CURIS INC
Form 10-K
March 14, 2008
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark one)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2007

OR

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

Commission File Number 000-30347

CURIS, INC.

(Exact Name of Registrant as Specified in Its Charter)

DELAWARE	**04-3505116**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

45 Moulton Street

Cambridge, Massachusetts 02138

(Address of principal executive offices) (Zip Code)

617-503-6500

(Registrant s telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, $0.01 par value per share	The NASDAQ Stock Market

Securities registered pursuant to Section 12(g) of the Act:

None

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

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

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

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

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

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨	Smaller reporting company x

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

The aggregate market value of the registrant s common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) based on the last reported sale price of the common stock on June 29, 2007 (the last trading day of the registrant s second fiscal quarter of 2007) was approximately $51,756,000.

As of March 12, 2008, there were 63,241,086 shares of the registrant s common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant s proxy statement for the annual meeting of stockholders scheduled to be held on June 3, 2008, which are to be filed with the Commission not later than 120 days after the close of the Registrant s fiscal year ended December 31, 2007 pursuant to Regulation 14A, have been incorporated by reference in Item 5 of Part II and Items 10-14 of Part III of this Annual Report on Form 10-K.

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PART I

This annual report on Form 10-K contains forward-looking statements that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause Curis financial, operating and business results to differ materially from those expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including any expectations of revenue, expenses, earnings or losses from operations, or other financial items; any statements of the plans, strategies and objectives of management for future operations; any statements concerning product research, development and commercialization timelines; any statements of expectation or belief; and any statements of assumptions underlying any of the foregoing. The risks, uncertainties and assumptions referred to above include risks that are described in Item 1A-Risk Factors and elsewhere in this annual report and that are otherwise described from time to time in our Securities and Exchange Commission reports filed after this report.

The forward-looking statements included in this annual report represent our estimates as of the date of this annual report. We specifically disclaim any obligation to update these forward-looking statements in the future. These forward-looking statements should not be relied upon as representing our estimates or views as of any date subsequent to the date of this annual report.

ITEM 1. BUSINESS

Overview

We are a drug discovery and development company that is committed to leveraging our innovative signaling pathway drug technologies in seeking to create new medicines, primarily for cancer. In expanding our drug development efforts in the field of cancer through our targeted cancer drug development platform, we are building upon our past experiences in targeting signaling pathways in the areas of cancer, neurological disease and cardiovascular disease.

Signaling pathways are the means by which cells exchange instructional messages that regulate specific biological functions. Healthy, normal cells require a balanced network of signaling pathways that govern daily cell function, including proliferation, metabolism, and ordinary cell death. Genetic, environmental and other factors can cause activation or repression of these signaling pathways, which can possibly lead to complex diseases such as cancer. In cancer, such abnormally regulated signaling pathways are believed to be used by the diseased cells to enhance their establishment, growth and metastasis. Our product development approach consists of generating small molecules to target one or more of the components of such abnormally regulated signaling pathway network to provide therapeutic effect.

Our cancer programs include a Hedgehog antagonist program for which the lead molecule, GDC-0449, is in phase I clinical testing under collaboration with Genentech. Genentech has stated that it plans to initiate three phase II clinical trials of GDC-0449 in 2008. Assuming that Genentech successfully initiates phase II trials as planned, we believe that GDC-0449 would be the first Hedgehog antagonist to advance to phase II clinical testing. Moreover, we have substantial intellectual property rights in the Hedgehog signaling pathway.

We are applying our signaling pathway-based preclinical drug development experience to begin developing cancer drug candidates to target other biological signaling pathways. Our targeted cancer drug development platform primarily consists of several proprietary cancer drug programs that target multiple signaling pathways other than the Hedgehog signaling pathway. However, unlike the Hedgehog pathway, a majority of these targeted pathways have been clinically validated by others in various cancer indications. By directing our efforts toward validated targets, we believe that we can expedite the drug development process by taking advantage of the accumulated scientific knowledge base relating to these targets and the molecules that have been developed to act on them.

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In addition, many of the preclinical drug candidates in our targeted cancer platform are designed to inhibit more than one of these validated cancer targets. We believe that this approach of targeting multiple nodes in various signaling pathway networks may provide for a better therapeutic effect than many of the targeted cancer drugs currently marketed or in development.

Recent Developments

In March 2008, Genentech provided an update on its Phase II clinical trial plans for GDC-0449. Genentech stated that it plans to initiate three Phase II clinical trials of GDC-0449 in 2008, which include a trial in metastatic colorectal cancer during the first quarter of 2008 and trials in advanced basal cell carcinoma and in an undisclosed advanced solid tumor of epithelial origin during the second half of 2008.

Genentech also announced that it has seen partial responses in advanced basal cell carcinoma tumors in the ongoing Phase I clinical trial of GDC-0449. Genentech has indicated that it will present more comprehensive Phase I data at an upcoming scientific conference.

On March 10, 2008, we announced that Wyeth Pharmaceuticals has decided that it will no longer pursue its development efforts on our Hedgehog agonist program and will terminate its January 2004 collaboration agreement with us. Pursuant to the collaboration agreement, we had licensed our Hedgehog protein and novel small molecule Hedgehog pathway agonists to Wyeth. Wyeth paid us an up-front license fee and provided research funding through February 2008. Research efforts under the collaboration focused on the preclinical development of small molecule and protein Hedgehog agonists, primarily for stroke and cardiovascular indications. Pursuant to the agreement, the collaboration will terminate on May 6, 2008. We intend to pursue other opportunities to enter into a new collaboration or licensing relationship with a third party relating to this technology.

Product Development Programs

We are developing drug product candidates primarily to treat cancer. These product development initiatives, described in the chart below, are being pursued using our internal resources or through collaboration with Genentech. We believe that Genentech is able to dedicate significant additional resources and clinical development expertise to our programs under collaboration. In addition, these collaborations provide us with potential future contingent cash payments upon the achievement of development and regulatory objectives and royalties on future product sales, if any. Our product development initiatives are derived primarily from our substantial intellectual property portfolio in key signaling pathways, including the Hedgehog signaling pathway and certain other cancer signaling pathways.

The table below summarizes our current research and development programs, including the current development status of each program.

Product Candidate	Primary Indication	Collaborator/Licensee	Status
Hedgehog systemic antagonist			
- GDC-0449 (small molecule)	Cancer	Genentech	Phase I expansion cohort
- Small molecule and antibody	Cancer	Genentech	Preclinical
Targeted cancer drug development platform			
- CUDC-101 (HDAC, EGFR, Her2 inhibitor)	Cancer	Internal development	Development candidate
- Other targeted cancer programs	Cancer	Internal development	Preclinical
Hedgehog protein agonist (1)	Stroke and cardiovascular disease	(1)	(1)

(1) On March 7, 2008, Wyeth provided us with written notice that it intends to terminate this collaboration agreement effective May 6, 2008. On the termination date, the licenses granted by us to Wyeth terminate and we intend to pursue other collaboration or licensing opportunities for this program.

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In the chart above, Phase I expansion cohort means that our collaborator is currently treating human patients in an expanded Phase I clinical trial, the principal purpose of which is to evaluate the safety and biological activity of the compound being tested in a specific solid tumor type. Development candidate means that from our testing in several preclinical models of human disease of various compounds from a particular compound class, we have selected a single lead candidate for potential future clinical development and are seeking to complete the relevant safety, toxicology, and other data required to submit an investigational new drug, or IND, application with the FDA seeking to commence a Phase I clinical trial. Preclinical means we are seeking to obtain evidence of therapeutic efficacy in preclinical models of human disease of one or more compounds within a particular class of drug candidates.

Since our inception in 2000, substantially all of our revenues have been derived from collaborations and other agreements with third parties. For the year ended December 31, 2007, our current collaborator, Genentech, and our former collaborators, Wyeth and Procter & Gamble, accounted for substantially all of our revenue, as follows: Genentech, $12,408,000, or 76%; Wyeth, $1,968,000, or 12%; and Procter & Gamble, $1,878,000, or 11%.

Hedgehog Systemic Antagonist Programs

Our Hedgehog antagonist technologies are being developed under a June 2003 collaboration agreement with Genentech. Genentech is a biotechnology company with broad expertise in the development of cancer therapeutics.

The Hedgehog signaling pathway controls the development and growth of many kinds of tissues in the body by directly promoting cell division in specific cell types, and by activating other secondary signaling pathways that control the synthesis of growth factors and angiogenic (blood vessel-forming) factors.

In recent years, it has been widely published that abnormal Hedgehog signaling may contribute to the growth of certain cancers, including basal cell carcinoma, breast, colorectal, esophageal, pancreatic, prostrate and small cell lung cancers, among others. Our preclinical evidence suggests that Hedgehog protein produced by tumor cells may signal adjacent stromal cells within the tumor environment to produce various growth and angiogenic factors that can enhance tumor maintenance and growth. Systemic administration of our Hedgehog signaling pathway inhibitors has been shown to slow or halt the progression of various types of tumors in our preclinical models of cancer. We believe that our Hedgehog pathway antagonists selectively target fundamental mechanisms involved in the maintenance and progression of tumor growth and, as such, may represent a new generation of cancer therapeutics.

Small Molecule Hedgehog Antagonist Program

In January 2007, Genentech began a phase I clinical trial of GDC-0449, a first-in-class systemically administered small molecule Hedgehog antagonist drug candidate, in patients with locally advanced or metastatic cancers that are refractory to standard therapy or for which no standard therapies exist. The primary objectives of this phase I trial are to evaluate the safety and tolerability of escalating doses of GDC-0449, primarily to establish the maximum tolerated dose and dose limiting toxicities and to characterize its pharmacokinetic and pharmacodynamic properties. In October 2007, Genentech notified us that these initial objectives of the phase I clinical trial were achieved and that Genentech had initiated a Phase I clinical trial expansion cohort to enroll additional patients with advanced basal cell carcinoma to assess preliminary signs of biological activity as well as to continue the accumulation of phase I safety data.

In addition to meeting the primary objectives of the phase I clinical trial, Genentech reported regression of an established metastatic basal cell tumor in this trial. Genentech also stated that GDC-0449 appears to remain in the body long enough to adequately expose the tumor to the drug compound. We are encouraged by the early

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evidence of clinical activity with this molecule, which could potentially represent a way to block Hedgehog signaling in those cancers utilizing the Hedgehog pathway. Genentech has indicated that it expects to present more comprehensive phase I data at an upcoming scientific conference.

In March 2008, Genentech provided an update on its Phase II clinical trial plans for GDC-0449. Genentech stated that it plans to initiate three Phase II clinical trials of GDC-0449 in 2008, which include a trial in metastatic colorectal cancer during the first quarter of 2008 and trials in advanced basal cell carcinoma and in an undisclosed advanced solid tumor of epithelial origin during the second half of 2008.

Antibody Hedgehog Antagonist Program

Genentech is also conducting preclinical research on an antibody antagonist of the Hedgehog signaling pathway. We expect to provide further updates on this program only if Genentech selects a development candidate from this program. We can not predict whether Genentech will pursue the further development of Hedgehog antibody antagonists.

Under the terms of the June 2003 agreement with Genentech, we granted Genentech an exclusive, royalty-bearing license, with the right to sublicense, make, use, sell and import small molecule and antibody inhibitors of the Hedgehog signaling pathway for applications in cancer therapy. We had responsibilities to perform certain funded preclinical research activities and, from January 2005 through August 2006, co-funded clinical development costs for certain products. Genentech has primary responsibility for clinical development, regulatory affairs, manufacturing and supply, formulation and sales and marketing.

Pursuant to the collaboration agreement, Genentech made up-front payments of $8,500,000, which consisted of a $3,509,000 non-refundable license fee payment and a payment of $4,991,000 in exchange for 1,323,835 shares of our common stock. Genentech also made license maintenance fee payments totaling $4,000,000 over the first two years of the collaboration. We have entered into three amendments to the June 2003 collaboration agreement. Pursuant to the amendments, Genentech increased its funded research commitment and extended its funding obligation through December 2006. As part of these amendments, Genentech provided us with $5,846,000 in incremental research funding over the period from December 2004 to December 2006. All research funding ended in December 2006, and we do not expect to receive additional future research funding from Genentech or incur any material research costs related to this program. In October 2006, Genentech submitted an IND application for which we received a $3,000,000 cash payment. Assuming that Genentech proceeds with three Phase II clinical trials in 2008 as planned, in connection with the treatment of the first patient in the Phase II colorectal cancer trial, we have the right to receive a $3,000,000 cash payment from Genentech. We also have the right to receive an additional $3,000,000 cash payment upon initiation of the Phase II testing of the undisclosed advanced epithelial solid tumor. We have already received a $3,000,000 cash payment for the initiation of Phase II testing in advanced basal cell carcinoma. Genentech had determined that it was obligated to make this payment since the Phase I clinical trial expansion cohort in advanced basal cell carcinoma, which was initiated in October 2007, satisfied the criteria for a Phase II clinical trial under the parties collaboration agreement. We are eligible to receive additional payments upon the achievement of further development milestones in this indication. In addition to these payments, we will be eligible to receive cash payments from Genentech only upon the achievement of additional specified clinical development objectives as well as royalties on product sales if any Hedgehog systemic antagonist products are successfully developed and commercialized.

Unless terminated earlier, the agreement will expire six months after the later of the expiration of Genentech s obligation to pay royalties to us under the agreement or such time as no activities have occurred under the agreement for a period of twelve months. The agreement may be terminated earlier, by either party for cause, upon sixty days prior written notice. In addition, Genentech may terminate the agreement, either in whole or in part, without cause, upon six months prior written notice. In the event of any termination where specific

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license grants survive, we will continue to receive clinical development and drug approval milestones and royalties on product sales for such licensed compound.

If we terminate the agreement for cause or Genentech terminates the agreement without cause, all licenses granted to Genentech automatically terminate and revert to us. In addition, Genentech has agreed that it will no longer conduct any development or commercialization activities on any compounds identified during the course of the agreement for so long as such compounds continue to be covered by valid patent claims.

As a result of our licensing agreements with various universities, we are obligated to make payments to these university licensors when we receive certain payments from Genentech. To date, we have made an aggregate of $300,000 in such payments.

Targeted Cancer Drug Development Platform

Over the past several years, targeted cancer drugs have been considered among the most promising cancer treatments for obtaining better therapeutic effect with less toxicity when compared with traditional chemotherapy, which, in addition to attacking cancerous cells, also tends to attack a broad range of healthy cells. A large body of published data shows cancers to have multiple, intersecting signaling pathways that support survival, growth, and invasion. Targeting only one or two of these pathways with single-targeted agents has generally only led to modest improvements to existing standards-of-care and most cancer patients with solid tumors do not respond in a clinically meaningful manner. Identifying the correct combination of critical targets within the network of cancer cell signaling pathways wherein simultaneous blockade could provide a major improvement in outcomes for cancer patients is an area of intense research.

In 2006, we utilized medicinal chemistry and biological expertise to initiate our proprietary targeted cancer drug development platform. This platform focuses on the development of single agent drug candidates targeting one or more molecular components within the signaling pathways associated with certain cancers. These programs are primarily focused on developing a number of proprietary, small molecule, single agent, multi-targeted inhibitor drug compounds, including CUDC-101, the first drug candidate selected as a development candidate. Each proprietary compound is being designed to inhibit validated cancer targets, including the epidermal growth factor receptor (EGFR), vascular endothelial growth factor receptor (VEGFR), heat shock protein 90 (Hsp90), epidermal growth factor 2 (Her2) and in combination with inhibition of histone deacetylase, or HDAC, which is a validated non-kinase cancer target. We are also seeking to use this platform to develop proprietary single agent, single target drug candidates for cancer indications, including an Hsp90 inhibitor.

HDAC inhibition is a core component in each of our multi-targeted inhibitors. We believe that HDAC inhibition is a very promising non-kinase target for cancer therapy. There is substantial preclinical evidence of synergistic induction of cancer cell death when HDAC inhibitors are combined with a diverse range of other targeted therapies or standard chemotherapeutic agents, demonstrating that HDAC inhibition may be more broadly effective in the treatment of cancer when integrated with other inhibitory activities. Currently there is one FDA-approved HDAC inhibitor and several other HDAC-targeted drug candidates in clinical trials for cancer.

In furtherance of the development of our targeted cancer drug development platform, since May 2006, we have outsourced certain medicinal chemistry functions to a leading provider in Shanghai, China. More recently, we have engaged another provider to perform certain biological functions in Beijing, China. We have developed these relationships with Chinese providers to support our U.S. operations and we are currently engaging a total of 27 chemists and 6 biologists in China. We believe that these relationships have been important to our efforts to create a broad portfolio of proprietary cancer drugs.

We have filed a number of patents including a broad omnibus patent application that covers the drug design concept that is the basis for the targeted cancer drug development platform as well as numerous species filings

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relating to specific classes of compounds which we believe will constitute novel compositions from a patentability standpoint. We expect that we will continue to file additional patent applications covering new compositions in the future.

We are concurrently engaged in collaboration discussions with several companies and remain optimistic that we may consummate a collaboration for one of our targeted inhibitors during 2008, although we cannot assure that such a collaboration will occur in the time frame expected, if at all. When evaluating potential collaborative opportunities, we are seeking a corporate collaboration that will provide us with the opportunity for significant involvement into the early stages of human clinical testing.

CUDC-101

CUDC-101 is our lead multi-target inhibitor drug candidate under development. CUDC-101 is being designed as a single agent to inhibit HDAC, EGFR and Her2, three validated cancer targets. EGFR and Her2 are cell receptors involved in growth and survival. Overexpression of EGFR and Her2 are known to play a primary role in the uncontrolled proliferation of various tumor cell types including breast and lung. HDACs are enzymes that are involved in turning genes on or off by controlling access to a cell s DNA, which is referred to as epigenetic regulation. We believe that CUDC-101 is the first-in-class compound designed to simultaneously inhibit HDAC, EGFR and Her2. Currently marketed EGFR and/or Her2 inhibitors have had limited efficacy in a small percentage of the respective patient populations. This may be due in part to factors other than EGFR and Her2 that independently drive dysfunctional cell signaling and therefore potentially contribute to cancer cell growth. We have demonstrated in *in vitro* preclinical data that the administration of CUDC-101, as a single agent, provides increased potency and cancer cell killing when compared to the combination of individual HDAC inhibitors with EGFR or EGFR/Her2 inhibitors. We believe that CUDC-101 may therefore provide for significant cancer cell death in patients which exceeds the cell death that could be achieved with a combination of separate anticancer agents.

We have demonstrated in preclinical studies that CUDC-101 inhibits all three of these molecular targets, resulting in the potent killing *in vitro* of a wide range of cancer cell lines that are representative of a variety of human cancer types, many of which have demonstrated resistance to various approved targeted agents. When a number of these cancer cell lines were evaluated in xenograft efficacy models in mice, both inhibition in tumor growth and tumor regression were observed, depending upon the cancer cell line and dose regimen tested.

While CUDC-101 s mechanism of action is not known, our data suggest that CUDC-101 s mechanism of action involves the sensitization of cancer cells to EGFR and Her2 inhibition through HDAC inhibition. CUDC-101 simultaneously inhibits both EGFR and Her2 at the receptor level while blocking downstream HDAC inhibition within the cancer cells. Despite the existence of other multi-targeted inhibitors, CUDC-101 is unique in its choice of targets which we believe enables a synergistic attack on multiple nodes or points in the overall pathway network that are used by tumors to survive, grow, and invade surrounding tissue. Utilizing the same targeted strategy with other currently available drugs would require combining two or three separate agents, which typically have mismatched dosing schedules and tend to display additive dose limiting toxicities. In contrast, we believe that CUDC-101, as a single small molecule, has the potential to act in the same cancer cells at the same time with fewer toxic side effects and thus potentially represents an important advance in targeted agent anti-cancer therapy.

We have been actively working toward our goal of filing an IND application for CUDC-101, and expect to do so early in the second quarter of 2008.

Other Targeted Cancer Programs

In addition to CUDC-101, we are also seeking to advance several other small molecule drug candidates in our targeted cancer drug development platform. Currently, the more advanced of these programs includes a

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single agent multi-targeted inhibitor that is designed to inhibit HDAC, Bcr-Abl and Src kinases, a single agent multi-targeted inhibitor of HDAC and Hsp90, a single agent inhibitor of Hsp90, and a single agent multi-targeted inhibitor of HDAC and CDK2. We anticipate that, in the first half of 2008, we will select a compound from one of these programs as the second development candidate from our targeted cancer drug development platform. Assuming that we meet this selection timeline and that subsequent preclinical studies are successful, we anticipate that we would submit an IND application for this second development candidate during the first half of 2009. We also plan to select a third development candidate from this platform during 2008.

Other Research Programs

Wnt Signaling Pathway

Wnt is a key developmental pathway that affects the expression of multiple target genes. Mutations in this pathway have been linked to multiple cancers and it is believed that a modulator of components within the pathway may provide a therapeutic for the treatment of cancer.

In April 2005 we entered into a collaboration with Genentech focused on the discovery and development of small molecule compounds that modulate the Wnt signaling pathway. We conducted research activities under this collaboration from April 2005 until March 2007, at which time Genentech assumed further responsibility for any future development of this program. We will not receive future research funding under this program under the terms of the April 2005 agreement.

We have the right to receive contingent cash payments under the agreement assuming that Genentech pursues the development of one or more drug candidates and specified development objectives are achieved. We are also eligible to receive royalties on product sales, should any products under this collaboration be successfully commercialized. If Genentech does not advance drug candidates generated under this collaboration beyond the discovery research stage, we are not entitled to receive any future cash payments under this collaboration. We cannot predict whether Genentech will pursue the further development of drug candidates under the agreement and/or whether any development objectives for which we may be entitled to a cash payment will be successfully achieved.

Hedgehog Agonist

The Hedgehog signaling pathway is essential for the formation of normal nerves and nerve networks in the central and peripheral nervous systems. Our scientists and academic collaborators have shown that treatment with a Hedgehog protein appears to accelerate the restoration of nerve function in preclinical models of nerve trauma and disease. This finding suggests that the Hedgehog pathway may have a potential therapeutic effect in treating certain human neurological disorders. Published preclinical data, as well as data generated by Wyeth, also suggests that the Hedgehog pathway may have benefit in treating cardiovascular disease. Additional internally generated data have shown therapeutic effect in preclinical models of hair regrowth and published third-party data also suggests that Hedgehog agonists may have a therapeutic use in wound healing and in certain bone disorders.

In January 2004, we entered into a collaboration agreement with Wyeth to continue the development of our Hedgehog agonist drug candidates for the treatment of neurological disorders and other potential indications, including cardiovascular disease. From February 2004 through February 2008, we had been engaged in Wyeth-funded preclincial research for the treatment of stroke. On March 7, 2008, Wyeth provided us with written notice that it will terminate this collaboration agreement effective May 6, 2008. On the termination date, the licenses granted by us to Wyeth shall terminate and all terminated license rights will revert to us. We intend to evaluate developing additional data under this program and will seek to license this technology to a third party collaborator following the May 6, 2008 termination date.

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Corporate Information

We were organized as a Delaware corporation in February 2000. We began our operations in July 2000 upon the completion of the merger of Creative BioMolecules, Inc., Ontogeny, Inc. and Reprogenesis, Inc. Our principal executive office is located at 45 Moulton Street, Cambridge, Massachusetts, 02138 and our telephone number is (617) 503-6500.

Curis and the Curis logo are our trademarks. This annual report on Form 10-K may also contain trademarks and trade names of others.

Website Access to Reports

We maintain a website with the address www.curis.com. We are not including the information contained in our website as part of, or incorporating it by reference into, this annual report on Form 10-K. Our website address is included in this annual report on Form 10-K as an inactive textual reference only. We make available free of charge through our website our annual reports on Form 10-K, our quarterly reports on Form 10-Q, current reports on Form 8-K and any such amendments to those reports as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the Securities and Exchange Commission. The Securities and Exchange Commission maintains a website, www.sec.gov, that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. The public may read and copy any materials we file with the Securities and Exchange Commission at the SEC s Public Reference Room at 110 F Street, N.E., Washington, D.C. 20549. In addition, we provide paper copies of our filings free of charge upon request. We also make available on our website our corporate governance guidelines, the charters for our audit committee, compensation committee and nominating and corporate governance committee, and our code of business conduct and ethics, and such information is available in print to any stockholder of Curis who requests it.

Intellectual Property

Our policy is to prosecute and enforce the patents and proprietary technology rights that are key to our business. We intend to continue to file U.S. and foreign patent applications to protect technology, inventions and improvements that are considered important to the development of our business. We will be able to protect our proprietary technologies from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets.

We have issued patents in the U.S. expiring on various dates between 2014 and 2023 with pending U.S. and foreign counterpart patent filings for most of these patents and patent applications. These patents and patent applications are directed to compositions of matter, methods of making and using these compositions, methods of repairing, replacing, augmenting and creating tissue for multiple applications, methods for drug screening and discovery, developmental biological processes, and patents relating to our proprietary technologies.

Targeted Cancer Drug Development Platform. We have filed U.S. provisional patent applications and U.S. and foreign utility patent applications directed to our single- and multi-target inhibitor classes of novel small molecules, as well as U.S. and foreign patent applications which generically claim the platform concept itself. These patent applications claim compositions of matter, methods of manufacturing these molecules, formulations, and methods of using these molecules to treat a variety of therapeutic indications. We intend to continue to file additional U.S. and foreign applications as the program progresses.

Hedgehog Pathway. We have issued U.S. patents and allowed U.S. applications expiring on various dates between 2014 and 2023, which relate to the Hedgehog pathway. Our patents and patent applications cover proteins, nucleic acids, antibodies, and certain small molecule agonists and antagonists of the Hedgehog pathway, drug screening and discovery methods, methods of protein manufacturing, as well as methods of using the aforementioned proteins, nucleic acids, antibodies or small molecules to activate or inhibit the Hedgehog

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pathway for a variety of therapeutic indications or diagnostic uses. In addition, we have filed foreign patent applications corresponding to many of the aforementioned U.S. filings that could provide additional patent protection for products that activate or inhibit the Hedgehog pathway.

Our academic and research institution collaborators have certain rights to publish data and information regarding their discoveries to which we have rights. While we believe that the prepublication access to the data developed by our collaborators pursuant to our collaboration agreements will be sufficient to permit us to apply for patent protection in the areas in which we are interested in pursuing further research, there is considerable pressure on such institutions to rapidly publish discoveries arising from their efforts. This may affect our ability to obtain patent protection in the areas in which we may have an interest. In addition, these collaboration agreements typically contain provisions that provide us with, at a minimum, an option to license the institution s rights to intellectual property arising from the collaboration.

We are party to various license agreements that give us rights to commercialize various technologies, particularly our Hedgehog pathway technologies, and to use technologies in our research and development processes. Our most significant license agreements include our license agreements dated February 9, 1995 and September 1, 2000 with the President and Fellows of Harvard University, each of which were amended and restated effective June 10, 2003; a license agreement dated January 1, 1995 and as subsequently amended with The Trustees of the Columbia University; a license agreement dated September 26, 1996 which was amended and restated effective June 1, 2003 with the Johns Hopkins University and the University of Washington School of Medicine; a license agreement dated May 3, 2000 with the Johns Hopkins University; and a February 12, 1996 license agreement with the Leland Stanford Junior University. The consideration payable in exchange for these licenses includes up-front fees, issuances of shares of common stock, annual royalties, milestone payments and royalties on net sales by our sub-licensees and us. The licensors may terminate these agreements if we fail to meet certain diligence requirements, fail to make payments or otherwise commit a material breach that is not cured after notice.

In addition, we depend upon trade secrets, know-how and continuing technological advances to develop and maintain our competitive position. To maintain the confidentiality of trade secrets and proprietary information, we require our employees, scientific advisors, consultants and collaborators, upon commencement of a relationship with us, to execute confidentiality agreements and, in the case of parties other than our research and development collaborators, to agree to assign their inventions to us. These agreements are designed to protect our proprietary information and to grant us ownership of technologies that are developed in connection with their relationship to us.

Research Program

We have a research group that seeks to identify and develop new therapeutic applications for our existing patent portfolio and seeks to identify new signaling pathways that may have therapeutic potential. As of December 31, 2007, our research group consists of 27 employees, consisting of molecular biologists, cell biologists, pharmacologists and other scientific disciplines.

During the years ended December 31, 2007, 2006 and 2005, our total company-sponsored research and development expenses were approximately $12,260,000, $6,340,000 and $3,751,000, respectively, and our collaborator-sponsored research and development expenses were approximately $2,519,000, $8,250,000 and $9,954,000, respectively.

Regulatory Matters

FDA Requirements for New Drug Compounds

Numerous governmental authorities in the U.S. and other countries extensively regulate, among other things, the research, testing, manufacture, import and export and marketing of drug products. In the U.S., drugs

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are subject to rigorous regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, labeling, promotion, sampling and marketing and distribution of pharmaceutical products. Failure to comply with applicable regulatory requirements may subject a company to a variety of administrative or judicially imposed sanctions. These sanctions could include the FDA s refusal to approve pending applications, withdrawal of approvals, clinical holds, warning letters, product recalls, product seizures, total or partial suspension of our operations, injunctions, fines, civil penalties or criminal prosecution.

The steps ordinarily required before a new pharmaceutical product may be marketed in the U.S. include preclinical laboratory tests, animal tests and formulation studies, under the FDA s good laboratory practice, or GLP, regulations, the submission to the FDA of a notice of claimed investigational exemption or an IND application, which must become effective before clinical testing may commence, adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought, submission to the FDA of a new drug application, satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practice, or cGMP, requirements and FDA review and approval of the new drug application. Satisfaction of FDA pre-market approval requirements typically takes several years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures upon a manufacturer s activities. Success in early stage clinical trials does not assure success in later stage clinical trials. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. Even if a product receives regulatory approval, later discovery of previously unknown problems with a product, including new safety risks, may result in restrictions on the product or even complete withdrawal of the product from the market.

Preclinical tests include laboratory evaluation of product chemistry and formulation, as well as animal trials to assess the potential safety and efficacy of the product. The conduct of the preclinical tests and formulation of compounds for testing must comply with federal regulations and requirements, including the FDA s GLP regulations. Preclinical testing is highly uncertain and may not be completed successfully within any specified time period, if at all. Further, the successful completion of preclinical trials does not assure success in clinical human trials. The results of preclinical testing are submitted to the FDA as part of an IND application, together with manufacturing information and analytical and stability data of the drug formulation. The IND application must become effective before clinical trials can begin in the United States. An IND application becomes effective 30 days after receipt by the FDA unless before that time the FDA raises concerns or questions about issues such as the proposed clinical trials outlined in the IND application and places a clinical hold on the trials. In that case, the IND application sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. If these concerns or questions are unresolved, the FDA may not allow the clinical trials to commence.

Clinical trials involve the administration of the IND to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal regulations and requirements, including good clinical practices, under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. subjects must be submitted to the FDA as part of the IND application. The study protocol and informed consent information for patients in clinical trials must be submitted to institutional review boards for approval.

Clinical trials to support new drug applications for marketing approval are typically conducted in three sequential phases, but the phases may overlap or be combined. In phase I, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics and pharmacological actions and safety, including side effects associated with increasing doses and, if possible, early evidence of effectiveness. Phase II usually involves trials in a limited patient population, to determine dosage

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tolerance and optimum dosage, identify possible adverse effects and safety risks, and provide preliminary support for the efficacy of the drug in the indication being studied. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in phase II evaluations, phase III trials are undertaken to further evaluate clinical efficacy and to further test for safety within an expanded patient population, typically at geographically dispersed clinical trial sites to establish the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. Phase I, phase II or phase III testing of any product candidates may not be completed successfully within any specified time period, if at all. The FDA closely monitors the progress of each of the three phases of clinical trials that are conducted in the U.S. In addition, the recently enacted Food and Drug Administration Amendments Act of 2007, or FDAAA, significantly expands the federal government s clinical trial registry to cover more trials and more information, including information on the results of completed trials. The FDA may, at its discretion, reevaluate, alter, suspend or terminate the testing based upon the data accumulated to that point and the FDA s assessment of the risk/benefit ratio to the subject. The FDA, an institutional review board, or a clinical trial sponsor may suspend or terminate clinical trials at any time for various reasons, including a finding that the subjects or patients are being exposed to an unacceptable health risk. The FDA can also request additional clinical trials be conducted as a condition to product approval.

After successful completion of the required clinical testing, generally a new drug application, or NDA, is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The new drug application must include the results of extensive preclinical and clinical testing and a compilation of data relating to the product s pharmacology, chemistry, manufacture, and controls. In most cases, a substantial user fee must accompany the new drug application.

If the FDA s evaluation of the NDA and inspection of the manufacturing facilities are favorable, the FDA may issue an approval letter, or, in some cases, an approvable letter. An approvable letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA. If and when those conditions have been met to the FDA s satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require post-approval testing, including phase IV trials, and surveillance to monitor the drug s safety or efficacy and may impose other conditions, including labeling restrictions which can materially impact the potential market and profitability of the drug. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Once the new drug application is approved, a product will be subject to certain post-approval requirements, including requirements for adverse event reporting, submission of periodic reports, and drug sampling and distribution requirements. Additionally, the FDA strictly regulates the promotional claims that may be made about prescription drug products. In particular, a drug may not be promoted for uses that are not approved by the FDA as reflected in the drug s approved labeling. Moreover, the Department of Justice can bring civil or criminal actions against companies that promote drugs for unapproved uses, based on the False Claims Act and other Federal laws governing reimbursement for drugs under the Medicare and Medicaid laws. Monetary penalties in such cases have often been in excess of $100 million. In addition, the FDA requires substantiation of any claims of superiority of one product over another including, in many cases, requirements that such claims be proven by adequate and well-controlled head-to-head clinical trials. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to FDA review and approval of a new NDA or NDA supplement before the change can be implemented. Quality control and manufacturing procedures must continue to conform to cGMPs after approval. Drug manufacturers and their subcontractors are required to register their facilities with the FDA and are subject to periodic unannounced inspections by the FDA to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

If the FDA s evaluation of the NDA submission or manufacturing facilities is not favorable, the FDA may refuse to approve the NDA or issue a not approvable letter. The not approvable letter outlines the deficiencies in the

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submission and often requires additional testing or information in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. With limited exceptions, FDA may withhold approval of a NDA regardless of prior advice it may have provided or commitments it may have made to the sponsor.

New Legislation

On September 27, 2007, the President signed the FDAAA. The new legislation grants significant new powers to the FDA, many of which are aimed at improving the safety of drug products before and after approval. In particular, the new law authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information, and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. In addition, it significantly expands the federal government s clinical trial registry and results databank and creates new restrictions on the advertising and promotion of drug products. Under the FDAAA, companies that violate these and other provisions of the new law are subject to substantial civil monetary penalties.

While we expect these provisions of the FDAAA, among others, to have a substantial effect on the pharmaceutical industry, the extent of that effect is not yet known. As the FDA issues regulations, guidance and interpretations relating to the new legislation, the impact on the industry, as well as our business, will become clearer. The new requirements and other changes that the FDAAA imposes may make it more difficult, and likely more costly, to obtain approval of new pharmaceutical products and to produce, market and distribute existing products.

Foreign Regulation of New Drug Compounds

Approval of a drug product by comparable regulatory authorities will be necessary in foreign countries prior to the commencement of marketing of the product in those countries, whether or not FDA approval has been obtained. While clinical data generated in the U.S. may be accepted in many foreign jurisdictions in lieu of early stage clinical trials (phase I), the approval procedure varies among countries and can involve requirements for additional testing equivalent to phases II and III. The time required may differ from that required for FDA approval and may be longer than that required to obtain FDA approval. There can be substantial delays in obtaining required approvals from foreign regulatory authorities after the relevant applications are filed.

In Europe, marketing authorizations may be submitted under a centralized or decentralized procedure. The centralized procedure is mandatory for the approval of biotechnology products and many pharmaceutical products, and provides for the grant of a single marketing authorization, which is valid in all European Union member states. The decentralized procedure is a mutual recognition procedure that is available at the request of the applicant for medicinal products that are not subject to the centralized procedure.

Hazardous Materials

Our research and development processes involve the controlled use of hazardous materials, chemicals and radioactive materials and produce waste products. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products.

Competition

Our product candidates, if approved, will compete with existing and new products being developed by others for treatment of the same indications. Competition in the development of human therapeutics and, in particular, human therapeutics based upon signaling pathways, is intense. Our competitors may include many large pharmaceutical and biopharmaceutical companies, as well as specialized biotechnology firms. There are several companies developing drug candidates that target the same cancer pathways that we are also targeting utilizing our proprietary targeted cancer drug development platform. We believe that our competitive advantage

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over these companies is our strategy of developing drug candidates to target unique combinations of these cancer pathways to achieve synergistic effect. In addition to these competitors, we have identified biotechnology and pharmaceutical companies that claim to have intellectual property rights and drug development programs relating to compounds that modulate the Hedgehog pathway.

Many of the companies competing against us have financial, marketing and human resource capacities that are substantially greater than our own, which may provide these competitors with significant competitive advantages over us. Others have extensive experience in undertaking clinical trials, in obtaining regulatory approval to market products, in manufacturing products on a large scale and in effectively promoting products to healthcare providers, health plans and consumers which may enhance their competitive position relative to ours. Most of the major pharmaceutical and biotechnology companies are developing targeted cancer therapies. In addition to competing with pharmaceutical, biotechnology and medical device companies, the products we are developing would also compete with those being developed by academic and research institutions, government agencies and other public organizations. Any of these organizations may discover new therapies, seek patent protection or establish collaborative arrangements for products and technologies that are competitive with our products and technologies.

The technologies underlying the development of human therapeutic products are expected to continue to undergo rapid and significant advancement and unpredictable changes. Accordingly, our technological and commercial success will be based, among other things, on our ability to develop proprietary positions in key scientific areas and efficiently evaluate potential product opportunities.

The timing of a product s introduction may be a major factor in determining eventual commercial success and profitability. Early entry may have important advantages in gaining product acceptance and market share. Accordingly, we believe the relative speed with which we or any current or future collaborator can complete preclinical and clinical testing, obtain regulatory approvals, and supply commercial quantities of a product will have an important impact on our competitive position, both in the U.S. and abroad. Other companies may succeed in developing similar products that are introduced earlier, are more effective, or are produced and marketed more effectively, or at a minimum obtain a portion of the market share. For example, our competitors may discover, characterize and develop important targeted cancer molecules before we do, which could have a material adverse effect on any of our related research programs. If research and development by others renders any of our products obsolete or noncompetitive, then our potential for success and profitability may be adversely affected.

For certain of our programs, we rely on, or intend to rely on, strategic collaborators for support in our disease research programs and for preclinical evaluation and clinical development of our potential products and manufacturing and marketing of any products. Our strategic collaborators may conduct multiple product development efforts within each disease area that is the subject of our strategic collaboration with them. Our strategic collaboration agreements may not restrict the strategic collaborator from pursuing competing internal development efforts. Any of our product candidates, therefore, may be subject to competition with a product candidate under development by a strategic collaborator.

Manufacturing

We have no experience or capabilities in manufacturing. We have no current plans to develop manufacturing capability and instead plan to rely on corporate collaborators or subcontractors to manufacture products. If any of our current or planned collaborators or subcontractors encounters regulatory compliance problems or enforcement actions for their own or a collaborative product, it could have a material adverse effect on our business prospects.

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Sales and Marketing

We have no sales, marketing or distribution experience or infrastructure and we have no current plans to develop a sales, marketing and distribution capability. We currently plan to rely on corporate collaborators for product sales, marketing and distribution.

Scientific Governance

We have established a scientific advisory board as well as a clinical advisory board, each made up of leading scientists and physicians in the field of cancer drug development. Members of these boards consult with us on matters relating to our research and development programs, including clinical trial designs, new technologies relevant to our research and development programs and other scientific and technical issues relevant to our business.

The current members of our scientific advisory board are as follows:

Name	Position/Institutional Affiliation
Joseph M. Davie, Ph.D., M.D. (Chairman)	Director, Curis, Inc. Director, CV Therapeutics, Inc. Director, Keel Pharmaceuticals, Inc. Director, GENTIAE Clinical Research, Inc. Director, Ocera, Inc. Director, Stratatech Corporation Director, Targeted Genetics, Inc. Director, BG Medicine Institute of Medicine since 1987
Stuart Aaronson, M.D	Chairman of the Department of Oncological Sciences and the Jane B. and Jack R. Aron Professor of Neoplastic Diseases, Mount Sinai School of Medicine
Kenneth Pienta, M.D	Professor, Internal Medicine and Urology and Co-director, Urologic Oncology Program, The University of Michigan Comprehensive Cancer Center Director, Translational Medicine Committee of the Southwest Oncology Group (SWOG) Principal investigator, The University of Michigan s SPORE (Specialized Program of Research Excellence) in prostate cancer awarded from the National Cancer Institute
George Vande Woude, Ph.D	Director, Van Andel Research Institute Co-editor, *Advances in Cancer Research*

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The current members of our clinical advisory board are as follows:

Name	Position/Institutional Affiliation
Kenneth Pienta, M.D (chairman)	See scientific advisory board table
Philip A. Philip, M.D.	Professor of Medicine, Wayne State University School of Medicine Clinical Professor of Oncology, Barbara Ann Karmanos Cancer Institute Editorial Board Member, Internet Journal of Oncology and Community Oncology Member, American Pancreatic Association Member, American Society of Clinical Oncology American Board of Internal Medicine-Certified, Internal Medicine and Medical Oncology
Samir Witta, M.D., Ph.D.	Clinical Assistant Professor, Internal Medicine, Division of Oncology, University of Colorado Cancer Center Member, American Society of Clinical Oncology

Employees

As of December 31, 2007, we had 42 full-time employees, of whom 19 hold a Ph.D. or other advanced degree. Of these employees, 27 are currently involved in research and development. None of our employees is a party to a collective bargaining agreement, and we consider our relations with our employees to be good.

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ITEM 1A. RISK FACTORS

RISKS RELATING TO OUR FINANCIAL RESULTS AND NEED FOR FINANCING

We have incurred substantial losses, we expect to continue to incur substantial losses for the foreseeable future and we may never generate significant revenue or achieve profitability.

As of December 31, 2007, we had an accumulated deficit of approximately $695,848,000. We have not successfully commercialized any products to date, either alone or in collaboration with others. If we are not able to successfully commercialize any products, whether alone or with a collaborator, we will not achieve profitability. All of our product candidates are in early stages of development. As a result, for the foreseeable future, we will need to spend significant capital, particularly on our internally funded targeted cancer drug development platform, in an effort to produce products that we can commercialize. As such, we expect to incur substantial operating losses for the foreseeable future.

We have no current sources of material ongoing research funding revenue. We have historically derived a substantial portion of our revenue from the research funding portion of our collaboration agreements. Research funding related to our ongoing Hedgehog antagonist and Wnt signaling pathway collaborations with Genentech concluded in the fourth quarter of 2006 and the first quarter of 2007, respectively. In addition, research funding under our Hedgehog agonist collaboration with Wyeth concluded in February 2008 and on March 7, 2008, Wyeth provided us with written notice that it will terminate this collaboration agreement effective May 6, 2008. Accordingly, our future revenues will be limited to (i) the amortization of previously received license payments from Wyeth and Stryker Corporation at December 31, 2007, (ii) potential future cash payments, if any, that are principally contingent upon the successful completion of contractually defined development and regulatory approval objectives under our collaborations with Genentech, and (iii) royalty payments, if any, that we may receive upon the successful commercialization of any products based upon our licensed programs and technologies. The pursuit and achievement of any development or commercialization objectives is substantially within the collaborators sole control. In addition, there is considerable inherent uncertainty in the successful development and commercialization of pharmaceutical drugs. As a result, we cannot assure you that any further revenue will be attained by us under these collaborations.

We will need to generate significant revenues in order to fund our operations and achieve profitability. We cannot be certain whether or when this will occur because of the significant uncertainties that affect our business, including the various risks described in this section titled Risk Factors . Our failure to become and remain profitable may depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our research and development programs or continue our operations.

We will require substantial additional capital, which may be difficult to obtain and may result in stockholder dilution.

We will require substantial funds to continue our research and development programs and to fulfill our planned operating goals. In particular, our currently planned operating and capital requirements include the need for working capital to:

- support our research and development activities for CUDC-101 and other small molecule multi-targeted inhibitors that we are seeking to develop under our targeted cancer drug development platform;
- fund our general and administrative costs and expenses; and
- potentially expand our infrastructure.

We believe that our existing cash, cash equivalents and other working capital, should be sufficient to fund our operations into the second half of 2009; however, our future capital requirements may vary from what we

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currently expect. There are factors that may adversely affect our planned future capital requirements and accelerate our need for additional financing. These factors, many of which are outside our control, include the following:

- unanticipated costs in our research and development programs;
- the timing and cost of obtaining regulatory approvals for our product candidates;
- the cost of additional facility requirements;
- the timing, receipt and amount of research funding and contingent cash payments, license, royalty and other payments, if any, from current and potential future collaborators;
- the timing, payment and amount of research funding and contingent cash payments, license, royalty and other payments due to licensors of patent rights and technology used in our product candidates;
- the timing, receipt and amount of sales revenues and/or royalties, if any, that we may receive in the future if any of our product candidates are successfully developed and commercialized; and
- the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including litigation costs and technology license fees.

We expect to seek additional funding through public or private financings of debt or equity as well as from additional strategic collaborations. The market for biotechnology stocks in general, and the market for our common stock in particular, is highly volatile. Due to this and various other factors, including general market conditions and the early-stage status of our development pipeline, additional funding may not be available to us on acceptable terms, if at all. If we fail to obtain such additional financing on a timely basis, our ability to continue all of our research and development activities will be adversely affected.

If we raise additional funds by issuing equity securities, dilution to our stockholders will result. In addition, the terms of such a financing may adversely affect other rights of our stockholders. We also could elect to seek funds through arrangements with collaborators or others that may require us to relinquish rights to certain technologies, product candidates or products.

We may face fluctuations in our operating results from period to period, which may result in a drop in our stock price.

Our operating results have fluctuated significantly from period to period in the past and may rise or fall significantly from period to period in the future as a result of many factors, including:

- the cost of research and development that we engage in;
- the timing, receipt and amount of research funding and contingent cash payments, license, royalty and other payments, if any, from current and potential future collaborators;
- the entry into, or termination of, collaboration agreements;

the number of product candidates we have and their progress in achieving pre-clinical and clinical development objectives;

the scope, duration and effectiveness of our collaborative arrangements;

the costs involved in prosecuting, maintaining and enforcing patent claims;

costs to comply with changes in government regulations;

changes in management and reductions or additions of personnel;

changes in accounting estimates, policies or principles; and

the introduction of competitive products and technologies by third parties.

Except for our systemically administered Hedgehog antagonist program, which is being evaluated by our collaborator, Genentech, in an expansion cohort of an ongoing phase I clinical trial, all of our programs are in

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various stages of preclinical drug development. Accordingly, our revenues from sales of approved products may not occur for several years, if at all. While we may receive contingent cash payments upon the achievement of certain objectives defined within our collaboration agreements with Genentech, the timing of such payments is uncertain. In addition, the amount of these payments and the methodology that we would record such payments to revenue vary for each of our collaborator agreements. As a result, we may experience fluctuations in our operating results from quarter to quarter and continue to generate losses. Quarterly comparisons of our financial results may not necessarily be meaningful, and investors should not rely upon such results as an indication of our future performance. In addition, investors may react adversely if our reported operating results are less favorable than in a prior period or are less favorable than those anticipated by investors or the financial community, which may result in a drop of our stock price.

We determined that certain accounting errors in our financial statements had a material impact on our previously reported financial information. As a result of this determination, we restated our financial results for 2003, 2004 and for the quarters ended March 31, 2005, June 30, 2005 and September 30, 2005. The restatement could subject us to securities litigation.

As discussed in Note 2 of the notes to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2005, in March 2006, we restated our financial results for 2003, 2004 and for the quarters ended March 31, 2005, June 30, 2005, and September 30, 2005. The restatement relates primarily to accounting errors in prior periods with respect to our revenue recognition accounting for $7,509,000 in license and maintenance fee payments paid by Genentech as part of our June 2003 Hedgehog antagonist collaboration with Genentech. We had been recognizing revenue in connection with the $7,509,000 in payments over an eight-year period based on our estimate that our participation on the steering committees for the collaboration would become inconsequential after the first product was approved in each of the two programs covered under this collaboration, and would therefore no longer represent a performance obligation. Accordingly, from fiscal year 2003 through the third quarter of 2005, we had recognized $2,239,000 in license fee revenue related to these payments. Following discussions with the SEC, we determined we should not have recognized any of this revenue in 2003, 2004 or 2005. As a result, we restated our financial results for these periods to defer the $7,509,000 in payments and determined that we would only recognize this amount as revenue when we could reasonably estimate when our contractual steering committee obligations would become inconsequential or after we no longer had contractual steering committee obligations under this agreement with Genentech.

Securities class action litigation has often been brought in connection with restatements of financial statements. Defending against such potential litigation relating to a restatement of our financial statements would be expensive and would require significant attention and resources of our management. Moreover, our insurance to cover our obligations with respect to the ultimate resolution of any such litigation may be inadequate. As a result of these factors, any such potential litigation could have a material adverse effect on our business, results of operations and financial condition.

If the estimates we make and the assumptions on which we rely in preparing our financial statements prove inaccurate, our actual results may vary significantly.

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses, the amounts of charges taken by us and related disclosure. Such estimates and judgments include the carrying value of our property, equipment and intangible assets, revenue recognition and the value of certain liabilities. We base our estimates and judgments on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. However, these estimates and judgments, or the assumptions underlying them, may change over time. Accordingly, our actual financial results may vary significantly from the estimates contained in our financial statements. For example, as discussed above in March 2006 we determined that certain accounting errors in our financial statements had a material impact on our previously reported financial information. As a result of this

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determination, we restated our financial results for 2003, 2004 and for the quarters ended March 31, 2005, June 30, 2005 and September 30, 2005. The restatement could subject us to securities litigation.

For a further discussion of the estimates and judgments that we make and the critical accounting policies that affect these estimates and judgments, see Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates elsewhere in this annual report on Form 10-K.

Compliance with changing regulation of corporate governance and public disclosure as well as potential new accounting pronouncements are likely to impact our future financial position or results of operations.

Changing laws, regulations and standards relating to corporate governance and public disclosure, new SEC regulations and NASDAQ Global Market rules are creating uncertainty for companies such as ours. These new or changed laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. In addition, future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our financial position or results of operations. New accounting pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and may occur again in the future and as a result we may be required to make changes in our accounting policies, for example the 2006 requirement under SFAS 123(R) to expense stock options.

Our efforts to comply with evolving laws, regulations and standards have resulted in, and are likely to continue to result in, increased general and administrative expenses and management time related to compliance activities. We expect these efforts to require the continued commitment of significant resources. If our efforts to comply with new or changed laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, our reputation may be harmed and we might be subject to sanctions or investigation by regulatory authorities, such as the SEC. Any such action could adversely affect our financial results and the market price of our common stock.

Failure to maintain effective internal controls in accordance with section 404 of the Sarbanes-Oxley act could have a material adverse effect on our business and stock price.

Section 404 of the Sarbanes-Oxley Act of 2002 requires management s annual review and evaluation of our internal controls, and attestations of the effectiveness of our internal controls by our independent auditors. Our failure to maintain the effectiveness of our internal controls in accordance with the requirements of Section 404 of the Sarbanes-Oxley Act, as such standards are modified, supplemented or amended from time to time, could have a material adverse effect on our business, operating results and stock price.

RISKS RELATING TO COLLABORATIONS

We depend on Genentech for the development and commercialization of certain product candidates based upon our technologies and plan to enter into additional collaborations in the future. If any of our current or planned agreements with collaborators are terminated, or if such collaborators fail or delay in developing or commercializing our product candidates, our anticipated product pipeline and operating results would suffer.

The success of our strategy for development and commercialization of certain licensed product candidates depends upon our ability to form and maintain productive and successful strategic collaborations. We currently have two collaborations with Genentech pursuant to which we have granted to Genentech exclusive rights to develop and commercialize products based upon our

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technologies in defined fields of use. In addition, we are seeking to enter into additional collaborations in the future, including a potential collaboration related to the development of one or more candidates from our targeted cancer drug development platform. Our existing and any future collaborations may not be scientifically or commercially successful.

The risks that we face in connection with our current and potential future collaborations include the following:

- Our current collaborator has, and we expect any planned future collaborators will have, significant discretion in determining the efforts and resources that it will apply to the collaboration. The timing and amount of any cash payments related to future royalties, research support and the achievement of development objectives that we may receive under any such collaborative arrangements will depend on, among other things, each collaborator s efforts and allocation of resources.

- Our strategic collaboration agreements with Genentech permit, and our planned future collaborations are expected to permit, our collaborators wide discretion in terms of deciding which product candidates to advance to development candidate selection and through the clinical trial process. It is possible for product candidates to be rejected by a collaborator, at any point in the clinical trial process, without triggering a termination of the collaboration agreement with us. In the event of such decisions, we may be adversely affected due to our inability to progress product candidates ourselves.

- Our current and planned collaborators may develop and commercialize, either alone or with others, products and services that are similar to or competitive with the products and services that are the subject of the collaboration with us.

- Our current and planned collaborators may change the focus of their development and commercialization efforts or pursue higher-priority programs. The ability of certain of our product candidates to be successfully commercialized could be limited if our current and planned collaborators decrease or fail to increase spending related to such product candidates.

We may not be successful in establishing additional strategic collaborations, which could adversely affect our ability to develop and commercialize products.

As an integral part of our ongoing research and development efforts, we periodically review opportunities to establish new strategic collaborations for the development and commercialization of products in our development pipeline. For example, we are currently seeking a corporate collaboration for one or more programs that we are developing under our propriety targeted cancer drug development platform and also intend to seek a collaborative partner for our Hedgehog agonist program. We face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. We may not be successful in our efforts to establish a collaboration or other alternative arrangements for any of these programs because, for example, our research and development pipeline may be insufficient or our programs may be deemed to be at too early of a stage of development for collaborative effort. Even if we are successful in our efforts to establish new collaborations, the terms that we agree upon may not be favorable to us. Finally, any such strategic alliances or other arrangements may not result in the successful development and commercialization of products and associated revenue.

RISKS RELATED TO OUR BUSINESS, INDUSTRY, STRATEGY AND OPERATIONS

We and our current and planned collaborators may not achieve our projected research and development goals in the time frames we announce and expect, which could have an adverse impact on our business and could cause our stock price to decline.

We set goals for, and make public statements regarding, the timing of certain accomplishments, such as the commencement and completion of preclinical studies, initiation and completion of clinical trials, and other developments and milestones under our proprietary programs and those programs being developed under collaboration

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agreements. For example, we have estimated that we will seek to submit an IND application to commence clinical trials of CUDC-101 early in the second quarter of 2008 and select a second development candidate from our targeted cancer drug development platform in the first half of 2008. The actual timing of these events can vary dramatically due to a number of factors such as delays or failures in our preclinical studies or clinical trials, the amount of time, effort and resources committed to our programs by us and the uncertainties inherent in the regulatory approval process. There can be no assurance that our or our current and planned collaborators preclinical studies and clinical trials will advance or be completed in the time frames we announce or expect, that we or our current and planned collaborators will make regulatory submissions or receive regulatory approvals as planned or that we or our current and planned collaborators will be able to adhere to our current schedule for the achievement of key milestones under any of our internal or collaborative programs. If we or any collaborators fail to achieve one or more of these milestones as planned, our business could be materially adversely affected and the price of our common stock could decline.

We face substantial competition, which may result in our competitors discovering, developing or commercializing products before or more successfully than we do.

Our product candidates face competition from existing and new technologies and products being developed by biotechnology, medical device and pharmaceutical companies, as well as universities and other research institutions. For example, research in the Hedgehog signaling pathway is increasingly competitive. We are developing Hedgehog-based therapies under our collaborations with Genentech in the field of cancer. Competitors may discover, characterize and develop Hedgehog antagonist drug candidates before we do.

In addition, our multi-target inhibitors being developed under our targeted cancer drug development platform, which are focused primarily on clinically validated cancer targets, face significant competition from marketed drugs and drugs under development that seek to inhibit the same targets as our drug candidates.

Many of our competitors have substantially greater capital resources, research and development staffs and facilities than we have. Efforts by other biotechnology, medical device and pharmaceutical companies could render our programs or products uneconomical or result in therapies superior to those that we develop alone or with a collaborator.

For those programs that we have selected for internal development, we face competition from companies that are more experienced in product development and commercialization, obtaining regulatory approvals and product manufacturing. Other smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. As a result, any of these companies may be more successful in obtaining collaboration agreements or other monetary support, approval and commercialization of their products and/or may develop competing products more rapidly and/or at a lower cost. For those programs that are subject to a collaboration agreement, competitors may have greater expertise in discovery, research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and marketing than our collaborators and, consequently, may discover, develop and commercialize products that render our products non-competitive or obsolete.

We expect competition to intensify in cancer generally and, specifically, in targeted approaches to develop potential cancer therapies as technical advances in the field are made and become more widely known.

If we or any of our current and planned collaborators fail to achieve market acceptance for our products under development, our future revenue and ability to achieve profitability may be adversely affected.

Our future products, if any are successfully developed, may not gain commercial acceptance among physicians, patients and third-party payors, even if necessary marketing approvals have been obtained. We believe that recommendations and endorsements by physicians will be essential for market acceptance of any products we successfully develop. If we are not able to obtain market acceptance for such products, our expected revenues from sales of these products would be adversely affected and our business may not be successful.

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We could be exposed to significant monetary damages and business harm if we are unable to obtain or maintain adequate product liability insurance at acceptable costs or otherwise protect ourselves against potential product liability claims.

Product liability claims inherent in the process of researching, developing and commercializing human health care products could expose us to significant liabilities and prevent or interfere with the development or commercialization of our product candidates. Product liability insurance is expensive to procure for biopharmaceutical companies such as ours. Product liability claims would require us to spend significant time, money and other resources to defend such claims and could ultimately to pay a significant damage award. Because we are not currently conducting any clinical trials or commercializing any products, we do not currently carry any product liability insurance. We plan to purchase product liability insurance for our expected phase I clinical trial of CUDC-101, which we expect will begin in the first half of 2008. Although we would seek to obtain and maintain product liability insurance coverage for this and any other future clinical trials of our products under development, it is possible that we will not be able to obtain this product liability insurance on acceptable terms, if at all, and that our product liability insurance coverage would not prove to be adequate to protect us from all potential claims.

If we are not able to attract and retain key management and scientific personnel and advisors, we may not successfully develop our product candidates or achieve our other business objectives.

We depend upon our senior management and scientific staff, including Daniel R. Passeri, our President and Chief Executive Officer, Michael P. Gray, our Chief Operating Officer and Chief Financial Officer, and Changgeng Qian, Ph.D., M.D., our Vice President, Discovery and Preclinical Development. The loss of the service of any of the key members of our senior management may significantly delay or prevent the achievement of product development and other business objectives. Our officers can terminate their employment with us at any time, although we are not aware of any present intention of any of these individuals to leave our company. Replacing key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to research, develop and successfully commercialize products in our areas of core competency. We do not maintain key man life insurance on any of these executive officers.

Our ability to operate successfully will depend on our ability to attract and retain qualified personnel, consultants and advisors. We face intense competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities, governmental entities and other research institutions. We may be unable to attract and retain these individuals, and our failure to do so would have an adverse effect on our business.

We may seek to acquire complementary businesses and technologies in the future or otherwise seek to expand our operations to grow our business, which may divert management resources and adversely affect our financial condition and operating results.

We may seek to expand our operations in the future, including without limitation through internal growth and/or the acquisition of businesses and technologies that we believe are a strategic complement to our business model. We may not be able to identify suitable acquisition candidates or expansion strategies and successfully complete such acquisitions or successfully execute any such other expansion strategies. We may never realize the anticipated benefits of any efforts to expand our business. Furthermore, the expansion of our business, either through internal growth or through acquisitions, poses significant risks to our existing operations, financial condition and operating results, including:

- a diversion of management from our existing operations;
- increased operating complexity of our business, requiring greater personnel and resources;
- significant additional cash expenditures to expand our operations and acquire and integrate new businesses and technologies;

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incurrence of debt, other liabilities and contingent liabilities; and

dilutive stock issuances.

Any business that we conduct in China will expose us to the risk of adverse changes in political, legal and economic policies of the Chinese government, which changes could impede our preclinical efforts in China and materially and adversely affect the development of our Targeted Cancer Drug Development platform.

We are developing our targeted cancer drug development platform using standard medicinal chemistry approaches to create proprietary targeted cancer drugs. In order to satisfy the platform s extensive medicinal chemistry requirements, we currently engage 25 to 30 medicinal chemists in Shanghai, China pursuant to an agreement with a medicinal chemistry provider in Shanghai. The economics of doing business in China allow us to engage approximately five chemists for the same price as one chemist at U.S. or European chemistry providers. We also currently engage approximately 6 biologists at another third-party provider in Beijing, China. In addition, we have a subsidiary in China, Curis Shanghai, that is currently licensed but is not operational.

Conducting business in China exposes us to a variety of risks and uncertainties that are unique to China. The economy of China has been transitioning from a planned economy to a more market-oriented economy. Although in recent years the Chinese government has implemented measures emphasizing the utilization of market forces for economic reform, the reduction of state ownership of productive assets and the establishment of sound corporate governance in business enterprises, a substantial portion of productive assets in China is still owned by the Chinese government. In addition, the Chinese government continues to play a significant role in regulating industrial development. It also exercises significant control over China s economic growth through the allocation of resources, controlling payment of foreign currency-denominated obligations, setting monetary policy and providing preferential treatment to particular industries or companies. Efforts by the Chinese government to slow the pace of growth of the Chinese economy could result in interruptions of our development efforts in China. If our development efforts in China are delayed due to such interruptions, we may not realize the reductions in costs anticipated from engaging chemists in China. We would also have to consider moving our chemistry and/or biology that is currently conducted in China to U.S. or European providers, thereby either increasing our overall costs for such services or reducing the total number of chemists and or/biologists that we could engage.

In addition, the Chinese legal system is a civil law system based on written statutes. Unlike common law systems, it is a system in which decided legal cases have little precedential value. In 1979, the Chinese government began to promulgate a comprehensive system of laws and regulations governing economic matters in general. Accordingly, we cannot predict the effect of future developments in the Chinese legal system, including the promulgation of new laws, changes to existing laws or the interpretation or enforcement thereof, or the preemption of local regulations by national laws. Our business could be materially harmed by any changes in the political, legal or economic climate in China or the inability to enforce applicable Chinese laws and regulations.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY

If we or any of our licensees or assignees breach any of the agreements under which we license or transfer intellectual property to others, we could be deprived of important intellectual property rights and future revenue.

We are a party to intellectual property out-licenses, collaborations and agreements that are important to our business, including our June 2003 and April 2005 collaboration agreements with Genentech and our December 2007 assignment agreement with Stryker Corporation, and we expect to enter into similar agreements with third parties in the future. Under these agreements, we generally license or transfer intellectual property to third parties and impose various research, development, commercialization, sublicensing, royalty, indemnification, insurance, and other obligations on them. If a third party fails to comply with these requirements, we generally retain the right to terminate the agreement, and to bring a legal action in court or in arbitration. In the event of breach, we may need to enforce our rights under

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these agreements by resorting to arbitration or litigation. During the period of arbitration or litigation, we may be unable to effectively use, assign or license the relevant intellectual property rights and may be deprived of current or future revenues that are associated with such intellectual property.

We in-license certain of our principal proprietary technologies, and if we fail to comply with our obligations under any of the related agreements, or fail to secure any required new licenses, we could lose license rights that are necessary to commercializing our product candidates.

We are party to various license agreements that give us rights to commercialize various technologies, particularly our Hedgehog pathway technologies, and to use technologies in our research and development processes. Our most significant in-license agreements are with Harvard University, Columbia University, the Johns Hopkins University both alone and with the University of Washington, and Leland Stanford Junior University. Some of these license agreements impose various development, commercialization, funding, royalty, diligence, and other obligations on us, which provide that our failure to meet any agreed upon requirements may allow the licensor to terminate the agreement. Some of our license agreements grant us exclusive licenses to the underlying technologies. If our licensors terminate our license agreements or if we are unable to maintain the exclusivity of our exclusive license agreements, we may be unable to continue to develop and commercialize our product candidates. In addition, continued development and commercialization of our product candidates may require us to secure licenses to additional technologies. We may not be able to secure these licenses on commercially reasonable terms, if at all.

We may not be able to obtain patent protection for our technologies and the patent protection we do obtain may not be sufficient to stop our competitors from using similar technology.

The patent positions of pharmaceutical and biotechnology companies, including ours, are generally uncertain and involve complex legal, scientific and factual questions. The procedures and standards that the United States Patent and Trademark Office and various foreign intellectual property offices use to grant patents, and the standards that courts use to interpret patents, are not always applied predictably or uniformly and have recently changed in a significant way and are expected to continue to change. Consequently, the level of protection, if any, that will be obtained and provided by our patents if we attempt to enforce them, and they are challenged, is uncertain. The long-term success of our business depends in significant part on our ability to:

- obtain patents to protect our technologies and discoveries;
- protect trade secrets from disclosure to third-party competitors;
- operate without infringing upon the proprietary rights of others; and
- prevent others from infringing on our proprietary rights.

Patents may not issue from any of the patent applications that we own or license. If patents do issue, the type and extent of patent claims issued to us may not be sufficient to protect our technology from exploitation by our competitors. In addition, issued patents that we own or license may be challenged, invalidated or circumvented. Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the United States and abroad are maintained in secrecy until 18 months after filing, it is possible that third parties have filed or maintained patent applications for technology used by us or covered by our pending patent applications without our knowledge.

We may not have rights under patents that may cover one or more of our product candidates. In some cases, these patents may be owned or controlled by third-party competitors and may prevent or impair our ability to exploit our technology. As a result, we or our current or planned collaborative partners may be required to obtain licenses under third-party patents to develop and commercialize some of our product candidates. If we are unable to secure licenses to such patented technology on acceptable terms, we or our collaborative partners will not be able to develop and commercialize the affected product candidate or candidates.

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We may become involved in expensive and unpredictable litigation, and in particular, patent litigation or other intellectual property proceedings, which could result in liability for damages or stop our development and commercialization efforts.

Substantial, complex or extended litigation could cause us to incur large expenditures and distract our management, and could result in significant monetary or equitable judgments against us. For example, lawsuits by employees, licensors, licensees, suppliers, distributors, stockholders, or competitors could be very costly and substantially disrupt our business. Disputes from time to time with such companies or individuals are not uncommon, and we cannot assure that we will always be able to resolve such disputes out of court or on terms favorable to us. Any claims, with or without merit, and regardless of whether we prevail in the dispute, would be time-consuming, could result in costly litigation and the diversion of technical and management personnel.

In recent years, there have been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. We may become a party to patent litigation or other proceedings regarding intellectual property rights.

Situations that may give rise to patent litigation or other disputes over the use of our intellectual property include:

- initiation of litigation or other proceedings against third parties to enforce our patent rights;
- initiation of litigation or other proceedings against third parties to seek to invalidate the patents held by these third parties or to obtain a judgment that our product candidates do not infringe the third parties patents;
- participation in interference proceedings to determine the priority of invention if our competitors file U.S. patent applications that claim technology also claimed by us;
- initiation of foreign opposition proceedings by third parties that seek to limit or eliminate the scope of our patent protection in a foreign jurisdiction;
- initiation of litigation by third parties claiming that our processes or product candidates or the intended use of our product candidates infringe their patent or other intellectual property rights; and
- initiation of litigation by us or third parties seeking to enforce contract rights relating to intellectual property that may be important to our business.

The costs associated with any patent litigation or other proceeding, even if resolved favorably, will likely be substantial. Some of our competitors may be able to sustain the cost of such litigation or other proceedings more effectively than we can because of their substantially greater financial resources. If a patent litigation or other intellectual property proceeding is resolved unfavorably, we or any collaborative partners may be enjoined from manufacturing or selling our products and services without a license from the other party and be held liable for significant damages. Moreover, we may not be able to obtain required licenses on commercially acceptable terms or any terms at all. In addition, we could be held liable for lost profits if we are found to have infringed a valid patent, or liable for treble damages if we are found to have willfully infringed a valid patent. Litigation results are highly unpredictable and we or any collaborative partners may not prevail in any patent litigation or other proceeding in which we may become involved. Any changes in, or unexpected interpretations of the patent laws may adversely affect our ability to enforce our patent position. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could damage our ability to compete in the marketplace.

Our commercial success will depend in part on our ability to obtain and maintain protection of our intellectual property in China.

We rely on trade secrets, proprietary know-how and other non-patentable technology, which we seek to protect through agreements containing non-disclosure provisions with the chemists and biologists we have

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engaged in China. We cannot assure you that these agreements will not be breached, that we will have adequate remedies for any breach, or that our trade secrets, proprietary know-how and other non-patentable technology will not otherwise become known to, or be independently developed by, our competitors.

Implementation and enforcement of Chinese intellectual property-related laws has historically been deficient and ineffective, and is hampered by corruption and local protectionism. Accordingly, intellectual property rights and confidentiality protections in China may not be as effective as in the United States or other countries. Policing unauthorized use of proprietary technology is difficult and expensive, and we might need to resort to litigation to enforce or defend patents issued to us or to determine the enforceability, scope and validity of our proprietary rights or those of others. The experience and capabilities of Chinese courts in handling intellectual property litigation varies, and outcomes are unpredictable. Further, such litigation may require significant expenditure of cash and management efforts and could harm our business, financial condition and results of operations. An adverse determination in any such litigation will impair our intellectual property rights and may harm our business, prospects and reputation.

If we are unable to keep our trade secrets confidential, our technology and proprietary information may be used by others to compete against us.

We rely significantly upon proprietary technology, information, processes and know-how that are not subject to patent protection. We seek to protect this information through confidentiality and intellectual property license or assignment provisions in agreements with our employees, consultants and other third-party contractors as well as through other security measures. The confidentiality and intellectual property provisions of our agreements and security measures may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently developed by competitors.

RISKS RELATING TO PRECLINICAL, CLINICAL AND REGULATORY MATTERS

If preclinical studies and clinical trials of our product candidates are not successful, and we or our current or any planned collaborators are not able to obtain the necessary regulatory approvals, then we and such collaborators will not be able to commercialize those product candidates on a timely basis, if at all, which would adversely affect our future profitability and success.

In order to obtain regulatory approval for the commercial sale of our product candidates, we and any current or planned collaborators will be required to complete extensive preclinical studies as well as clinical trials in humans to demonstrate to the FDA and foreign regulatory authorities that our product candidates are safe and effective. Development, including preclinical and clinical testing, is a long, expensive and uncertain process. Accordingly, preclinical testing and clinical trials of our product candidates under development may not be successful. We and any collaborators could experience delays or failures in preclinical or clinical trials of any of our product candidates for a number of reasons. For example:

- preclinical studies or clinical trials may produce negative, inconsistent or inconclusive results, and we or any collaborators may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or terminate testing for a particular product candidate;

- the results from preclinical studies and early clinical trials may not be statistically significant or predictive of results that will be obtained from expanded, advanced clinical trials;

- we may encounter difficulties or delays in manufacturing sufficient quantities of the product candidate used in any preclinical study or clinical trial;

- the timing and completion of clinical trials of our product candidates depend on, among other factors, the number of patients we will be required to enroll in the clinical trials and the rate at which those patients are enrolled, and any increase in the required number of patients, decrease in recruitment rates or difficulties retaining study participants may result in increased costs, program delays or program termination;

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- our products under development may not be effective in treating any of our targeted disorders or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may prevent or limit their commercial use;

- institutional review boards or regulators, including the FDA, or any collaborators may hold, suspend or terminate our clinical research or the clinical trials of our product candidates for various reasons, including failure to achieve established success criteria, noncompliance with regulatory requirements or if, in their opinion, the participating subjects are being exposed to unacceptable health risks; and

- we, along with any of our current or planned collaborators and subcontractors, may not employ, in any capacity, persons who have been debarred under the FDA s Application Integrity Policy. Employment of such a debarred person may result in delays in FDA s review or approval of our products, or the rejection of data developed with the involvement of such person(s).

If the preclinical studies and/or clinical trials for any product candidates that we and any collaborators pursue are not successful, then our ability to successfully develop and commercialize products on the basis of the respective technologies will be materially adversely affected, our reputation and our ability to raise additional capital will be materially impaired and the value of an investment in our stock price is likely to decline.

We have very limited experience in conducting clinical trials. We are currently recruiting clinical/regulatory management but we expect to rely primarily on a combination of collaborative partners, consultants and contract research organizations for the performance and management of any clinical trials of our product candidates. If such third parties fail to perform then we will not be able to successfully develop and commercialize product candidates and grow our business.

We have limited experience in conducting clinical trials. We expect to rely to varying degrees on third parties to conduct our clinical trials and provide services in connection with such clinical trials. For example, we have granted development and commercialization rights under our existing collaboration agreements and we expect that any future collaboration partners may similarly be fully responsible for conducting clinical trials of product candidates. In some instances, such as product candidates associated with new programs that successfully advance into the clinic, we may be responsible for clinical trials. While we are currently seeking to add clinical/regulatory employees, we expect that hiring such employees will be difficult since competition for skilled clinical and regulatory employees is intense. In the near term, we are likely to rely primarily on third parties such as consultants, contract research organizations and other similar entities to complete IND-enabling preclinical studies, create and submit IND applications, enroll qualified subjects, conduct our clinical trials and provide services in connection with such clinical trials. Our reliance on these third parties for clinical development activities will reduce our control over these activities. These third parties may not complete activities on schedule, or may not conduct our clinical trials in accordance with regulatory requirements or the trial design. If any such events were to occur, efforts to obtain regulatory approvals for and commercialize our drug candidates may be delayed.

In addition, for those product candidates where we are responsible for clinical trials, we must ensure that each such clinical trial is conducted in accordance with the general investigational plan and protocols for the trial. The FDA requires us to comply with certain standards, referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. If any of the third-party contractors on whom we may in the future rely do not comply with good clinical practices or other applicable regulatory requirements, we may not be able to use the data and reported results from the trial. If this were to occur, our efforts to obtain regulatory approvals for and commercialize our product candidates may be delayed.

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The development process necessary to obtain regulatory approval is lengthy, complex and expensive. If we and our current and planned collaborative partners do not obtain necessary regulatory approvals, then our business will be unsuccessful and the market price of our common stock could substantially decline.

We and our current and planned collaborative partners will be required to obtain regulatory approval in order to successfully advance our product candidates through the clinic and prior to marketing and selling such products.

The process of obtaining FDA and other required regulatory approvals is expensive. The time required for FDA and other approvals is uncertain and typically takes a number of years, depending on the complexity and novelty of the product. With respect to internal programs to date, we have limited experience in filing and prosecuting applications to obtain marketing approval.

Any regulatory approval to market a product may be subject to limitations on the indicated uses for which we, or our collaborative partners, may market the product. These limitations may restrict the size of the market for the product and affect reimbursement by third-party payors. In addition, regulatory agencies may not grant approvals on a timely basis or may revoke or significantly modify previously granted approvals.

We are subject to, and our current and planned collaborative partners are, or will be subject to, numerous foreign regulatory requirements governing the manufacturing and marketing of our potential future products outside of the United States. The approval procedure varies among countries, additional testing may be required in some jurisdictions, and the time required to obtain foreign approvals often differs from that required to obtain FDA approvals. Moreover, approval by the FDA does not ensure approval by regulatory authorities in other countries, and vice versa.

In addition, regulatory agencies may change existing requirements or adopt new requirements or policies. We and any collaborative partners may be slow to adapt or may not be able to adapt to these changes or new requirements.

As a result of these factors, we and any collaborators may not successfully begin or complete clinical trials and/or obtain regulatory approval to market and sell our product candidates in the time periods estimated, if at all. Moreover, if we or any collaborators incur costs and delays in development programs or fail to successfully develop and commercialize products based upon our technologies, we may not become profitable and our stock price could decline.

Recently enacted legislation may make it more difficult and costly for us to obtain regulatory approval of our product candidates and to produce, market and distribute products after approval.

On September 27, 2007, the President signed the FDAAA. The FDAAA grants a variety of new powers to the FDA, many of which are aimed at improving the safety of drug products before and after approval. Under the FDAAA, companies that violate the new law are subject to substantial civil monetary penalties. While we expect the FDAAA to have a substantial effect on the pharmaceutical industry, the extent of that effect is not yet known. As the FDA issues regulations, guidance and interpretations relating to the new legislation, the impact on the industry, as well as our business, will become clearer. The new requirements and other changes that the FDAAA imposes may make it more difficult, and likely more costly, to obtain approval of new pharmaceutical products and to produce, market and distribute products after approval.

Even if marketing approval is obtained, any products we or any current or planned collaborators develop will be subject to ongoing regulatory oversight, which may affect the successful commercialization of such products.

Even if we or any current or planned collaborators obtain regulatory approval of a product candidate, the approval may be subject to limitations on the indicated uses for which the product is marketed or require costly post-marketing follow-up studies. After marketing approval for any product is obtained, the manufacturer and the

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manufacturing facilities for that product will be subject to continual review and periodic inspections by the FDA and other regulatory agencies. The subsequent discovery of previously unknown problems with the product, or with the manufacturer or facility, may result in restrictions on the product or manufacturer, including withdrawal of the product from the market.

If there is a failure to comply with applicable regulatory requirements, we or any collaborator may be subject to fines, refusal to approve pending applications or supplements, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, refusal to permit the import or export of our products and criminal prosecution.

We and any current or planned collaborators are subject to governmental regulations other than those imposed by the FDA. We and any such collaborators may not be able to comply with these regulations, which could subject us, or such collaborators, to penalties and otherwise result in the limitation of our or such collaborators operations.

In addition to regulations imposed by the FDA, we and any current or planned collaborators are subject to regulation under, among other laws, the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Research Conservation and Recovery Act, as well as regulations administered by the Nuclear Regulatory Commission, national restrictions on technology transfer, import, export and customs regulations and certain other local, state or federal regulations. From time to time, other federal agencies and congressional committees have indicated an interest in implementing further regulation of pharmaceutical and biotechnology applications. We are not able to predict whether any such regulations will be adopted or whether, if adopted, such regulations will apply to our business, or whether we or our collaborators would be able to comply with any applicable regulations.

Our research and development activities involve the controlled use of hazardous materials and chemicals. Although we believe that our safety procedures for handling and disposing of such materials comply with all applicable laws and regulations, we cannot completely eliminate the risk of accidental contamination or injury caused by these materials.

RISKS RELATING TO MANUFACTURING AND SALES

We will depend on collaborators and third-party manufacturers to produce most, if not all, of our products under development, and if these third parties do not successfully manufacture these products, our business will be harmed.

We have no manufacturing experience or manufacturing capabilities. In order to continue to develop product candidates, apply for regulatory approvals, and commercialize our products under development, we or any collaborators must be able to manufacture products in adequate clinical and commercial quantities, in compliance with regulatory requirements, including those related to quality control and quality assurance, at acceptable costs and in a timely manner. The manufacture of our product candidates may be complex, difficult to accomplish and difficult to scale-up when large-scale production is required. Manufacture may be subject to delays, inefficiencies and poor or low yields of quality products. The cost of manufacturing some of our products may make them prohibitively expensive. If supplies of any of our product candidates or related materials become unavailable or are not delivered on a timely basis or at all, or are contaminated or otherwise lost, certain preclinical studies and/or clinical trials by us and any collaborators could be seriously delayed. This is due to the fact that such materials are time-consuming to manufacture and cannot be readily obtained from third-party sources.

To the extent that we or any collaborators seek to enter into manufacturing arrangements with third parties, we and such collaborators will depend upon these third parties to perform their obligations in a timely and effective manner and in accordance with government regulations. Contract manufacturers may breach their manufacturing agreements because of factors beyond our control or may terminate or fail to renew a manufacturing agreement based on their own business priorities at a time that is costly or inconvenient for us.

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Any contract manufacturers with which we enter into manufacturing arrangements will be subject to ongoing periodic, unannounced inspection by the FDA and corresponding state and foreign agencies or their designees to ensure strict compliance with current good manufacturing practices and other governmental regulations and corresponding foreign standards. Any failure by our contract manufacturers, any collaborators or us to comply with applicable regulations could result in sanctions being imposed, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. If we need to change manufacturers, the FDA and corresponding foreign regulatory agencies must approve any new manufacturers in advance. This would involve testing and pre-approval inspections to ensure compliance with FDA and foreign regulations and standards.

If third-party manufacturers fail to perform their obligations, our competitive position and ability to generate revenue may be adversely affected in a number of ways, including;

- we and any collaborators may not be able to initiate or continue certain preclinical and/or clinical trials of products that are under development;
- we and any collaborators may be delayed in submitting applications for regulatory approvals for our product candidates; and
- we and any collaborators may not be able to meet commercial demands for any approved products.

We have no sales or marketing experience and, as such, will depend significantly on third parties who may not successfully sell our products.

We have no sales, marketing or product distribution experience. If we receive required regulatory approvals, we plan to rely primarily on sales, marketing and distribution arrangements with third parties, including our collaborative partners. For example, as part of our agreements with Genentech, we have granted Genentech the exclusive rights to distribute certain products resulting from such collaborations, if any are ever successfully developed. We may have to enter into additional marketing arrangements in the future and we may not be able to enter into these additional arrangements on terms that are favorable to us, if at all. In addition, we may have limited or no control over the sales, marketing and distribution activities of these third parties and sales through these third parties could be less profitable to us than direct sales. These third parties could sell competing products and may devote insufficient sales efforts to our products. Our future revenues will be materially dependent upon the success of the efforts of these third parties.

We may seek to independently market products that are not already subject to marketing agreements with other parties. If we determine to perform sales, marketing and distribution functions ourselves, we could face a number of additional risks, including:

- we may not be able to attract and build a significant and skilled marketing staff or sales force;
- the cost of establishing a marketing staff or sales force may not be justifiable in light of the revenues generated by any particular product; and
- our direct sales and marketing efforts may not be successful.

Even if we successfully commercialize any products under development, either alone or in collaboration, we face uncertainty with respect to coverage, pricing, third-party reimbursements and healthcare reform, all of which could affect our future profitability.

Our ability to collect significant royalties from our products may depend on our ability, and the ability of any current or planned collaboration partners or customers, to obtain adequate levels of coverage for our products and reimbursement from third-party payers such as:

government health administration authorities;

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private health insurers;

health maintenance organizations;

health maintenance organizations;

pharmacy benefit management companies; and

other healthcare-related organizations.

Third-party payers may deny coverage or offer inadequate levels of reimbursement if they determine that a prescribed product has not received appropriate clearances from the FDA or other government regulators, is not used in accordance with cost-effective treatment methods as determined by the third-party payer, or is experimental, unnecessary or inappropriate. If third-party payers deny coverage or offer inadequate levels of reimbursement, we or any collaborators may not be able to market our products effectively. We also face the risk that we will have to offer our products at prices lower than anticipated as a result of the current trend in the United States towards managed healthcare through health maintenance organizations. Currently, third-party payers are increasingly challenging the prices charged for medical products and services. Prices could be driven down by health maintenance organizations that control or significantly influence purchases of healthcare services and products. Existing U.S. laws, such as the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or future legislation to reform healthcare or reduce government insurance programs could also adversely affect prices of our approved products, if any. The cost-containment measures that healthcare providers are instituting and the results of potential healthcare reforms may prevent us from maintaining prices for our products that are sufficient for us to realize profits and may otherwise significantly harm our business, financial condition and operating results. In addition, to the extent that our products are marketed outside of the United States, foreign government pricing controls and other regulations may prevent us from maintaining prices for our products that are sufficient for us to realize profits and may otherwise significantly harm our business, financial condition and operating results.

Recent proposed legislation may permit re-importation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could force us to lower the prices at which we sell our products, if approved, and impair our ability to derive revenue from these products.

Legislation has been introduced in the U.S. Congress that, if enacted, would permit more widespread re-importation of drugs from foreign countries into the United States. This could include re-importation from foreign countries where the drugs are sold at lower prices than in the United States. Such legislation, or similar regulatory changes, could lead to a decrease in the price we receive for any approved products, which, in turn, could impair our ability to generate revenue. Alternatively, in response to legislation such as this, we might elect not to seek approval for or market our products in foreign jurisdictions in order to minimize the risk of re-importation, which could also reduce the revenue we generate from our product sales.

RISKS RELATED TO OUR COMMON STOCK

If we fail to meet the requirements for continued listing on the Nasdaq Global Market, our common stock could be delisted from trading, which would adversely affect the liquidity of our common stock and our ability to raise additional capital.

Our common stock is currently listed for quotation on the Nasdaq Global Market. We are required to meet specified financial requirements in order to maintain our listing on the Nasdaq Global Market. One such requirement is that we maintain a minimum closing bid price of at least $1.00 per share for our common stock. Our common stock has recently closed at prices that are below the minimum bid price requirement. If our stock price falls below $1.00 per share for 30 consecutive business days, we will receive a deficiency notice from Nasdaq advising us that we have 180 days to regain compliance by maintaining a minimum bid price of at least $1.00 for a minimum of ten consecutive business days. Under certain circumstances, Nasdaq could require that

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the minimum bid price exceed $1.00 for more than ten consecutive days before determining that a company complies with its continued listing standards. If in the future we fail to satisfy the Nasdaq Global Market s continued listing requirements, our common stock could be delisted from the Nasdaq Global Market, in which case we may transfer to the Nasdaq Capital Market, which generally has lower financial requirements for initial listing or, if we fail to meet its listing requirements, the OTC Bulletin Board. Any potential delisting of our common stock from the Nasdaq Global Market would make it more difficult for our stockholders to sell our stock in the public market and would likely result in decreased liquidity and increased volatility for our common stock.

Our stock price may fluctuate significantly and the market price of our common stock could drop below the price paid.

The trading price of our common stock has been volatile and may continue to be volatile in the future. For example, our stock has traded as high as $6.59 and as low as $0.86 per share for the period January 1, 2004 through December 31, 2007. The stock market, particularly in recent years, has experienced significant volatility with respect to pharmaceutical- and biotechnology-based company stocks. Prices for our stock will be determined in the marketplace and may be influenced by many factors, including:

- announcements regarding new technologies by us or our competitors;
- market conditions in the biotechnology and pharmaceutical sectors;
- rumors relating to us or our competitors;
- litigation or public concern about the safety of our potential products;
- actual or anticipated variations in our quarterly operating results and any subsequent restatement of such results;
- actual or anticipated changes to our research and development plans;
- deviations in our operating results from the estimates of securities analysts;
- entering into new collaboration agreements or termination of existing collaboration agreements;
- adverse results or delays in clinical trials being conducted by us or any collaborators;
- any intellectual property or other lawsuits involving us;
- third-party sales of large blocks of our common stock;
- sales of our common stock by our executive officers, directors or significant stockholders;

equity sales by us of our common stock to fund our operations;

the loss of any of our key scientific or management personnel;

FDA or international regulatory actions; and

general market conditions.

While we cannot predict the individual effect that these factors may have on the price of our common stock, these factors, either individually or in the aggregate, could result in significant variations in price during any given period of time. Moreover, in the past, securities class action litigation has often been instituted against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management s attention and resources.

Substantially all of our outstanding common stock may be sold into the market at any time. This could cause the market price of our common stock to drop significantly.

As of December 31, 2007, we had outstanding approximately 63.2 million shares of common stock, most of which can be traded without restriction at any time. Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a

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large number of shares intend to sell such shares, could reduce the market price of our common stock. In addition, we have a significant number of shares that are subject to outstanding options and warrants. The exercise of these options and warrants and the subsequent sale of the underlying common stock could cause a further decline in our stock price. These sales also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

Insiders have substantial control over us and could delay or prevent a change in corporate control.

As of December 31, 2007, our directors, executive officers and principal stockholders, together with their affiliates, owned, in the aggregate, approximately 40% of our outstanding common stock. As a result, these stockholders, if acting together, may have the ability to determine the outcome of matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these persons, if acting together, will have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership may harm the market price of our common stock by:

delaying, deferring or preventing a change in control of our company;

impeding a merger, consolidation, takeover or other business combination involving our company; or

discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company.

We have anti-takeover defenses that could delay or prevent an acquisition that our stockholders may consider favorable and the market price of our common stock may be lower as a result.

Provisions of our certificate of incorporation, our bylaws and Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing changes in control of our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interest. For example, we have divided our board of directors into three classes that serve staggered three-year terms, we may issue shares of our authorized blank check preferred stock and our stockholders are limited in their ability to call special stockholder meetings.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. These provisions could discourage, delay or prevent a change in control transaction.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We currently lease a facility for our administrative, research and development requirements located at 45 Moulton Street in Cambridge, Massachusetts consisting of 35,095 square feet pursuant to a lease that expires in 2010. We also have the right to extend our lease term for two additional terms of three years each, with the first such additional term commencing as of January 1, 2011 and expiring as of December 31, 2013 and the second such additional term commencing as of January 1, 2014 and expiring as of December 31, 2016. We believe that our existing facilities will be suitable and adequate to meet our needs for the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS

We are currently not a party to any material legal proceedings.

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ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

We did not submit any matter to a vote of security holders during the fourth quarter of the fiscal year covered by this annual report.

EXECUTIVE OFFICERS OF THE REGISTRANT

Our executive officers are as follows:

Name	Age	Position
Daniel R. Passeri, MSc., J.D.	47	President and Chief Executive Officer
Michael P. Gray	37	Chief Operating Officer and Chief Financial Officer
Mark W. Noel	49	Vice President, Technology Management and Business Development
Changgeng Qian, Ph.D., M.D.	52	Vice President, Discovery and Preclinical Research

Daniel R. Passeri, MSc., J.D.

Mr. Passeri has served as our President and Chief ExecutiveOfficer and as a director since September 2001. FromNovember 2000 to September 2001, Mr. Passeri served asSenior Vice President, Corporate Development and StrategicPlanning of the Company. From March 1997 to November2000, Mr. Passeri was employed by GeneLogic Inc., abiotechnology company, most recently as Senior Vice President,Corporate Development and Strategic Planning. From February1995 to March 1997, Mr. Passeri was employed by BoehringerMannheim, a pharmaceutical, biotechnology and diagnosticcompany, as Director of Technology Management. Mr. Passeriis a graduate of the National Law Center at George WashingtonUniversity, with a J.D., of the Imperial College of Science,Technology and Medicine at the University of London, with anM.Sc. in biotechnology, and of Northeastern University, with aB.S. in biology.

Michael P. Gray

Mr. Gray has served as our Chief Operating Officer and ChiefFinancial Officer since December 2006. From December 2003until December 2006, Mr. Gray served as our Vice President ofFinance and Chief Financial Officer and served as our SeniorDirector of Finance and Controller from August 2000 untilDecember 2003. From January 1998 to July 2000, Mr. Gray wasController at Reprogenesis, Inc., a predecessor biotechnologycompany. Mr. Gray previously served as an audit professionalfor the accounting and consulting firm of Ernst & Young, LLP.Mr. Gray is a certified public accountant, holds an M.B.A. fromthe F.W. Olin Graduate School of Business at Babson College,and has a B.S. in accounting from Bryant College.

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Mark W. Noel	Mr. Noel has served as our Vice President, TechnologyManagement and Business Development since March 2001.From March 2000 to February 2001, Mr. Noel was employed byGeneLogic, as Vice President of Customer Relations. FromJanuary 1998 to February 2000, Mr. Noel was employed byGeneLogic as Senior Director of Program Management. FromDecember 1993 to January 1998, Mr. Noel was employed by theNational Cancer Institute s Office of Technology Development(now the Technology Transfer Branch of the NCI Office ofTechnology and Industrial Relations), where from July 1997 toJanuary 1998, he served as Acting Deputy Director. FromFebruary 1989 to November 1993, Mr. Noel worked as a patentagent at Gist Brocades NV, a supplier of ingredients to thepharmaceutical and food sectors. Mr. Noel holds a B.S. from theUniversity of Maryland.
Changgeng Qian, Ph.D., M.D.	Dr. Qian has served as our Vice President, Discovery andPreclinical Research since September 2006. From May 2005 toSeptember 2006, Dr. Qian served as our Senior Director,Pharmacology. From May 2002 to May 2005 Dr. Qian served asour Director, Pharmacology, and from May 2001 to May 2002,Dr. Qian served as our Associate Director, Pharmacology. FromNovember 1999 to May 2001, Dr. Qian was Senior Scientist IIat Millennium Pharmaceuticals, Inc., a biopharmaceuticalcompany. From October 1996 to November 1999, Dr. Qian wasSenior Research Scientist III at LeukoSite, Inc., abiopharmaceutical company that was acquired by MillenniumPharmaceuticals in December 1999. From January 1992 toDecember 1995, Dr. Qian was Head of Pharmacology atCytoMed, Inc., a biopharmaceutical company. Dr. Qian holds aPh.D. in Pharmacology and an M.D. from the Hunan MedicalUniversity in Changsha, China and has served as a professor ofthe Hunan Medical University since 1992.

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PART II

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

(a) *Market Information*. Our common stock is traded on the NASDAQ Global Market under the trading symbol CRIS. The following table sets forth, for the fiscal periods indicated, the high and low sales prices per share of our common stock as reported on the NASDAQ Global Market:

	Curis Common Stock	
Year ended December 31, 2006	**High**	**Low**
First Quarter	$ 4.10	$ 2.28
Second Quarter	$ 2.43	$