase 3
XL139	Bristol-Myers Squibb	Hedgehog	Cancer	Phase 1b
XL413	Bristol-Myers Squibb	CDC7	Cancer	Phase 1
XL888	Unpartnered	HSP90	Cancer	Phase 1
XL499	Unpartnered	PI3K-d	Cancer and inflammation	Preclinical

The following table sets forth those compounds that we have out-licensed to third parties:

Compound	Partner	Principal Targets	Indication	Stage of Development
XL880	GlaxoSmithKline	MET, VEGFR2	Cancer	Phase 2
XL147	sanofi-aventis	PI3K	Cancer	Phase 1b/2
XL765	sanofi-aventis	PI3K, mTOR	Cancer	Phase 1b/2
XL518	Genentech	MEK	Cancer	Phase 1b
XL281	Bristol-Myers Squibb	RAF	Cancer	Phase 1
XL652	Bristol-Myers Squibb	LXR	Metabolic and cardiovascular diseases	Phase 1
XL041	Bristol-Myers Squibb	LXR	Metabolic and cardiovascular diseases	Phase 1
XL550	Daiichi-Sankyo	MR	Metabolic and cardiovascular diseases	Preclinical
FXR	Pfizer	FXR	Metabolic and liver disorders	Preclinical
S1P1R	Boehringer Ingelheim	S1P1R (agonist)	Inflammation	Preclinical

The following table sets forth those compounds for which we are pursuing collaborations or other external opportunities:

Compound	Principal Targets	Indication	Stage of Development
XL228	IGF1R , ABL, SRC	Cancer	Phase 1
XL388	TORC1 & 2	Cancer	IND
XL541	S1P1R (antagonist)	Cancer	Preclinical
XL475	TGR5	Metabolic disease	Preclinical

**Certain Factors Important to Understanding Our Financial Condition and Results of Operations**

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. Our financial performance is driven by many factors, including those described below.

**Limited Sources of Revenues**

We currently have no pharmaceutical products that have received marketing approval, and we have generated no revenues to date from the sale of such products. We do not expect to generate 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, license fees and milestone payments and royalty revenues, will be generated from collaboration agreements with our current and potential future 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.

**Clinical Trials**

## Edgar Filing: GENTEX CORP - Form 5

We currently have multiple compounds in clinical development and expect to expand the development programs for our compounds. 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 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 in clinical development, whereas expenses will end for compounds that do not warrant further clinical development.

---

## **Table of Contents**

We are responsible for all development costs for compounds in our pipeline that are not partnered and for a portion of development costs for those compounds that we are co-developing with partners. We share development costs with partners in our co-development collaborations and have no unreimbursed cost obligations with respect to compounds that we have out-licensed. We expect that over the next several years an increasingly greater portion of our development expenses will be funded by our partners.

### ***Liquidity***

As of March 31, 2010, we had \$168.5 million in cash and cash equivalents and short-term and long-term marketable securities, which included restricted cash and investments of \$6.4 million. We anticipate that our current cash and cash equivalents, short-term and long-term marketable securities and funding that we expect to receive from collaborators, which includes anticipated cash from additional 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 following:

whether we repay amounts outstanding under our loan and security agreement with GlaxoSmithKline (described below) in cash or shares of our common stock;

the progress and scope of the development activity with respect to XL184, our most advanced compound;

the progress and scope of other research and development activities conducted by us;

the level of payments received under existing collaboration agreements, licensing agreements and other arrangements;

the degree to which we conduct funded development activity on behalf of partners to whom we have out-licensed compounds; and

our ability to enter into new collaboration agreements, licensing agreements and other arrangements that provide additional payments.

Our minimum liquidity needs are also determined by financial covenants in our loan and security agreement, as amended, with GlaxoSmithKline and our collaboration agreement with Bristol-Myers Squibb for XL184, as well as other factors, which are described under **Liquidity and Capital Resources** **Cash Requirements** .

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.

### ***sanofi-aventis***

In May 2009, we entered into a global license agreement with sanofi-aventis for XL147 and XL765 and a broad collaboration for the discovery of inhibitors of PI3K for the treatment of cancer. The license agreement and collaboration agreement became effective on July 7, 2009. In connection with the effectiveness of the license and collaboration on July 20, 2009, we received upfront payments of \$140.0 million (\$120.0 million for the license and \$20.0 million for the collaboration), less applicable withholding taxes of \$7.0 million, for a net receipt of \$133.0 million. We expect to receive a refund payment from the French government in 2010 with respect to the withholding taxes previously withheld.

Under the license agreement, sanofi-aventis received a worldwide exclusive license to XL147 and XL765, which are currently in phase 1, phase 1b/2 and phase 2 clinical trials, and has sole responsibility for all subsequent clinical, regulatory, commercial and manufacturing activities. It is expected that we will continue to participate in the conduct of ongoing and potential future clinical trials and manufacturing activities.

Sanofi-aventis is responsible for funding all future development activities with respect to XL147 and XL765, including our activities. Under the collaboration agreement, the parties are combining efforts in establishing several pre-clinical PI3K programs and jointly share responsibility for research and preclinical activities related to isoform-selective inhibitors of PI3K- $\alpha$  and - $\beta$ . Sanofi-aventis will provide us with guaranteed annual

## Edgar Filing: GENTEX CORP - Form 5

research and development funding during the research term and is responsible for funding all development activities for each product following approval of the investigational new drug application filed with the applicable regulatory authorities for such product. Sanofi-aventis will have sole responsibility for all subsequent clinical, regulatory, commercial and manufacturing activities of any products arising from the collaboration; however, we may be requested to conduct certain clinical trials at sanofi-aventis expense. The research term under the collaboration is three years, although sanofi-aventis has the right to extend the term for an additional one-year period upon prior written notice.

In addition to the aggregate upfront cash payments for the license and collaboration agreements, we are entitled to receive guaranteed research funding of \$21.0 million over three years to cover certain of our costs under the collaboration agreement. For both the license and the collaboration combined, we will be eligible to receive development, regulatory and commercial milestones of over \$1.0 billion in the aggregate, as well as royalties on sales of any products commercialized under the license or collaboration.

**Table of Contents**

Sanofi-aventis may, upon certain prior notice to us, terminate the license as to products containing XL147 or XL765. In the event of such termination election, sanofi-aventis' license relating to such product would terminate and revert to us, and we would receive, subject to certain terms, conditions and potential payment obligations, licenses from sanofi-aventis to research, develop and commercialize such products.

The collaboration will automatically terminate under certain circumstances upon the expiration of the research term, in which case all licenses granted by the parties to each other would terminate and revert to the respective party, subject to sanofi-aventis' right to receive, under certain circumstances, the first opportunity to obtain a license from us to any isoform-selective PI3K inhibitor. In addition, sanofi-aventis may, upon certain prior written notice to us, terminate the collaboration in whole or as to certain products following expiration of the research term, in which case we would receive, subject to certain terms, conditions and potential payment obligations by us, licenses from sanofi-aventis to research, develop and commercialize such products.

***2008 Cancer Collaboration with Bristol-Myers Squibb***

In December 2008, we entered into a worldwide collaboration with Bristol-Myers Squibb for XL184 and XL281. Upon effectiveness of the agreement in December 2008, Bristol-Myers Squibb made an upfront cash payment of \$195.0 million for the development and commercialization rights to both programs. The agreement required Bristol-Myers Squibb to make additional license payments to us of \$45.0 million, which were received during 2009.

We and Bristol-Myers Squibb have agreed to co-develop XL184, and potentially a backup program for XL184. The companies will share worldwide (except for Japan) development costs for XL184. We are responsible for 35% of such costs and Bristol-Myers Squibb is responsible for 65% of such costs, except that we are responsible for funding the initial \$100.0 million of combined costs and have the option to defer payments for development costs above certain thresholds. We expect that we will complete our required funding of the initial \$100.0 million of the combined costs during the second quarter of 2010, after which we will be responsible for 35% of the combined costs going forward. In return, we will share 50% of the commercial profits and losses (including pre-launch commercialization expenses) in the United States and have the option to co-promote XL184 in the United States. Bristol-Myers Squibb is responsible for all costs intended to support regulatory approval in Japan. We have the right to defer payment for certain early commercialization and other related costs above certain thresholds. We are eligible to receive sales performance milestones of up to \$150.0 million and double-digit royalties on sales on XL184 outside the United States. The clinical development of XL184 is directed by a joint committee. It is anticipated that we will continue to conduct certain clinical development activities for XL184. We may opt out of the co-development for XL184, in which case we would instead be eligible to receive development and regulatory milestones of up to \$295.0 million, double-digit royalties on XL184 product sales worldwide and sales performance milestones. Our co-development and co-promotion rights may be terminated in the event that we have cash reserves below \$80.0 million and we are unable to increase such cash reserves to \$80.0 million or more within 90 days, in which case we would receive development and regulatory milestones, sales milestones and double-digit royalties, instead of sharing product profits on XL184 in the United States. For purposes of the agreement, cash reserves includes our total cash, cash equivalents and investments (excluding any restricted cash), plus the amount then available for borrowing by us under certain financing arrangements. Our co-promotion rights on XL184 in the United States, and possibly our right to share product profits on XL184, may be terminated in the event we undergo certain change of control transactions. Bristol-Myers Squibb may, upon certain prior notice to us, terminate the agreement as to products containing XL184 or XL281. 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 such products.

Bristol-Myers Squibb received an exclusive worldwide license to develop and commercialize XL281. We will carry out certain clinical trials of XL281 which may include a backup program on XL281. Bristol-Myers Squibb is responsible for funding all future development of XL281, including our activities. We are eligible for development and regulatory milestones of up to \$315.0 million on XL281, sales performance milestones of up to \$150.0 million and double-digit royalties on worldwide sales of XL281.

The upfront payment of \$195.0 million we received upon effectiveness of the collaboration agreement and the license payments of \$20.0 million and \$25.0 million that we received in the first quarter and second quarter of 2009, respectively, will be recognized ratably over the estimated development term of five years, and recorded as license revenue, from the effective date of the agreement in December 2008. Any milestone payments that we may receive under the agreement will be recognized ratably over the same period but will be recorded as contract revenue. We will record as operating expense 100% of the cost incurred for work performed by us on the two programs. During the term of the collaboration, so long as we have not opted out of the co-development of XL184, there may be periods during which Bristol-Myers Squibb will partially reimburse us for certain research and development expenses, and other periods during which we will owe Bristol-Myers Squibb for research and development expenses that Bristol-Myers Squibb incurred on joint development projects, less amounts reimbursable to us by Bristol-Myers Squibb on these projects. To the extent that net research and development funding payments are received from Bristol-Myers Squibb, these payments will be presented as collaboration revenue. In periods when net research and development funding payments are payable to Bristol-Myers Squibb, these payments will be presented as collaboration cost sharing expense. Net amounts due from or payable to Bristol-Myers Squibb will be





---

**Table of Contents**

determined and reflected on an annual basis. As we expect to have fulfilled our responsibility for funding the initial \$100.0 million of combined costs in the second quarter of 2010, we expect aggregate collaboration reimbursements during the fiscal year ended December 31, 2010. Generally, the direction of cash flows will depend on the level of development activity by either party, which may change during the development term. Our capital requirements will be impacted by the level of our expenses for the development activity conducted by us and the degree to which we will be required to make payments to, or we will receive payments from, Bristol-Myers Squibb. If we opt out of the co-development of XL184, we would have no further unreimbursed cost obligations with respect to that compound.

***GlaxoSmithKline Loan Repayment Obligations***

In October 2002, we entered into a collaboration with GlaxoSmithKline to discover and develop novel therapeutics in the areas of vascular biology, inflammatory disease and oncology. As part of the collaboration, we entered into a loan and security agreement with GlaxoSmithKline, pursuant to which we borrowed \$85.0 million for use in our efforts under the collaboration. The loan bears interest at a rate of 4.0% per annum and is secured by certain intellectual property, technology and equipment created or utilized pursuant to the collaboration. As of March 31, 2010, the aggregate principal and interest outstanding under our GlaxoSmithKline loan was \$71.4 million, after giving effect to a cash payment we made to GlaxoSmithKline of \$34.7 million on October 27, 2009 for the first of three annual installments of principal and accrued interest due under the loan. The second and third installments of principal and accrued interest under the loan are due on October 27, 2010 and October 27, 2011, respectively. Repayment of all or any of the amounts advanced to us under the loan agreement may, at our election, be made in the form of our common stock at fair market value, subject to certain conditions, or cash. Following the conclusion on October 27, 2008 of the development term under our collaboration with GlaxoSmithKline, we are no longer eligible to receive selection milestone payments from GlaxoSmithKline to credit against outstanding loan amounts, and in the event the market price for our common stock is depressed, we may not be able to repay the loan in full using shares of our common stock due to restrictions in the agreement on the number of shares we may issue. In addition, the issuance of shares of our common stock to repay the loan may result in significant dilution to our stockholders. As a result, we may need to obtain additional funding to satisfy our repayment obligations. There can be no assurance that we will have sufficient funds to repay amounts outstanding under the loan when due or that we will satisfy the conditions to our ability to repay the loan in shares of our common stock.

During 2010, we may pursue a potential refinancing of the GlaxoSmithKline loan with a third party, although there can be no assurance that we would be able to do so on terms that are acceptable to us, if at all.

***Critical Accounting Estimates***

Our consolidated financial statements and related notes are prepared in accordance with U.S. generally accepted accounting principles, or GAAP, which require 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***

Our revenues are derived from three primary sources: license fees, milestone payments and collaborative agreement reimbursements.

Revenues from license fees and milestone payments primarily consist of up-front license fees and milestone payments received under various collaboration agreements. We initially recognize upfront fees received from third party collaborators as unearned revenue and then recognize these amounts on a ratable basis over the expected term of the research collaboration. Often, the total research term is not contractually defined and an estimate of the term of our total obligation must be made. For example, under the 2008 cancer collaboration with Bristol-Myers Squibb, we have estimated our term to be five years, or through the completion of phase 3 trials. We estimate that this is the longest possible period that we could be obligated to perform services and therefore the appropriate term with which to amortize any license fees. However, if we submit an NDA earlier than anticipated, or Bristol-Myers Squibb decides to take over management of trials prior to their completion, the estimated term of our obligation would be shortened, resulting in an increase in revenue recognition in the period in which our estimated term changes. For example, in the first quarter of 2010, the



**Table of Contents**

estimated research term under the Boehringer Ingelheim agreement was extended through September 2010, resulting in an extension in the period over which we will recognize license revenue and decreasing our license revenue recognized in the period to \$1.4 million. License fees are classified as license revenue in our consolidated statement of operations.

Although milestone payments are generally non-refundable once the milestone is achieved, we recognize milestone revenues on a straight-line basis over the expected research term of the arrangement. This typically results in a portion of a milestone being recognized on the date the milestone is achieved, with the balance being recognized over the remaining research term of the agreement. There is diversity in practice on the recognition of milestone revenue. Other companies have adopted an alternative 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. Milestones are classified as contract revenue in our consolidated statement of operations.

Collaborative agreement reimbursement revenue consists of research and development support received from collaborators. Collaborative agreement reimbursement revenue is recorded as earned based on the performance requirements by both parties under the respective contracts. Under the 2008 cancer collaboration with Bristol-Myers Squibb, certain research and development expenses are partially reimbursable to us. On an annual basis, the amounts that Bristol-Myers Squibb owes us, net of amounts reimbursable to Bristol-Myers Squibb by us on those projects, are recorded as revenue. Conversely, research and development expenses may include the net settlement of amounts we owe Bristol-Myers Squibb for research and development expenses that Bristol-Myers Squibb incurred on joint development projects, less amounts reimbursable to us by Bristol-Myers Squibb on these projects. In annual periods when net research and development funding payments are payable to Bristol-Myers Squibb, these payments will be presented as collaboration cost-sharing expense. Reimbursements under co-development agreements are classified as collaboration reimbursements while reimbursements under other arrangements are classified as contract revenue in our consolidated statement of operations.

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 intellectual property rights and research and development services. Multiple element revenue agreements are evaluated 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 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. In 2008, under our collaboration with GlaxoSmithKline, we accelerated \$18.5 million in previously deferred revenue as a result of the development term concluding on the earliest scheduled end date of October 27, 2008, instead of the previously estimated end date of October 27, 2010.

***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.

***Stock Option Valuation***

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.



**Table of Contents**

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 March 31, 2010, \$25.4 million of total unrecognized compensation expense related to stock options was expected to be recognized over a weighted-average period of 1.92 years in addition to \$13.4 million of total unrecognized compensation expense relating to RSUs, which was expected to be recognized over 3.87 years. See Note 3 to the Consolidated Financial Statements for a further discussion on stock-based compensation.

**Restructuring Charges**

We record costs and liabilities associated with exit and disposal activities at fair value in the period in which the cost or liability is incurred. Restructuring charges consist of charges related to employee severance and benefits, lease termination costs, equipment write-downs and other restructuring related charges. Charges related to employee severance and benefits are determined based on the estimated severance and fringe benefit charge for identified employees. Our facility charges are based upon our ability to vacate certain of our facilities and the timing and nature of potential future sublease rates. Based on our future equipment needs, we have disposed of certain assets no longer in use and recorded a charge to impair the book value to an amount relative to our expected future use of the remaining assets.

If the actual amounts differ from our estimates, the amount of restructuring charges could be materially impacted. See Note 5 to the Consolidated Financial Statements for a further discussion on our restructuring plan.

**Fiscal Year Convention**

We have adopted a 52- or 53-week fiscal year that ends on the Friday closest to December 31<sup>st</sup> of each year. Fiscal year 2009, a 52-week year, ended on January 1, 2010, and fiscal year 2010, a 52-week year, will end on December 31, 2010. For convenience, references in this report as of and for the fiscal year ended January 1, 2010 are indicated on a calendar year basis, ended December 31, 2009, and as of and for the fiscal quarters ended April 3, 2009 and April 2, 2010 are indicated as ended March 31, 2009 and 2010, respectively.

**Results of Operations****Revenues**

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

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
Contract revenue:		
Research and development funding	\$ 11.1	\$ 2.0
Milestones	8.6	4.7
License revenue, amortization of upfront payments, including amortization of premiums for equity purchases	24.6	18.6
Collaboration reimbursements	(2.1)	
Total revenues	\$ 42.2	\$ 25.3
Dollar increase	\$ 16.9	
Percentage increase	67%	



**Table of Contents**

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

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
sanofi-aventis	\$ 19.7	\$
Bristol-Myers Squibb	14.1	20.6
Genentech	7.0	4.2
GlaxoSmithKline		0.5
Boehringer Ingelheim	1.4	
Total revenues	\$ 42.2	\$ 25.3
Dollar increase	\$ 16.9	
Percentage increase	67%	

The increase in revenues for the three months ended March 31, 2010, as compared to the comparable period for the prior year, was primarily due to our May 2009 collaboration agreements with sanofi-aventis for XL147, XL765 and the discovery of inhibitors of P13K. In addition to the increase from sanofi-aventis, we also recognized increases of \$5.2 million in milestone revenue related to our MEK collaboration with Genentech and \$1.4 million in revenue from our May 2009 collaboration with Boehringer Ingelheim. These increases in revenue were partially offset by a reduction in revenues related to our 2007 cancer collaboration with Bristol-Myers Squibb Company and the completion of revenue recognition under our LXR collaboration with Bristol-Myers Squibb Company.

Total collaboration reimbursements consist of research and development expenses and reimbursements related to our 2008 cancer collaboration agreement with Bristol Myers-Squibb for XL184 and XL281. To the extent that net annual research and development funding payments are expected to be received from Bristol-Myers Squibb, these payments will be presented as collaboration reimbursement. In years when net research and development funding payments are expected to be payable to Bristol-Myers Squibb, these payments will be presented as collaboration cost sharing expense. For the year ending December 31, 2010, we expect to receive net collaboration reimbursement revenues. However, for the three months ended March 31, 2010, we recorded a net payable to Bristol-Myers Squibb, resulting in negative revenues of \$2.1 million. For the three months ended March 31, 2009, we recorded a net receivable from Bristol-Myers Squibb of \$1.8 million, which was included in operating expenses.

**Research and Development Expenses**

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

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
Research and development expenses	\$ 64.8	\$ 55.3
Dollar increase	\$ 9.4	
Percentage increase	17%	

Research and development expenses consist primarily of personnel expenses, clinical trials, consulting, laboratory supplies and facilities costs. The increase for the three months ended March 31, 2010, as compared to the comparable period in 2009, resulted primarily from the following:

**Clinical Trials** Clinical trial expenses, which include services performed by third-party contract research organizations and other vendors, increased by \$9.4 million, or 69%, primarily due to the increase in phase 3 clinical trial activity for XL184 and increased clinical trial activity for XL147 and XL388. These increases were partially offset by the wind down of activities associated with XL647 and XL019 and reduced activities associated with XL281, XL765 and XL888, as well as no 2010 activity for XL518 and XL999.



## Edgar Filing: GENTEX CORP - Form 5

**Personnel** Personnel expense, which includes salaries, bonuses, related fringe benefits, recruiting and relocation costs, decreased by \$1.3 million, or 7%, primarily due to a reduction in headcount related to our restructuring implemented in March 2010.

**Cost Reimbursement** Under our 2007 contract research agreement with Agrigenetics, Inc., we received additional research and development funding of \$1.6 million that was recognized as a reduction to research and development expense in 2009. This agreement ended in 2009, resulting in a reduction in reimbursement of \$1.4 million, or 83%. The 2010 research and development funding relates to our agreement with Diana Ingredients in regards to the Exelixis Plant Science business.

**Table of Contents**

We do not track total research and development expenses separately for each of our research and development programs. We group our research and development expenses into three categories: drug discovery, development and other. Our drug discovery group utilizes 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 clinical development. Drug discovery expenses relate primarily to personnel expense, lab supplies and general corporate costs. Our development group leads the development and implementation of our clinical and regulatory strategies and prioritizes disease indications in which our compounds may be studied in clinical trials. Development expenses relate primarily to clinical trial, personnel and general corporate costs. The other category primarily includes stock compensation expense.

In addition to reviewing the three categories of research and development expenses described above, we principally consider qualitative factors in making decisions regarding our research and development programs. Such factors include enrollment in clinical trials for our drug candidates, the results of and data from clinical trials, the potential indications for our drug candidates and the clinical and commercial potential for our drug candidates and competitive dynamics. We also make our research and development decisions in the context of our overall business strategy, which includes the pursuit of commercial collaborations with major pharmaceutical and biotechnology companies for the development of our drug candidates.

The expenditures summarized in the following table reflect total research and development expenses by category, including allocations for general and administrative expense (dollar amounts are presented in millions):

	<b>Three Months Ended March 31,</b>		<b>Inception</b>
	<b>2010</b>	<b>2009</b>	<b>to date (1)</b>
Drug discovery	\$ 20.6	\$ 23.4	\$ 405.1
Development	39.4	27.4	477.5
Other	4.8	4.5	85.2
Total	\$ 64.8	\$ 55.3	\$ 967.8

(1) Inception is as of January 1, 2006, the date on which we began tracking research and development expenses by category.

While we do not track total research and development expenses separately for each program, beginning in fiscal 2006, we began tracking third party expenditures directly relating to each program as a way of monitoring external costs. Our third party research and development expenditures relate principally to our clinical trial and related development activities, such as preclinical and clinical studies and contract manufacturing, and represent only a portion of the costs related to each program. Third party expenditures for programs initiated prior to the beginning of fiscal 2006 have not been tracked from project inception, and therefore such expenditures from the actual inception for most of our programs are not available. We do not accumulate on a program-specific basis internal research and development expenses, such as salaries and personnel expenses, facilities overhead expenses and external costs not directly attributable to a specific project. Nevertheless, we believe that third party expenditures by program provide a reasonable estimate of the percentage of our total research and development expenses that are attributable to each such program. For the three months ended March 31, 2010, the programs representing the greatest portion of our external third party research and development expenditures were XL184 (68%), XL147 (15%), XL765 (4%), XL281 (4%) and XL228 (3%). The expenses for these programs were primarily included in the development category of our research and development expenses and exclude the impact of any amounts reimbursed by our partners.

We currently do not have reliable estimates regarding the timing of our 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 drug candidate, the clinical trial design and the ability to enroll suitable patients. In general, we will incur increased research and development expenses for compounds that advance in clinical development, whereas expenses will end for compounds that do not warrant further clinical 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.

**Table of Contents****General and Administrative Expenses**

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

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
General and administrative expenses	\$ 8.8	\$ 8.5
Dollar increase	\$ 0.3	
Percentage increase	4%	

General and administrative expenses consist primarily of personnel expenses, employee stock-based compensation expense, facility costs and consulting and professional expenses, such as legal and accounting fees. The increase in expenses for the three months ended March 31, 2010, as compared to the comparable period in 2009, was primarily due to small increases in legal and personnel costs offset by decreases in facility costs.

**Collaboration Cost-Sharing Reimbursements (Expenses)**

Total collaboration cost-sharing reimbursements (expenses), as compared to the prior year period, were as follows (dollar amounts are presented in millions):

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
Collaboration cost-sharing reimbursement (expenses)	\$ (2.1)	\$ 1.8
Dollar change	\$ (3.9)	
Percentage change	(217)%	

Total collaboration reimbursements (expenses) consist of research and development expenses and reimbursements related to our 2008 cancer collaboration agreement with Bristol Myers-Squibb for XL184 and XL281. To the extent that net annual research and development funding payments are expected to be received from Bristol-Myers Squibb, these payments will be presented as collaboration reimbursement. In years when net research and development funding payments expected to be payable to Bristol-Myers Squibb, these payments will be presented as collaboration cost sharing expense. For the year ending December 31, 2010, we expect to incur net reimbursements. However, for the three months ended March 31, 2010, we recorded a net payable to Bristol-Myers Squibb, resulting in negative revenues of \$2.1 million. For the three months ended March 31, 2009, we recorded a net receivable from Bristol-Myers Squibb of \$1.8 million, which was included in operating expense.

**Restructuring Charge**

On March 8, 2010, we implemented a restructuring plan that resulted in a reduction of our workforce by approximately 40%, or 270 employees. Approximately 5% of these employees will continue to provide services through December 31, 2010 while the remainder of the employees were terminated immediately or by the end of March 31, 2010. The decision to restructure our operations was based on our recently announced corporate strategy to focus our efforts on our lead clinical compounds, XL184, XL147 and XL765, by dedicating the majority of our resources to aggressively drive these drug candidates through development towards commercialization.

In connection with the 2010 restructuring plan, we recorded a charge of approximately \$16.1 million in the first quarter of 2010 primarily related to one-time termination benefits, which includes the modification of certain stock option awards previously granted to the terminated employees. The modification accelerates the vesting of any stock options that would have vested over the period beginning from cessation of employment through August 5, 2010. Employees who were terminated immediately also received an additional two months to exercise their options, for which a small charge was taken. The remainder of the charge was for the impairment of various assets and for non-cash charges relating to the closure of our facility in San Diego, California. We expect further restructuring expenses of approximately \$9.0 million during 2010 associated primarily with facility-related charges in connection with the anticipated sublease and exit of one of our buildings in South San Francisco, California.

The additional estimated \$9.0 million charge that we expect to incur in connection with the restructuring is subject to a number of assumptions, and actual results may materially differ. For example, the estimate for sublease income is based upon significant assumptions including signing a

## Edgar Filing: GENTEX CORP - Form 5

definitive sublease agreement and the timing for exiting the facility. If we are unable to sign a definitive agreement or the timing to exit the South San Francisco building changes, then we would need to update the estimate of the lease exit costs in our financial statements.

We expect that the restructuring plan will result in total cash expenditures of approximately \$25.0 million, of which approximately \$15.0 million is expected to be paid in 2010. The balance will be paid out over an additional five years and primarily relates to payments due under the lease for the building we plan to exit in South San Francisco.

**Table of Contents****Total Other Income (Expense), Net**

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

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
Total other income (expense), net	\$ 4.2	\$ (1.6)
Dollar change	\$ 5.8	
Percentage change	369%	

Total other income (expense), net consists primarily of interest income earned on our marketable securities and gains on asset sales, offset by interest expense incurred on our notes payable, bank obligations, capital lease obligations, convertible notes and loans and credit facility. The change in total other income for the three months ended March 31, 2010, as compared to the comparable period in 2009, was primarily due to a gain of \$4.5 million on the sale of our plant trait business and decreased interest expense of \$1.5 million resulting primarily from the November 2009 termination of our credit facility with Deerfield Private Design Fund, L.P., Deerfield Private Design International, L.P., Deerfield Partners, L.P. and Deerfield International Limited.

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

In 2005, we licensed three of our compounds, XL647, XL784 and XL999, to Symphony Evolution, Inc., or SEI, in return for an \$80.0 million investment for the clinical development of these compounds. As part of the agreement, we received 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. The purchase option expired on June 9, 2009. The expiration of the purchase option triggered a reconsideration event regarding our need to consolidate SEI, a variable interest entity. Upon the expiration of the purchase option, we no longer held a variable interest in the variable interest entity. Accordingly, we deconsolidated SEI and derecognized the SEI assets, liabilities and noncontrolling interest from our financial statements. For the three months ended March 31, 2010 and 2009, the losses attributed to the noncontrolling interest holders were zero and \$2.2 million, respectively. The decrease in the losses attributable to noncontrolling interest holders were due to the deconsolidation of SEI in June 2009.

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

The following table summarizes our cash flow activities for the three months ended March 31, 2010 and 2009, respectively (dollar amounts presented in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
Consolidated net loss	\$ (43,249)	\$ (38,336)
Adjustments to reconcile net loss to net cash provided by operating activities	8,510	8,734
Changes in operating assets and liabilities	(19,000)	(12,525)
Net cash used in operating activities	(53,739)	(42,127)
Net cash provided by (used in) investing activities	27,611	(218)
Net cash used in financing activities	(2,376)	(3,928)
Net decrease in cash and cash equivalents	(28,504)	(46,273)
Cash and cash equivalents, at beginning of period	86,796	247,698
Cash and cash equivalents, at end of period	\$ 58,292	\$ 201,425

To date, we have financed our operations primarily through the sale of equity, payments and loans from collaborators and equipment financing facilities. We have also financed certain of our research and development activities under our agreements with SEI. As of March 31, 2010, we

## Edgar Filing: GENTEX CORP - Form 5

had \$168.5 million in cash and cash equivalents and short-term and long-term marketable securities which included restricted cash and investments of \$6.4 million. In addition, as of March 31, 2010, approximately \$20.4 million of cash and cash equivalents and marketable securities served as collateral for bank lines of credit.

---

**Table of Contents***Operating Activities*

Our operating activities used cash of \$53.7 million for the three months ended March 31, 2010, compared to cash used of \$42.1 million for the comparable period in 2009. Cash used by operating activities for the 2010 period related primarily to our net loss attributable to Exelixis, Inc. of \$43.2 million, in addition to a \$26.4 million reduction in deferred revenue and an increase in current assets of \$3.4 million. These increases in cash used were partially offset by non-cash charges totaling \$12.1 million relating to stock-based compensation and depreciation and amortization and asset impairment as a result of our restructuring. In addition, we had increases in our accrued liabilities relating to our March 2010 restructuring and decreases in our receivables balance relating to our collaboration partners. Cash used by operating activities for the 2009 period related primarily to our net loss attributable to Exelixis, Inc. of \$38.3 million, in addition to \$12.6 million of cash used as the result of increases in other receivables and decreases in accounts payable and other accrued expenses and deferred revenue. These increases in cash used were partially offset by non-cash charges totaling \$8.4 million relating to stock-based compensation and depreciation and amortization. We expect an increase in cash used in the period ending July 2, 2010 as a result of our restructuring activities as we pay out the majority of the one-time severance benefits in this period.

Cash used in our operating activities increased by \$11.6 million for the three months ended March 31, 2010 as compared to the comparable period in 2009. The increase was primarily driven by an increase in net loss attributable to Exelixis, Inc. of \$4.9 million as a result of our March 2010 restructuring and a reduction in deferred revenue. The decrease in deferred revenue relates principally to the ratable recognition of deferred revenues over the period of continuing involvement from our various collaborations.

*Investing Activities*

Our investing activities provided cash of \$27.6 million for the three months ended March 31, 2010, compared to cash used of \$0.2 million for the comparable period in 2009. Cash provided by investing activities for the 2010 period was primarily driven by proceeds from the maturity of marketable securities of \$34.0 million in addition to the sale of investments prior to maturity of \$12.8 million and an additional gain of \$4.5 million associated with our 2007 transaction with Agrigenetics. These cash proceeds were offset by the purchase of \$23.6 million of marketable securities and additional purchases of property and equipment of \$0.3 million. The proceeds provided by the sale and maturity of our investments were used to fund our operations.

Cash used by investing activities for the 2009 period was primarily driven by proceeds of \$2.2 million from the sale on investments held by SEI and proceeds of \$2.9 million from the maturity of long term investments. This cash inflow was offset by purchases of \$4.0 million of marketable securities, a decrease in restricted cash and investments of \$0.8 million, and purchases of property and equipment of \$0.4 million. The proceeds provided by the sale and maturity of our investments were used to fund our operations. We expect to continue to make moderate investments in property and equipment to support our operations.

*Financing Activities*

Our financing activities used cash of \$2.4 million for the three months ended March 31, 2010, compared to cash used of \$3.9 million for the comparable period in 2009. Cash used by our financing activities for the 2010 period was due to principal payments on notes payable and bank obligations of \$3.2 million offset by proceeds from employee option exercises of \$0.9 million. Cash used by our financing activities for the 2009 period was due to principal payments on notes payable and bank obligations of \$3.9 million.

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 and other general corporate purposes. Over the next several years, we are required to make certain payments on notes, bank obligations and our loan from GlaxoSmithKline.

*Cash Requirements*

We have incurred net losses since inception, including a net loss attributable to Exelixis, Inc. of \$43.2 million for the three months ended March 31, 2010. We expect our net loss to increase and anticipate negative operating cash flow for the foreseeable future. As March 31, 2010, we had \$168.5 million in cash and cash equivalents and short-term and long-term marketable securities, which included restricted cash and investments of \$6.4 million. We anticipate that our current cash and cash equivalents, short-term and long-term marketable securities and funding that we expect to receive from collaborators, which includes anticipated cash from additional 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:



repayment of our loan from GlaxoSmithKline In October 2002, we entered into a collaboration with GlaxoSmithKline, to discover and develop novel therapeutics in the areas of vascular biology, inflammatory disease and oncology. As part of the collaboration, we entered into a loan and security agreement with GlaxoSmithKline, pursuant to which we borrowed \$85.0 million for use in our efforts under the collaboration. The loan bears interest at a rate of 4.0% per annum and is secured by certain intellectual property, technology and equipment created or utilized pursuant to the collaboration. As of March 31, 2010, the aggregate principal and interest outstanding under our GlaxoSmithKline loan was \$71.4 million, after giving effect to a cash payment we made to GlaxoSmithKline of \$34.7 million on October 27, 2009 for the first of three annual installments of principal and accrued interest due under the loan. The second and third installments of principal

---

**Table of Contents**

and accrued interest under the loan are due on October 27, 2010 and October 27, 2011, respectively. Repayment of all or any of the amounts advanced to us under the loan agreement may, at our election, be made in the form of our common stock at fair market value, subject to certain conditions, or cash. Following the conclusion on October 27, 2008 of the development term under our collaboration with GlaxoSmithKline, we are no longer eligible to receive selection milestone payments from GlaxoSmithKline to credit against outstanding loan amounts, and in the event the market price for our common stock is depressed, we may not be able to repay the loan in full using shares of our common stock due to restrictions in the agreement on the number of shares we may issue. In addition, the issuance of shares of our common stock to repay the loan may result in significant dilution to our stockholders. As a result, we may need to obtain additional funding to satisfy our repayment obligations. There can be no assurance that we will have sufficient funds to repay amounts outstanding under the loan when due or that we will satisfy the conditions to our ability to repay the loan in shares of our common stock. During 2010, we may pursue a potential refinancing of the GlaxoSmithKline loan with a third party, although there can be no assurance that we would be able to do so on terms that are acceptable to us, if at all;

the progress and scope of the development activity with respect to XL184, our most advanced compound We are focusing our development efforts on XL184, which is being studied in a variety of tumor types, with the goal of rapidly commercializing the compound. As described under Certain Factors Important to Understanding Our Financial Condition and Results of Operations 2008 Cancer Collaboration with Bristol-Myers Squibb, we entered into a worldwide co-development collaboration with Bristol-Myers Squibb for the development and commercialization of XL184. The companies will share worldwide (except for Japan) development costs for XL184. We are responsible for 35% of such costs and Bristol-Myers Squibb is responsible for 65% of such costs, except that we are responsible for funding the initial \$100.0 million of combined costs and have the option to defer payments for development costs above certain thresholds. In return, we will share 50% of the commercial profits and losses (including pre-launch commercialization expenses) in the United States and have the option to co-promote XL184 in the United States. Bristol-Myers Squibb is responsible for all costs intended to support regulatory approval in Japan. We have the right to defer payment for certain early commercialization and other related costs above certain thresholds. During the term of the collaboration, so long as we have not opted out of the co-development of XL184, there may be periods during which Bristol-Myers Squibb will partially reimburse us for certain research and development expenses, and other periods during which we will owe Bristol-Myers Squibb for research and development expenses that Bristol-Myers Squibb incurred on joint development projects, less amounts reimbursable to us by Bristol-Myers Squibb on these projects. On an annual basis, to the extent that net research and development funding payments are received from Bristol-Myers Squibb, these payments will be presented as collaboration revenue. In annual periods when net research and development funding payments are payable to Bristol-Myers Squibb, these payments will be presented as collaboration cost sharing expense. Generally, the direction of cash flows will depend on the level of development activity by either party, which may change during the development term. Our capital requirements will be impacted by the level of our expenses for the development activity conducted by us and the degree to which we will be required to make payments to, or we will receive payments from, Bristol-Myers Squibb. If we opt out of the co-development of XL184, we would have no further unreimbursed cost obligations for that compound;

the progress and scope of other research and development activities conducted by us;

the level of payments received under existing collaboration agreements, licensing agreements and other arrangements;

the degree to which we conduct funded development activity on behalf of partners to whom we have out-licensed compounds;

our ability to enter into new collaboration agreements, licensing agreements and other arrangements that provide additional payments;

our ability to control costs;

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

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

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;

**Table of Contents**

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

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

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 seek to raise funds through the sale of equity or debt securities or through external borrowings. In addition, we may enter into additional strategic partnerships or collaborative arrangements for the development and commercialization of our compounds. 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 may need to obtain additional funding in order to stay in compliance with financial covenants contained in agreements with third parties. For example, our loan and security agreement with GlaxoSmithKline contains financial covenants pursuant to which our working capital (the amount by which our current assets exceed our current liabilities as defined by the agreement, which excludes restricted cash and deferred revenue) 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 March 31, 2010, our working capital was \$69.0 million and our cash and investments were \$162.0 million. If we default on the financial covenants under the loan and security agreement, GlaxoSmithKline may, among other remedies, declare immediately due and payable all obligations under the loan and security agreement. Outstanding borrowings and accrued interest under the loan and security agreement totaled \$71.4 million at March 31, 2010. The second and third installments of principal and accrued interest under the loan are due on October 27, 2010 and October 27, 2011, respectively. In addition, if our cash reserves fall below \$80.0 million and we are unable to increase such cash reserves to \$80.0 million or more within 90 days, our co-development and co-promotion rights with respect to XL184 under our 2008 collaboration agreement with Bristol-Myers Squibb may be terminated. Cash reserves for purposes of our 2008 collaboration agreement with Bristol-Myers Squibb includes our total cash, cash equivalents and investments (excluding any restricted cash), plus the amount then available for borrowing by us under certain financing arrangements. As of March 31, 2010, our cash reserves were \$162.0 million. 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.

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

Our market risks at March 31, 2010 have not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2009, filed with the Securities and Exchange Commission on March 10, 2010. Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio and our long-term debt. We have estimated the effects on our interest rate sensitive assets and liabilities based on a one percentage point hypothetical adverse change in interest rates as of March 31, 2010 and December 31, 2009, respectively. As of March 31, 2010 and December 31, 2009, 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 \$0.3 million and \$0.3 million, respectively.

**ITEM 4. CONTROLS AND PROCEDURES**

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

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

---

**Table of Contents**

**PART II. OTHER INFORMATION**

**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.*

*We have marked with an asterisk (\*) those risk factors below that reflect substantive changes from the risk factors included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2009 filed with the Securities and Exchange Commission on March 10, 2010.*

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

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

We will need to raise additional capital to:

fund our operations and clinical trials;

continue our research and development efforts; and

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

As of March 31, 2010, we had \$168.5 million in cash and cash equivalents and short-term and long-term marketable securities, which included restricted cash and investments of \$6.4 million. We anticipate that our current cash and cash equivalents, short-term and long-term marketable securities and funding that we expect to receive from collaborators, which includes anticipated cash from additional 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:

repayment of our loan from GlaxoSmithKline In October 2002, we entered into a collaboration with GlaxoSmithKline, to discover and develop novel therapeutics in the areas of vascular biology, inflammatory disease and oncology. As part of the collaboration, we entered into a loan and security agreement with GlaxoSmithKline, pursuant to which we borrowed \$85.0 million for use in our efforts under the collaboration. The loan bears interest at a rate of 4.0% per annum and is secured by certain intellectual property, technology and equipment created or utilized pursuant to the collaboration. As of March 31, 2010, the aggregate principal and interest outstanding under our GlaxoSmithKline loan was \$71.4 million, after giving effect to a cash payment we made to GlaxoSmithKline of \$34.7 million on October 27, 2009 for the first of three annual installments of principal and accrued interest due under the loan. The second and third installments of principal and accrued interest under the loan are due on October 27, 2010 and October 27, 2011, respectively. Repayment of all or any of the amounts advanced to us under the loan agreement may, at our election, be made in the form of our common stock at fair market value, subject to certain conditions, or cash. Following the conclusion on October 27, 2008 of the development term under our collaboration with GlaxoSmithKline, we are no longer eligible to receive selection milestone payments from GlaxoSmithKline to credit against outstanding loan amounts, and in the event the market price for our common stock is depressed, we may not be able to repay the loan in full using shares of our common stock due to restrictions in the agreement on the number of shares we may issue. In addition, the issuance of shares of our common stock to repay the loan may result in significant dilution to our stockholders. As a result, we may need to obtain additional funding to satisfy our repayment obligations. There can be no assurance that we will have sufficient funds to repay amounts outstanding under the loan

## Edgar Filing: GENTEX CORP - Form 5

when due or that we will satisfy the conditions to our ability to repay the loan in shares of our common stock. During 2010, we may pursue a potential refinancing of the GlaxoSmithKline loan with a third party, although there can be no assurance that we would be able to do so on terms that are acceptable to us, if at all;

the progress and scope of the development activity with respect to XL184, our most advanced compound. We are focusing our development efforts on XL184, which is being studied in a variety of tumor types, with the goal of rapidly commercializing the compound. As described under Certain Factors Important to Understanding Our Financial Condition and Results of Operations 2008 Cancer Collaboration with Bristol-Myers Squibb, we entered into a worldwide co-development collaboration with Bristol-Myers Squibb for the development and commercialization of XL184. The companies will share worldwide (except for Japan) development costs for XL184. We are responsible for 35% of such costs and Bristol-Myers Squibb is responsible for 65% of such costs, except that we are responsible for funding the initial \$100.0 million of combined costs and have the option to defer payments for development costs above certain thresholds. In return, we will share 50% of the commercial profits and losses (including pre-launch commercialization expenses) in the United States and have the option to co-promote XL184 in the United States. Bristol-Myers Squibb is responsible for all costs intended to support regulatory approval in Japan. We have the right to defer payment for certain early commercialization and other related costs above certain thresholds. During the term of the collaboration, so long as we have not opted out of the co-development of XL184, there may be periods during which

**Table of Contents**

Bristol-Myers Squibb will partially reimburse us for certain research and development expenses, and other periods during which we will owe Bristol-Myers Squibb for research and development expenses that Bristol-Myers Squibb incurred on joint development projects, less amounts reimbursable to us by Bristol-Myers Squibb on these projects. On an annual basis, to the extent that net research and development funding payments are received from Bristol-Myers Squibb, these payments will be presented as collaboration revenue. In annual periods when net research and development funding payments are payable to Bristol-Myers Squibb, these payments will be presented as collaboration cost sharing expense. Generally, the direction of cash flows will depend on the level of development activity by either party, which may change during the development term. Our capital requirements will be impacted by the level of our expenses for the development activity conducted by us and the degree to which we will be required to make payments to, or we will receive payments from, Bristol-Myers Squibb. If we opt out of the co-development of XL184, we would have no further unreimbursed cost obligations for that compound;

the progress and scope of other research and development activities conducted by us;

the level of payments received under existing collaboration agreements, licensing agreements and other arrangements;

the degree to which we conduct funded development activity on behalf of partners to whom we have out-licensed compounds;

our ability to enter into new collaboration agreements, licensing agreements and other arrangements that provide additional payments;

our ability to control costs;

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

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

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;

## Edgar Filing: GENTEX CORP - Form 5

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

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

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 seek to raise funds through the sale of equity or debt securities or through external borrowings. In addition, we may enter into additional strategic partnerships or collaborative arrangements for the development and commercialization of our compounds. 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 may need to obtain additional funding in order to stay in compliance with financial covenants contained in agreements with third parties. For example, our loan and security agreement with GlaxoSmithKline contains financial covenants pursuant to which our working capital (the amount by which our current assets exceed our current liabilities as defined by the agreement, which excludes restricted cash and deferred revenue) 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 March 31, 2010, our working capital was \$69.0 million and our cash and investments were \$162.0 million. If we default on the financial covenants under the loan and security agreement, GlaxoSmithKline may, among other remedies, declare immediately due and payable all obligations under the loan and security agreement. Outstanding borrowings and accrued interest under the loan and security agreement totaled \$71.4 million at March 31, 2010. The second and third installments of principal and accrued interest under the loan are due on October 27, 2010 and October 27, 2011, respectively. In addition, if our cash reserves fall below \$80.0 million and we



---

**Table of Contents**

are unable to increase such cash reserves to \$80.0 million or more within 90 days, our co-development and co-promotion rights with respect to XL184 under our 2008 collaboration agreement with Bristol-Myers Squibb may be terminated. Cash reserves for purposes of our 2008 collaboration agreement with Bristol-Myers Squibb includes our total cash, cash equivalents and investments (excluding any restricted cash), plus the amount then available for borrowing by us under certain financing arrangements. As of March 31, 2010, our cash reserves were \$162.0 million. 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 attributable to Exelixis, Inc. of \$43.2 million for the three months ended March 31, 2010. As of that date, we had an accumulated deficit of \$1,133.0 million. We expect our net loss in 2010 to increase compared to 2009 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. 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, research funding, the achievement of milestones and royalties we earn from any future products developed from the collaborative research. If research funding we receive from collaborators decreases, 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. 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 drug candidates in various stages of clinical development and we anticipate filing an IND application for an additional drug candidate within the next 12 months. As a result, we expect to continue to incur substantial operating expenses, and, consequently, we will need to generate significant additional revenues to achieve profitability. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

***We may not realize the expected benefits of our initiatives to control costs.\****

Managing costs is a key element of our business strategy. Consistent with this element of our strategy, on March 8, 2010 we implemented a restructuring that resulted in a reduction of our workforce by approximately 40%, or 270 employees. We anticipate that we will incur restructuring charges through the end of 2010 as we implement this restructuring.

As a result of the restructuring, we expect to sublease and exit one of our buildings in South San Francisco, California. Our estimate for sublease income is based upon significant assumptions including signing a definitive sublease agreement and the timing for exiting the facility. If we are unable to sign a definitive agreement or the timing to exit the South San Francisco building changes, then we would need to update the estimate of the lease exit costs in our financial statements.

If we experience excessive unanticipated inefficiencies or incremental costs in connection with restructuring activities, such as unanticipated inefficiencies caused by reducing headcount, we may be unable to meaningfully realize cost savings and we may incur expenses in excess of what we anticipate. Either of these outcomes could prevent us from meeting our strategic objectives and could adversely impact our results of operations and financial condition.

***We are exposed to risks related to foreign currency exchange rates.\****

Most of our foreign expenses incurred are associated with establishing and conducting clinical trials for XL184 and various other compounds in our pipeline at sites outside of the United States. The amount of expenses incurred will be impacted by fluctuations in the currencies of those countries in which we conduct clinical trials. Our agreements with the foreign sites that conduct such clinical trials generally provide that payments for the services provided will be calculated in the currency of that country, and converted into U.S. dollars using various exchange rates based upon when services are rendered or the timing of invoices. When the U.S. dollar weakens against foreign currencies, the U.S. dollar value of the foreign-currency denominated expense increases, and when the U.S. dollar strengthens against these currencies, the U.S. dollar value of the foreign-currency denominated expense decreases. Consequently, changes in exchange rates may affect our results of operations.

***Global credit and financial market conditions could negatively impact the value of our current portfolio of cash equivalents or short-term investments and our ability to meet our financing objectives.***

## Edgar Filing: GENTEX CORP - Form 5

Our cash and cash equivalents are maintained in highly liquid investments with remaining maturities of 90 days or less at the time of purchase. Our short-term and long-term investments consist primarily of readily marketable debt securities with remaining maturities of more than 90 days at the time of purchase. While as of the date of this filing we are not aware of any downgrades,

## **Table of Contents**

material losses, or other significant deterioration in the fair value of our cash equivalents, short-term investments, or long-term investments since March 31, 2010, no assurance can be given that further deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or investments or our ability to meet our financing objectives.

### **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, or potentially 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;

we or our competitors may subsequently discover other compounds that we believe show significantly improved safety or efficacy compared to our product candidates;

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.

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

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

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

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

the number of clinical sites included in the trials; and

the length of time required to enroll suitable patient subjects.

Any delay or termination described above 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.

---

**Table of Contents**

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

*We are dependent upon our collaborations with major companies, which subjects us to a number of risks.*

We have established collaborations with leading pharmaceutical and biotechnology companies, including Bristol-Myers Squibb, sanofi-aventis, Genentech, Boehringer Ingelheim and GlaxoSmithKline, for the development and ultimate commercialization of a significant number of compounds generated from our research and development efforts. We continue to pursue collaborations for selected unpartnered preclinical and clinical compounds. Our dependence on our relationships with existing collaborators for the development and commercialization of our compounds subjects us to, and our dependence on future collaborators for development and commercialization of additional compounds will subject us to, a number of risks, including:

we are not able to control the amount and timing of resources that our collaborators will devote to the development or commercialization of drug candidates or to their marketing and distribution;

we may not be able to control the amount and timing of resources that our potential future collaborators may devote to the development or commercialization of drug candidates or to their marketing and distribution;

collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a drug candidate, repeat or conduct new clinical trials or require a new formulation of a drug candidate for clinical testing;

disputes may arise between us and our collaborators that result in the delay or termination of the research, development or commercialization of our drug candidates or that result in costly litigation or arbitration that diverts management's attention and resources;

collaborators may experience financial difficulties;

collaborators may not be successful in their efforts to obtain regulatory approvals in a timely manner, or at all;

collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;

business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;

a collaborator could independently move forward with a competing drug candidate developed either independently or in collaboration with others, including our competitors;

we may be precluded from entering into additional collaboration arrangements with other parties in an area or field of exclusivity;

future collaborators may require us to relinquish some important rights, such as marketing and distribution rights; and

## Edgar Filing: GENTEX CORP - Form 5

collaborations may be terminated or allowed to expire, which would delay the development and may increase the cost of developing our drug candidates.

If any of these risks materialize, our product development efforts could be delayed and otherwise adversely affected, which could adversely impact our business, operating results and financial condition.

***If we are unable to continue current collaborations and receive research funding or achieve milestones or royalties, our revenues would suffer.***

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, research funding, the achievement of milestones and royalties we earn from any future products developed from the collaborative research. If we are unable to receive research funding or successfully achieve milestones or royalties, or our collaborators fail to develop successful products, we will not earn the revenues contemplated under such collaborative agreements.

If any of these agreements is not renewed or is terminated early, whether unilaterally or by mutual agreement, our revenues could suffer. Most of our collaboration agreements 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.

*We may be unable to establish collaborations for selected preclinical and clinical compounds.*

Our strategy includes the pursuit of new collaborations with leading pharmaceutical and biotechnology companies for the development and ultimate commercialization of selected preclinical and clinical compounds, particularly those drug candidates for which we believe that the capabilities and resources of a partner can accelerate development and help to fully realize their therapeutic and commercial potential. We face significant competition in seeking appropriate collaborators, and these collaborations are complex and time consuming to negotiate and document. We may not be able to negotiate additional collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional collaborations because of the numerous risks and uncertainties associated with establishing additional collaborations. If we are unable to negotiate additional collaborations, we may not be able to realize value from a particular drug candidate, particularly those drug candidates for which we have determined not to continue to utilize our own resources to develop. As a result, our revenues, capital resources and product development efforts could be adversely affected.

---

**Table of Contents**

***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.



---

## **Table of Contents**

### **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 an NDA can be submitted to the FDA, the product candidate must undergo extensive clinical trials, which can take many years and requires 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. The FDA has substantial discretion in the approval process and may refuse to approve any NDA or decide that our or our collaborative partners' data is insufficient for approval and require additional preclinical, clinical or other studies. For example, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of any of our drug candidates. The FDA could also require additional studies or trials to satisfy particular safety concerns noted in our or our collaborative partners' preclinical or clinical testing.

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

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

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

Our ability to commercialize any products that we may develop will be highly dependent upon the extent to which these products gain market acceptance among physicians, patients, health care payors, such as Medicare and Medicaid, private health insurers, including managed care organizations and group purchasing organizations, and the medical community. If these products do not achieve an adequate level of acceptance, we may not generate adequate product revenues, 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.

---

**Table of Contents**

*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.

In recent years, there have been numerous legislative proposals to change the healthcare system in the United States that could significantly affect our business. Such proposals reflect the primary trend in the United States health care industry toward cost containment and include measures that may have the effect of reducing the prices that we are able to charge for any products we develop and sell and cause a reduction in the coverage and reimbursement of such products. If approved, such reform could limit our ability to successfully commercialize our potential products.

Another factor that may affect the pricing of drugs is proposed congressional action regarding drug reimportation into the United States. For example, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 gives discretion to the Secretary of Health and Human Services to allow drug reimportation into the United States under some circumstances from foreign countries, including countries where the drugs are sold at a lower price than in the United States. Proponents of drug reimportation may attempt to pass legislation, which would allow direct reimportation under certain circumstances. If legislation or regulations were passed allowing the reimportation of drugs, it could decrease the price we receive for any products that we may develop, thereby negatively affecting our revenues and prospects for profitability.

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

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

The biotechnology industry is highly fragmented and is characterized by rapid technological change. In particular, the area of kinase-targeted therapies is a rapidly evolving and competitive field. We face, and will continue to face, intense competition from 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. There may also be drug candidates of which we are not aware at an earlier stage of development that may compete with our drug candidates. In addition, any drug candidate that we successfully develop may compete with existing therapies that have long histories of use, such as chemotherapy and radiation treatments in cancer indications. Examples of potential competition for XL184 include AstraZeneca's development-stage VEGFR and EFGR inhibitor, vandetanib, and other VEGF pathway inhibitors, including Genentech's bevacizumab and AstraZeneca's cediranib. Examples of potential competition for XL147 and XL765 include early-stage development programs of various pharmaceutical and biotechnology companies, including Genentech, Novartis, Pfizer, Calistoga Pharmaceuticals and Semafore Pharmaceuticals.



---

**Table of Contents**

***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.



---

## **Table of Contents**

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 and Location**

*The loss of key personnel or the inability to retain and, where necessary, attract 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. Retaining and, where necessary, recruiting 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. The restructuring of the company that we implemented on March 8, 2010 could have an adverse impact on our ability to retain and recruit qualified personnel. 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.

*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.

---

## **Table of Contents**

### ***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 products approved for marketing. On occasion, juries have awarded large judgments in class action lawsuits for claims based on drugs that had unanticipated side effects. In addition, the pharmaceutical and biotechnology industries, in general, have been subject to significant medical malpractice litigation. A successful product liability claim or series of claims brought against us 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 to volatility, including:

the scope of our research and development activities;



## Edgar Filing: GENTEX CORP - Form 5

recognition of upfront licensing or other fees or revenue;

payments of non-refundable upfront or licensing fees, or payment for cost-sharing expenses, to third parties;

acceptance of our technologies and platforms;

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

the introduction of new technologies or products by our competitors;

the timing and willingness of collaborators to further develop or, if approved, commercialize our products;

our ability to enter into new collaborative relationships;

**Table of Contents**

the termination or non-renewal of existing collaborations;

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

adjustments to expenses accrued in prior periods based on management's estimates after the actual level of activity relating to such expenses becomes more certain;

the impairment of acquired goodwill and other assets;

the impact of the restructuring of the company implemented on March 8, 2010; 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. 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, many of which we cannot control:

adverse results or delays in our or our collaborators' clinical trials;

announcement of FDA approval or non-approval, or delays in the FDA review process, of our or our collaborators' product candidates or those of our competitors or actions taken by regulatory agencies with respect to our, our collaborators' or our competitors' clinical trials;

the timing of achievement of our clinical, regulatory, partnering and other milestones, such as the commencement of clinical development, the completion of a clinical trial, the filing for regulatory approval or the establishment of collaborative arrangements for one or more of our drug candidates;

actions taken by regulatory agencies with respect to our drug candidates or our clinical trials;

the announcement of new products by us or our competitors;

## Edgar Filing: GENTEX CORP - Form 5

quarterly variations in our or our competitors' results of operations;

developments in our relationships with our collaborators, including the termination or modification of our agreements;

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.

## **Table of Contents**

These factors, as well as general economic, political and market conditions, may materially adversely affect the market price of our common stock. As with the stock of many other public companies, the market price of our common stock has been particularly volatile during the recent period of upheaval in the capital markets and world economy. This excessive volatility may continue for an extended period of time following the filing date of this report.

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

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

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

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

diversion of management's attention from other operational matters;

the potential loss of key employees;

the potential loss of key collaborators;

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

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

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

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

If our stockholders sell substantial amounts of our common stock (including shares issued upon the exercise of options and warrants and shares issued under our employee stock purchase plan) 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.

### ***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;

**Table of Contents**

the ability of our Board of Directors to issue preferred stock without stockholder approval, which could be used to institute a poison pill that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our Board of Directors;

limitations on the removal of directors; and

advance notice requirements for director nominations and stockholder proposals.

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

**ITEM 6. EXHIBITS**

(a) Exhibits

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

**Table of Contents**

**SIGNATURES**

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

Date: May 11, 2010

EXELIXIS, INC.

/s/ Frank Karbe  
Frank Karbe

Executive Vice President and Chief Financial Officer

*(Principal Financial and Accounting Officer)*

**Table of Contents****EXHIBIT INDEX**

Exhibit Number	Exhibit Description	Form	Incorporation by Reference Exhibit/			Filed Herewith
			File Number	Appendix Reference	Filing Date	
2.1*	Asset Purchase and License Agreement, dated as of September 4, 2007, by and among Agrigenetics, Inc., Mycogen Corporation, Exelixis Plant Sciences, Inc., Agrinomics, LLC and Exelixis, Inc.	10-Q	000-30235	10.1	11/5/2007	
2.2*	Share Sale and Transfer Agreement, dated November 20, 2007, by and between Taconic Farms, Inc. and Exelixis, Inc.	10-K	000-30235	2.3	2/25/2008	
3.1	Amended and Restated Certificate of Incorporation of Exelixis, Inc.	10-K	000-30235	3.1	3/10/2010	
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Exelixis, Inc.	10-K	000-30235	3.2	3/10/2010	
3.3	Amended and Restated Bylaws of Exelixis, Inc.	8-K	000-30235	3.1	10/4/2007	
4.1	Specimen Common Stock Certificate.	S-1,	333-96335	4.1	2/7/2000	
		as amended				
4.2	Form of Warrant, dated June 9, 2005, to purchase 750,000 shares of Exelixis, Inc. common stock in favor of Symphony Evolution Holdings LLC.	10-Q	000-30235	4.1	8/9/2005	
4.3	Form of Warrant, dated June 13, 2006, to purchase 750,000 shares of Exelixis, Inc. common stock in favor of Symphony Evolution Holdings LLC.	8-K	000-30235	4.1	6/15/2006	
4.4*	Warrant Purchase Agreement, dated June 9, 2005, between Exelixis, Inc. and Symphony Evolution Holdings LLC.	10-Q	000-30235	10.8	8/9/2005	
4.5*	Form Warrant to Purchase Common Stock of Exelixis, Inc. issued or issuable to Deerfield Private Design Fund, L.P., Deerfield Private Design International, L.P., Deerfield Partners, L.P. and Deerfield International Limited	8-K	000-30235	4.9	6/9/2008	
4.6	Fourth Amended and Restated Registration Rights Agreement, dated February 26, 1999, among Exelixis, Inc. and certain Stockholders of Exelixis, Inc.	S-1,	333-96335	4.2	2/7/2000	
		as amended				
4.7	Registration Rights Agreement, dated October 18, 2004, by and among Exelixis, Inc., X-Cepto Therapeutics, Inc., and certain holders of capital stock of X-Cepto Therapeutics, Inc. listed in Annex I thereto.	8-K	000-30235	10.1	10/21/2004	
4.8	Registration Rights Agreement, dated October 18, 2004, by and among Exelixis, Inc., X-Cepto Therapeutics, Inc., and certain holders of capital stock of X-Cepto Therapeutics, Inc. listed in Annex I thereto.	8-K	000-30235	10.2	10/21/2004	



**Table of Contents**

4.9*	Registration Rights Agreement, dated June 9, 2005, between Exelixis, Inc. and Symphony Evolution Holdings LLC.	10-Q	000-30235	10.7	8/9/2005	
4.10	Registration Rights Agreement between Exelixis, Inc. and Deerfield Private Design Fund, L.P., Deerfield Private Design International, L.P., Deerfield Partners, L.P. and Deerfield International Limited dated June 4, 2008.	8-K	000-30235	4.10	6/9/2008	
4.11	Form of Warrant, dated June 10, 2009, to purchase 500,000 shares of Exelixis, Inc. common stock in favor of Symphony Evolution Holdings LLC.	10-Q,	000-30235	4.4	7/30/2009	
		as amended				
4.12	Form of Common Stock Agreement and Warrant Certificate	S-3,	333-158792	4.17	4/24/2009	
		as amended				
4.13	Form of Preferred Stock Agreement and Warrant Certificate	S-3,	333-158792	4.18	4/24/2009	
		as amended				
4.14	Form of Debt Securities Warrant Agreement and Warrant Certificate	S-3,	333-158792	4.19	4/24/2009	
		as amended				
4.15	Form of Senior Debt Indenture	S-3,	333-158792	4.13	5/28/2009	
		as amended				
4.16	Form of Subordinated Debt Indenture	S-3,	333-158792	4.14	5/28/2009	
		as amended				
10.1	Compensation Information for the Company's Named Executive Officers.	10-K	000-30235	10.21	3/10/2010	
31.1	Certification required by Rule 13a-14(a) or Rule 15d-14(a).					X
31.2	Certification required by Rule 13a-14(a) or Rule 15d-14(a).					X
32.1**	Certification by the Chief Executive Officer and the Chief Financial Officer of Exelixis, Inc., as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).					X

Management contract or compensatory plan.

\* Confidential treatment granted for certain portions of this exhibit.

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