CURIS INC
Form 10-K
February 26, 2009
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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, 2008

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 the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	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 30, 2008 was approximately $62,390,000.

As of February 24, 2009, there were 63,653,698 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, 2009, 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, 2008 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 develop next generation targeted cancer therapies. In expanding our drug development efforts with respect to these targeted cancer programs, we are building upon our past experiences in targeting signaling pathways, including the Hedgehog pathway. We seek to conduct research programs both internally and through strategic collaborations.

Our cancer programs include a Hedgehog pathway inhibitor program for which our collaborator Genentech is conducting clinical trials on the lead molecule, GDC-0449. These trials include a pivotal Phase II clinical trial in advanced basal cell carcinoma patients, as well as Phase II clinical trials in first-line metastatic colorectal cancer and in advanced ovarian cancer patients. In addition to these trials, a Phase I clinical trial to treat medulloblastoma patients was initiated by a third-party investigator under a Cooperative Research and Development Agreement (CRADA) between Genentech and the National Cancer Institute (NCI). We anticipate that additional clinical trials will be initiated in the future, including Phase II clinical trials in small cell lung and pancreatic cancers, among others. While the initiation of future trials conducted under the CRADA will not result in cash payments to us, we believe that such trials are important to the overall development of GDC-0449 since they may provide a greater opportunity to generate additional data in tumor types other than those currently under investigation by Genentech. We believe that GDC-0449 is the first Hedgehog pathway inhibitor to advance to Phase II clinical testing. Moreover, we and our collaborator Genentech have substantial intellectual property rights in the Hedgehog signaling pathway.

In addition to our Hedgehog pathway inhibitor program, since 2006 we have been applying our signaling pathway-based preclinical drug development experience to develop cancer drug candidates that target biological signaling pathways other than the Hedgehog 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. Our targeted cancer programs primarily consist of several proprietary drug programs through which we have produced single small molecules that target one or more signaling pathways. We believe that this approach of using a single small molecule to target critical nodes in various signaling pathway networks may provide for a better therapeutic effect than many of the targeted cancer drugs currently

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marketed or in development. Our lead candidate from these programs is CUDC-101, a small molecule that is currently in Phase I clinical testing and is designed to target histone deacetylase (HDAC), epidermal growth factor receptor (EGFR) and epidermal growth factor receptor 2 (Her2). In addition, we expect to file an Investigational Drug Application (IND) for CUDC-305, a Heat Shock Protein 90 (Hsp90) inhibitor, in mid-2009, and provided that we have adequate capital resources, begin clinical testing on this candidate during the second half of 2009.

Product Development Programs

We are developing drug candidates 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 provides significant additional resources and clinical development expertise to our Hedgehog pathway inhibitor program through our collaboration. In addition, this collaboration provides 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 intellectual property portfolio related to the Hedgehog signaling pathway as well as to our other targeted cancer programs.

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 Pathway Inhibitor			
- GDC-0449	Advanced basal cell carcinoma	Genentech	Pivotal Phase II
- GDC-0449	Metastatic colorectal cancer	Genentech	Phase II
- GDC-0449	Advanced ovarian cancer	Genentech	Phase II
Targeted cancer programs			
- CUDC-101 (HDAC, EGFR, Her2 inhibitor)	Cancer	Internal development	Phase I
- CUDC-305 (Hsp90 inhibitor)	Cancer	Internal development	Development candidate
- Other targeted cancer programs	Cancer	Internal development	Preclinical

In the chart above, Pivotal Phase II means that our collaborator Genentech is currently treating human patients in a pivotal Phase II clinical trial, the primary objective of which is a therapeutic response in human patients. The endpoints of this clinical trial, if positive, may serve as the basis for a future New Drug Application (NDA) submission by Genentech. Phase II means that our collaborator Genentech is currently treating human patients in a Phase II clinical trial, the primary objective of which is a therapeutic response (i.e., for the metastatic colorectal cancer trial, progression-free survival from randomization to disease progression or death). Phase I means that we are currently treating human patients in a Phase I clinical trial, the principal purpose of which is to evaluate the safety and tolerability of the compound being tested. Development candidate means that based on in vitro and in vivo 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 IND application with the Food & Drug Administration (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, 2008, Genentech, which is our only current collaborator, and Stryker Corporation, the assignee of our Bone Morphogenetic Protein (BMP) assets, accounted for substantially all of our revenue, as follows: Genentech, $6,282,000, or 75%, and Stryker, $1,750,000, or 21%.

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Hedgehog Pathway Inhibitor Program

Our Hedgehog pathway inhibitor technologies represent our most advanced program and are being developed in various cancer indications under a June 2003 collaboration agreement with Genentech. Genentech is a biotechnology company with broad expertise in the development and commercialization 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 also contribute to the growth of certain cancers, including basal cell carcinoma, breast, colorectal, esophageal, ovarian, pancreatic, prostrate and small cell lung cancers, among others. 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 Hedgehog pathway inhibitors selectively target fundamental mechanisms involved in the maintenance and progression of tumor growth and, as such, may represent a new generation of cancer therapeutics.

This preclinical scientific data, combined with strong Phase I efficacy data in advanced basal cell carcinoma patients, has resulted in a broad clinical development effort by our collaborator Genentech. Genentech is currently conducting three clinical trials of GDC-0449, an orally administered first-in-class Hedgehog pathway inhibitor, as follows:

Pivotal Phase II advanced basal cell carcinoma clinical trial: In February 2009, Genentech initiated a pivotal Phase II clinical trial of GDC-0449 as a single-agent therapy for patients with metastatic or locally advanced basal cell carcinoma (BCC). Genentech expects to evaluate GDC-0449 in approximately 100 patients with metastatic or locally advanced BCC in a global single-arm, two-cohort clinical trial. One cohort includes all patients with histologically-confirmed, RECIST measurable metastatic BCC. RECIST provides standard parameters to be used when documenting patient response for solid tumors. The second cohort includes histologically-confirmed locally advanced BCC that is considered inoperable by the treating physician. All patients will receive a daily oral dose of GDC-0449. This Phase II pivotal study builds upon the Phase I safety and efficacy data demonstrated by GDC-0449, which showed clinical benefit in a substantial proportion of advanced BCC patients. There is currently no standard of care for patients with these types of BCC and Genentech has indicated that it designed this pivotal trial so that its data, if positive, may serve as the basis for NDA submission by Genentech.

Upon initiation of this pivotal Phase II clinical trial, we earned $6,000,000 from Genentech, which we expect to be paid during the first quarter of 2009.

Phase II first-line metastatic colorectal cancer clinical trial: In May 2008, Genentech initiated a Phase II clinical trial of GDC-0449 in metastatic colorectal cancer. GDC-0449 is being evaluated in approximately 150 patients with metastatic colorectal cancer in combination with the current standard of care in a randomized, placebo-controlled, double-blind Phase II trial. Patients receive either FOLFOX or FOLFIRI chemotherapy in combination with Avastin and are randomized to receive GDC-0449 or placebo. The primary objective of the trial is progression-free survival from randomization to disease progression or death. Secondary outcome measures include the measurement of Hedgehog protein expression in archival tissue and tracking of adverse events.

Genentech made a $3,000,000 cash payment to us in May 2008 for the initiation of this Phase II clinical trial.

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Phase II advanced ovarian cancer clinical trial: In December 2008, Genentech initiated a Phase II clinical trial of GDC-0449 as a maintenance therapy for advanced ovarian cancer patients. GDC-0449 is being evaluated in approximately 100 patients with ovarian cancer in second or third complete remission in a randomized, placebo-controlled, double-blind, multi-center Phase II trial. Patients are randomized in a 1:1 ratio to receive either GDC-0449 or a placebo comparator and are stratified based on whether their cancer is in a second or third complete remission. The primary endpoint of the trial is progression-free survival. Secondary outcome measures include overall survival, measurement of Hedgehog ligand expression in archival tissue and number and attribution of adverse events. We believe that there is a significant unmet treatment need for patients with relapsed ovarian cancer. While many advanced ovarian cancer patients initially experience clinical remission with current therapies, the disease recurs for most patients. Genentech designed this Phase II trial to investigate if GDC-0449 may help delay tumor re-growth following clinical remission of cancer after second-line chemotherapy treatment for recurrent disease.

Curis received a $3,000,000 cash payment from Genentech in December 2008 for the initiation of this Phase II clinical trial. This is the final Phase II development objective under this collaboration for which we are eligible for compensation.

In addition to GDC-0449, which is a small molecule, Genentech has also conducted preclinical research on antibody-based Hedgehog pathway inhibitors. We expect to provide further updates on this program only if Genentech determines to pursue clinical development of an antibody candidate from this program, as we currently cannot predict whether Genentech will pursue the further development of Hedgehog antibody pathway inhibitors.

Under the terms of the June 2003 agreement with Genentech, we granted Genentech an exclusive, global, royalty-bearing license, with the right to sublicense, make, use, sell and import small molecule and antibody Hedgehog pathway inhibitors for human therapeutic applications, including 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. In November 2008, Genentech granted a license to F. Hoffmann-LaRoche, Ltd (Roche) for ex-U.S. rights to GDC-0449. Roche received this license pursuant to an agreement between Genentech and Roche under which Genentech granted Roche an option to obtain a license to commercialize certain Genentech products in non-U.S. markets. We believe that the collaborative worldwide development activities of Genentech and Roche could expand the potential value of this compound since Roche brings significant additional clinical development and commercialization experience to advance and market GDC-0449 outside of the U.S. Genentech and Roche have primary responsibility for worldwide clinical development, regulatory affairs, manufacturing and supply, formulation and sales and marketing. We are not a party to this agreement between Genentech and Roche but we are eligible to receive cash payments for regulatory filing and approval objectives achieved and future royalties on products developed outside of the U.S., if any, under our June 2003 collaboration agreement with Genentech.

Pursuant to the collaboration agreement, in June 2003 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 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 at which time, all research funding ended. We do not expect to receive additional future research funding from Genentech or incur any material research costs related to this program. The achievement of certain development objectives as outlined in the agreement provides us with an important source of financing, resulting in a total of $18,000,000, including the $6,000,000 we will receive in the first quarter of 2009 for the initiation of the pivotal Phase II trial initiated in February. In addition to these payments, we will be eligible to receive additional future

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cash payments from Genentech only upon the achievement of additional specified clinical development and regulatory approval objectives, as well as royalties on product sales if any Hedgehog pathway inhibitor 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 license grants survive, we will continue to receive clinical development and regulatory 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. As of December 31, 2008, we have incurred expenses of an aggregate of $600,000 related to such payments.

Our Proprietary Targeted Cancer Programs

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 and development.

In 2006, we utilized medicinal chemistry and our biological expertise to initiate a series of proprietary targeted cancer drug programs. These programs focus 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 from these programs to reach human clinical testing. Each proprietary compound is being designed to inhibit validated cancer targets, including among others EGFR, Her2, Bcr-Abl tyrosine kinase and phosphatidylinositol-3-kinase (PI3k), and in combination with inhibition of 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 CUDC-305, 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, particularly when combined with simultaneous inhibition of certain other targets. 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.

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In furtherance of the development of our targeted cancer programs, since May 2006, we have outsourced certain medicinal chemistry functions to a leading provider in Shanghai, China. We have developed these relationships with Chinese providers to support our U.S. operations and we are currently engaging 17 chemists in China. We believe that this relationship has 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 our multi-targeted cancer programs, as well as numerous species filings 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 pharmaceutical and biotechnology companies and are seeking to consummate a collaboration for one of our targeted inhibitors during 2009, although we cannot be certain that such a collaboration will occur in the time frame expected, if at all.

CUDC-101

CUDC-101 is the first compound selected as a drug candidate from our targeted cancer programs. CUDC-101 is designed as a first-in-class therapeutic to simultaneously inhibit HDAC, EGFR and Her2. In preclinical studies, CUDC-101 demonstrated the potential to inhibit all three molecular targets resulting in the potent killing 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.

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 cancer therapy.

In August 2008, we initiated a Phase I trial of CUDC-101in patients with advanced, refractory solid tumors. The primary objectives of this open-label Phase I trial are to evaluate the safety and tolerability of escalating doses of CUDC-101 and to establish the maximum tolerated dose and dose limiting toxicities. Secondary objectives are to assess the pharmacokinetics, efficacy and ability of CUDC-101 to inhibit HDAC, EGFR and HER2 in this patient population. The study is being conducted at two sites within the United States and is expected to enroll between 18 and 40 patients spread across several dose-escalating cohorts.

We currently expect to complete this Phase I trial in mid-2009.

CUDC-305

In July 2008, we selected CUDC-305 as a development candidate. In addition to demonstrating potent efficacy across a broad range of cancers in preclinical cancer models, CUDC-305 exhibited promising pharmacological features in preclinical testing, particularly its high oral bioavailability, high tumor penetration and extended tumor retention. Most notably, Curis scientists observed complete tumor regression following oral administration of CUDC-305 in a mouse xenograft model of acute myelogenous leukemia (AML). Tumor

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regression has also been observed after treatment of CUDC-305 in mouse xenograft models of breast, non-small cell lung, gastric and colon cancers as well as in glioblastoma brain cancers. In this preclinical testing, the compound also demonstrated an ability to effectively cross the blood brain barrier, and demonstrated an ability to extend survival in a preclinical intracranial glioblastoma model. We initiated IND-enabling studies during the second half of 2008 and anticipate that, assuming the outcome of those studies is favorable and that we have adequate capital resources, we will file an IND application for CUDC-305 in mid-2009.

Other Targeted Cancer Programs

We are also seeking to advance several other small molecule drug candidates from our targeted cancer programs. Provided that we have adequate capital resources, we anticipate that we will select a compound from one of these programs as a development candidate in the second half of 2009. 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 additional development candidate during the second half of 2010.

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 obtain 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.

In the U.S., we have issued patents expiring on various dates between 2013 and 2023 as well as pending patent applications. We have foreign counterpart patent filings for most of our U.S. issued patents and patent applications. These patents and patent applications are directed to compositions of matter, methods of making and using these compositions for multiple applications, methods for drug screening and discovery, developmental biological processes, and patents relating to our proprietary technologies.

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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 2013 and 2023, which relate to the Hedgehog pathway. Our patents and patent applications cover proteins, nucleic acids, antibodies, and certain small molecule agonists and inhibitors 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 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 and Development 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, 2008, our research group consists of 21 employees, consisting of molecular biologists, cell

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biologists, pharmacologists and other scientific disciplines. In an effort to expand our research capabilities in a fiscally prudent manner, we have also engaged 17 chemists on a contract basis at a leading preclinical service provider in Shanghai, China.

During the years ended December 31, 2008, 2007 and 2006, our total company-sponsored research and development expenses were approximately $13,092,000, $12,260,000 and $6,340,000, respectively, and our collaborator-sponsored research and development expenses were approximately $134,000, $2,519,000 and $8,250,000, 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 are subject to rigorous regulation by the Food and Drug Administration, or 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, among other things, 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, or NDA, seeking approval to market the drug product; 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 years, and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease. 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 human clinical 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 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.

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Clinical trials involve the administration of the investigational drug 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 assessing 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, or IRBs, 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 human subjects, 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 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. 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. Finally, sponsors are required to publicly disseminate information about ongoing and completed clinical trials on a government website administered by the National Institutes of Health, or NIH, and are subject to civil money penalties and other civil and criminal sanctions for failing to meet these obligations.

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 NDA.

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, a complete response letter. A complete response 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 and restrictions on distribution and use of the drug, 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. If new safety issues arise after approval, FDA may require the company to conduct additional post-market studies to assess the risk, change the labeling to address the risk, or impose distribution and use restrictions under a Risk Evaluation and Mitigation Strategy, or REMS. 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.

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Moreover, the Department of Justice can bring civil or criminal actions against companies that promote drugs for unapproved uses, based on the Federal Food, Drug, and Cosmetic Act, 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 and in some cases have exceeded $1 billion. 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. Manufacturing operations must continue to conform to cGMPs after approval. Drug manufacturers 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 complete response letter. The complete response letter outlines the deficiencies in the submission and may require 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.

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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 that target signaling pathways to treat cancers, 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 programs. We believe that our competitive advantage 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. Two of these companies, Infinity Pharmaceuticals, Inc. and Exelixis, Inc., filed IND applications in 2008 for molecules in their respective Hedgehog pathway inhibitor programs.

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 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

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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.

Sales and Marketing

We have no sales, marketing or distribution experience or infrastructure and we have no current plans to develop sales, marketing and distribution capabilities. 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 research and 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 Director, Multiple Sclerosis Research Center of New York 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)
George Vande Woude, Ph.D	Principal investigator, The University of Michigan s Specialized Program of Research Excellence (SPORE) in prostate cancer awarded from the National Cancer Institute 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, 2008, we had 34 full-time employees, of whom 15 hold a Ph.D. or other advanced degree. Of these employees, 21 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, 2008, we had an accumulated deficit of approximately $707,971,000. 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 drug candidates are in early stages of development. For the foreseeable future, we will need to spend significant capital in an effort to develop products that we can commercialize and we expect to incur substantial operating losses for the foreseeable future. Our failure to become and remain profitable is likely to 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 may not be able to generate substantial revenue from existing or future collaborations.

We have historically derived a substantial portion of our revenue from the research funding portion of our collaboration agreements. However, we have no current source of research funding revenue. We expect that our only source of cash flows from operations for the foreseeable future will be:

- up-front license payments and research and development funding that we may receive if we are able to successfully enter into new collaboration agreements;
- contingent cash payments that we may receive for the achievement of development objectives under any new collaborations or our existing collaborations with Genentech; and
- royalty payments that are contingent upon the successful commercialization of products based upon these collaborations.

We may not be able to successfully enter into or continue any corporate collaborations and the timing, amount and likelihood of us receiving payments under such collaborations is highly uncertain. As a result, we cannot assure you that we will attain any further revenue under any collaborations or licensing arrangements.

We will require substantial additional capital, which is likely to be difficult to obtain.

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, CUDC-305 and other small molecules that we are seeking to develop from our pipeline of targeted cancer programs, and to fund our general and administrative costs and expenses.

We anticipate that existing cash, cash equivalents and working capital at December 31, 2008, together with the $6,000,000 we will receive from Genentech in the first quarter of 2009, should enable us to maintain current and planned operations into mid-2010. Our future capital requirements, however, may vary from what we currently expect. There are a number of factors that may adversely affect our planned future capital requirements and accelerate our need for additional financing many of which are outside our control, including the following:

- unanticipated costs in our research and development programs;
- the timing and cost of obtaining regulatory approvals for our drug candidates;

the timing, receipt and amount of payments, if any, from current and potential future collaborators;

the timing and amount of payments due to licensors of patent rights and technology used in our drug candidates;

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- the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including litigation costs and technology license fees; and

- unexpected losses in our cash investments or an inability to otherwise liquidate our cash investments due to unfavorable conditions in the capital markets.

We may seek additional funding through public or private financings of debt or equity. The market for emerging life science stocks in general, and the market for our common stock in particular, is highly volatile. Due to this and various other factors, including the currently adverse 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. In addition, the terms of such a financing may be dilutive or otherwise adversely affect other rights of our stockholders. We also expect to seek additional funds through arrangements with collaborators, licensees or other third parties. These arrangements would generally require us to relinquish or encumber rights to some of our technologies or drug candidates, and we may not be able to enter into such arrangements on acceptable terms, if at all. If we are unable to obtain additional funding on a timely basis, whether through sales of debt or equity or through third party collaboration or license arrangements, we may be required to curtail or terminate some or all of our development programs, including some or all of our drug candidates.

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;

- a failure to successfully complete preclinical studies and clinical trials in a timely manner or at all, resulting in a delay in receiving, or a failure to receive, the required regulatory approvals to commercialize our drug candidates;

- the timing, receipt and amount of payments, if any, from current and potential future collaborators;

- the entry into, or termination of, collaboration agreements;

- the scope, duration and effectiveness of our collaborative arrangements;

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

- the ability to operate without infringing upon the proprietary rights of others;

- costs to comply with changes in government regulations;

- changes in management and reductions or additions of personnel;

- general and industry-specific adverse economic conditions that may affect, among other things, our and our collaborators operations and financial results;

revenue recognition policies;

changes in accounting estimates, policies or principles; and

the introduction of competitive products and technologies by third parties.

Due to fluctuations in our operating results, 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.

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Unstable market and economic conditions may have serious adverse consequences on our business.

Our general business strategy may be adversely affected by the recent economic downturn and volatile business environment and continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate further, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which would directly affect our ability to attain our operating goals on schedule and on budget.

At December 31, 2008, we had $28,853,000 of cash equivalents and marketable securities consisting of commercial paper, corporate debt securities, and government obligations. While as of the date of this filing, we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents or marketable securities since December 31, 2008, no assurance can be given that further deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or marketable securities or our ability to meet our financing objectives. Further dislocations in the credit market may adversely impact the value and/or liquidity of marketable securities owned by us.

There is a possibility that our stock price may decline, due in part to the volatility of the stock market and the general economic downturn.

RISKS RELATING TO THE DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCTS

We depend on our collaborative relationship with Genentech and if Genentech fails or delays in developing or commercializing drug candidates based upon our technologies, our business prospects and operating results would suffer and our stock price would likely decline.

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 technologies in defined fields of use, including GDC-0449, an orally-administered small molecule pathway inhibitor of the hedgehog signaling pathway. Genentech is currently testing GDC-0449 in two phase II clinical trials and a pivotal phase II trial in advanced basal cell carcinoma. Our collaborations with Genentech are our only current collaborations, and these collaborations may not be scientifically or commercially successful due to a number of factors, including the following:

- Genentech has significant discretion in determining the efforts and resources that it will apply to each collaboration. The timing and amount of any cash payments related to future royalties and the achievement of development objectives that we may receive under such collaborative arrangements will depend on, among other things, Genentech s efforts, allocation of resources and successful development and commercialization of our drug candidates.

- Our strategic collaboration agreements with Genentech permit Genentech wide discretion in deciding which drug candidates to advance through the clinical trial process. It is possible for Genentech to reject drug candidates at any point in the research, development and clinical trial process, without triggering a termination of the collaboration agreement with us. In the event of any such decision, our business and prospects may be adversely affected due to our inability to progress drug candidates ourselves.

- Genentech may develop and commercialize, either alone or with others, products that are similar to or competitive with the drug candidates that are the subject of its collaborations with us.

- Genentech may change the focus of its development and commercialization efforts or pursue higher-priority programs. Our ability to successfully commercialize drug candidates under collaboration with Genentech could be limited if Genentech decreases or fails to increase spending related to such drug candidates.

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Genentech may enter into one or more transactions with third parties, including a merger, consolidation, reorganization, sale of substantial assets, sale of substantial stock or change of control. For example, in February 2009, Roche Holdings Ltd announced that it is commencing a cash tender offer for all outstanding publicly-held shares of Genentech for $86.50 per share that will expire on March 12, 2009, unless the offer is extended. Any such third-party transaction, including a merger with Roche, could: divert the attention of Genentech s management and adversely affect Genentech s ability to retain and motivate key personnel who are important to the continued development of the programs under our collaboration. In addition, the third-party could determine to reprioritize Genentech s development programs such that it ceases to diligently pursue the development of our programs; and/or cause the collaboration with us to terminate.

Genentech may, under specified circumstances, terminate its collaborations with us on short notice and for circumstances outside of our control, which could make it difficult for us to attract new collaborators or adversely affect how we are perceived in the scientific and financial communities.

If Genentech fails to successfully develop and commercialize our drug candidates under collaboration, we may not be able to develop and commercialize these candidates independently or successfully enter into one or more alternative collaborations, in which event our financial condition, results of operations and stock price may be adversely affected.

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

Our current strategy is to seek corporate collaborators or licensees for the further development and commercialization of one or more drug candidates under our targeted cancer drug programs. For example, we are currently seeking corporate collaborations for CUDC-101 and CUDC-305, the first two drug candidates we have selected from these programs. We do not currently have the experience, resources or capacity to advance these programs into later stages of clinical development or commercialization. As such, our success will depend, in part, on our ability to enter into one or more such collaborations. We face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a collaboration or other alternative arrangements for CUDC-101, CUDC-305 or any future programs because our research and development pipeline may be insufficient, our programs may be deemed to be at too early of a stage of development for collaborative effort and/or third parties may not view our drug candidates and programs as having the requisite potential to demonstrate safety and efficacy. Even if we are successful in our efforts to establish new collaborations, the terms that we agree upon may not be favorable to us. If we are not able to successfully enter into one or more collaborations or licensing arrangements for CUDC-101, CUDC-305 or any future programs, the clinical development of these programs could be significantly delayed and our future prospects may be adversely affected and our stock price could decline.

The therapeutic efficacy of drug candidates under our targeted cancer programs is unproven in humans, and we may not be able to successfully develop and commercialize CUDC-101, CUDC-305 or any other future drug candidates that we may select from this program.

Our internal drug development efforts are focused on our proprietary targeted cancer programs. These programs focus on the development of single agent drug candidates targeting one or more molecular components within signaling pathways associated with certain cancers. We are also seeking to develop proprietary single agent, single target drug candidates for cancer indications. We have currently selected two drug candidates from this program for further development: CUDC-101, which is being designed to simultaneously inhibit HDAC, EGFR and Her2, and CUDC-305, an orally available, synthetic small molecule inhibitor of Hsp90. In August 2008, we treated the first patient in a phase I trial of CUDC-101, and we initiated IND-enabling studies of CUDC-305 in the second half of 2008.

CUDC-101 and CUDC-305 are novel compounds and their potential benefit as therapeutic cancer drugs is unproven. These drug candidates may not prove to be effective inhibitors of the validated cancer targets they are

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being designed to act against and may not demonstrate in patients any or all of the pharmacological benefits that we believe they may possess or that may have been demonstrated in preclinical trials. Moreover, there is a risk that these drug candidates may interact with human biological systems in unforeseen, ineffective or harmful ways. As a result of these and other risks described herein that are inherent in the development of novel therapeutic agents, we may never successfully develop, enter into third party licensing or collaboration transactions with respect to, or successfully commercialize CUDC-101, CUDC-305, or any other drug candidates under our targeted cancer drug development platform, in which case we will not achieve profitability and the value of our stock will decline.

If preclinical studies and clinical trials of our drug candidates are not successful then our future profitability and success could be adversely affected.

In order to obtain regulatory approval for the commercial sale of our drug candidates, we and any current or potential future 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 drug candidates are safe and effective. For example, our lead product candidate, GDC-0449, is currently being tested by our collaborator, Genentech, in a pivotal phase II clinical trial in advanced basal cell carcinoma and two phase II clinical trials in other cancer indications. In addition, in August 2008 we treated our first patient in a phase I clinical trial of CUDC-101, the lead drug candidate from our pipeline of proprietary targeted cancer programs.

Development, including preclinical and clinical testing, is a long, expensive and uncertain process. Accordingly, preclinical testing and clinical trials of our drug candidates under development may not be successful. We, Genentech and any future collaborators could experience delays or failures in preclinical or clinical trials of any of our drug 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 drug candidates depend on, among other factors, the number of patients required to be enrolled 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;

- our products under development may not be effective in treating any of our targeted cancer indications 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 drug 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 potential future 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 of our drug candidates that we, Genentech, and any future collaborators pursue are not successful, then our ability to successfully develop and commercialize

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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 expect to rely primarily on third parties for the performance and management of clinical trials and if such third parties fail to perform then we will not be able to successfully develop and commercialize drug candidates and grow our business.

We have very limited experience in conducting later-stage clinical trials. We expect to rely primarily 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 to Genentech under our existing collaboration agreements with Genentech and we expect that any future collaboration partners may similarly be fully responsible for conducting at least the later-stage clinical trials of drug candidates. In the near term, we expect 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 the trial design. In addition, 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. Any failure by a third party to conduct our clinical trials as planned or in accordance with regulatory requirements could delay or otherwise adversely affect our efforts to obtain regulatory approvals for and commercialize our drug candidates.

If we and our current and potential future 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, Genentech and any potential future collaborative partners will be required to obtain regulatory approval in order to successfully advance our drug 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 our internal programs, 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 potential future 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.

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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 drug 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 drug candidates and to produce, market and distribute products after approval.

On September 27, 2007, the President of the United States signed the Food and Drug Administration Amendments Act of 2007, or 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 potential future 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 potential future 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 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 Genentech are, and any potential future collaborators will be, subject to governmental regulations in connection with the research, development and commercialization of our drug candidates in addition to 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, our current collaborator, Genentech, and any potential future 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.

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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.

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.

RISKS RELATED TO OUR BUSINESS, INDUSTRY, STRATEGY AND OPERATIONS

We, our current collaborator, Genentech, and any potential future collaborators, may not achieve projected research and development goals in the time frames we or they announce, 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 agreements. Genentech has also made public statements regarding its expectations for the clinical development of GDC-0449 and may in the future make additional statements about its goals and expectations for this collaboration with us. The actual timing of these events can vary dramatically due to a number of factors such as delays or failures in our and our current and potential future collaborators preclinical studies or clinical trials, the amount of time, effort and resources committed to our programs by us and our current and potential future collaborators and the uncertainties inherent in the regulatory approval process. As a result, there can be no assurance that our or our current and potential future collaborators preclinical studies and clinical trials will advance or be completed in the time frames we or they announce or expect, that we or our current and potential future collaborators will make regulatory submissions or receive regulatory approvals as planned or that we or our current and potential future 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 drug 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 pathway inhibitor drug candidates before we do or may compete with us in the same market sector.

In addition, our small molecule targeted cancer drug development candidates, 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.

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Many of our competitors have substantially greater capital resources, research and development staffs and facilities, and more extensive experience, than we have. As a result, efforts by other life science, 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 are not able to compete effectively, then we may not be able, either alone or with others, to advance the development and commercialization of our drug candidates, which would adversely affect our ability to grow our business and become profitable.

The trend towards consolidation in the pharmaceutical and biotechnology industries may adversely affect us.

There is a trend towards consolidation in the pharmaceutical and biotechnology industries. This consolidation trend may result in the remaining companies having greater financial resources and discovery technological capabilities, thus intensifying competition in these industries. This trend may also result in fewer potential collaborators or licensees for our therapeutic product candidates. Also, if a consolidating company is already doing business with our competitors, we may lose existing licensees or collaborators as a result of such consolidation.

This trend may adversely affect our ability to enter into agreements for the development and commercialization of our product candidates, and as a result may harm our business.

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 drug candidates. Regardless of their merit or eventual outcome, product liability claims would require us to spend significant time, money and other resources to defend such claims, could result in decreased demand for our future products or result in reputational harm and could result in the payment of a significant damage award. We currently have product liability insurance for our phase I clinical trial of CUDC-101. However, this insurance is subject to deductibles and coverage limitations and may not be adequate in scope to protect us in the event of a successful product liability claim. If any of our drug candidates advance in clinical trials and/or are approved for marketing, we may seek additional insurance coverage. Product liability insurance is expensive and may be difficult to procure. As such, it is possible that we will not be able to obtain product liability insurance on acceptable terms, if at all, or that our product liability insurance coverage will prove to be inadequate to protect us from all potential claims, which may harm our business.

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If we are not able to attract and retain key management and scientific personnel and advisors, we may not successfully develop our drug 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.

While we have no current plans, in the future, 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;
- 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 Programs.

We currently engage medicinal chemists in Shanghai, China, pursuant to an agreement with a medicinal chemistry provider in Shanghai. In addition, we have a subsidiary in China, Curis Shanghai, which 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

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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 research and 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 research 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.

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 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 is 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 Statement of Financial Accounting Standards No. 123 (revised 2004), or SFAS 123(R), to expense stock options.

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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 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 breaches its responsibilities under these agreements, 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 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 drug 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 certain of our drug candidates. In addition, continued development and commercialization of our drug 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.

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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 life science 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 may be 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 drug 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 potential future collaborative partners may be required to obtain licenses under third-party patents to develop and commercialize some of our drug candidates. If we are unable to secure licenses to such patented technology on acceptable terms, we or our collaborative partners may not be able to develop and commercialize the affected product candidate or candidates.

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 life science 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, to seek to invalidate the patents held by these third parties or to obtain a judgment that our drug candidates do not infringe the third parties patents;

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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 drug candidates or the intended use of our drug 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, which covers inventions which may have been subject to chemistry or biology related work performed by contract research organizations 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 and intellectual property assignment provisions with the chemists and biologists we have 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 inconsistent and damages assessed fail to reflect the true value of the infringed technology and its market. 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.

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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 formulate or manufacture these products, our business will be harmed.

We have no manufacturing experience or manufacturing capabilities. In order to continue to develop drug 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 drug 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 drug 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.

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 drug candidates, delays, suspension or withdrawal of approvals, seizures or recalls of drug 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 drug 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

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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 potential future 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;
- private health insurers;
- 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.

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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 the minimum bid price exceed $1.00 for more than ten consecutive days before determining that a company complies with its continued listing standards. Given the continued extraordinary market conditions, however, NASDAQ has suspended the rules requiring a minimum $1.00 closing bid price of publicly held shares. Enforcement of these rules is scheduled to resume on Monday, April 20, 2009. 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 $2.35 and as low as $0.68 per share for the period January 1, 2007 through February 20, 2009. 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;

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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 economic and market conditions, including recent adverse changes in the domestic and international financial markets.

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.

The limited liquidity for our common stock could affect an investor s ability to sell our shares at a satisfactory price and makes the trading price of our common stock more volatile.

Our common stock is relatively illiquid. As of December 31, 2008, we had approximately 63.7 million shares of common stock outstanding. The average daily trading volume in the common stock during the prior 50 trading days ending on December 31, 2008 was 120,000 shares. A more active public market for our common stock, however, may not develop, which would continue to adversely affect the trading price and liquidity of the common stock. Moreover, a thin trading market for the common stock causes the market price for the common stock to fluctuate significantly more than the stock market as a whole. Without a large float, our common stock is less liquid than the stock of companies with broader public ownership and, as a result, the trading prices of our common stock may be more volatile.

Future sales of shares of our common stock, including upon the exercise of currently outstanding options and warrants or pursuant to our universal shelf registration statement could negatively affect our stock price.

Most of our outstanding common stock can be traded without restriction at any time. As such, 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 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.

We currently have the ability to offer and sell common stock, preferred stock and warrants under a currently effective universal shelf registration statement. Sales of substantial amounts of shares of our common stock or

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other securities under our universal shelf registration statement could lower the market price of our common stock and impair our ability to raise capital through the sale of equity securities. In the future, we may issue additional options, warrants or other derivative securities convertible into our common stock.

We do not intend to pay dividends on our common stock, and any return to investors will come, if at all, only from potential increases in the price of our common stock.

At the present time, we intend to use available funds to finance our operations. Accordingly, while payment of dividends rests within the discretion of our board of directors, no common stock dividends have been declared or paid by us and we have no intention of paying any common stock dividends in the foreseeable future.

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

As of December 31, 2008, we believe that our directors, executive officers and principal stockholders, together with their affiliates, owned, in the aggregate, approximately 39% 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

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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.

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.	48	President and Chief Executive Officer
Michael P. Gray	38	Chief Operating Officer and Chief Financial Officer
Mark W. Noel	50	Vice President, Technology Management and Intellectual Property
Changgeng Qian, Ph.D., M.D.	53	Vice President, Discovery and Preclinical Research

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

Mr. Passeri has served as our President and Chief Executive Officer and as a director since September 2001. From November 2000 to September 2001, Mr. Passeri served as Senior Vice President, Corporate Development and Strategic Planning of the Company. From March 1997 to November 2000, Mr. Passeri was employed by GeneLogic Inc., a biotechnology company, most recently as Senior Vice President, Corporate Development and Strategic Planning. From February 1995 to March 1997, Mr. Passeri was employed by Boehringer Mannheim, a pharmaceutical, biotechnology and diagnostic company, as Director of Technology Management. Mr. Passeri is a graduate of the National Law Center at George Washington University, with a J.D., of the Imperial College of Science, Technology and Medicine at the University of London, with an M.Sc. in biotechnology, and of Northeastern University, with a B.S. in biology.

Michael P. Gray

Mr. Gray has served as our Chief Operating Officer and Chief Financial Officer since December 2006. From December 2003 until December 2006, Mr. Gray served as our Vice President of Finance and Chief Financial Officer and served as our Senior Director of Finance and Controller from August 2000 until December 2003. From January 1998 to July 2000, Mr. Gray was Controller at Reprogenesis, Inc., a predecessor biotechnology company. Mr. Gray previously served as an audit professional for the accounting and consulting firm of Ernst & Young, LLP. Mr. Gray is a certified public accountant, holds an M.B.A. from the 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, Technology Management and Intellectual Property since September 2008. From March 2001 until September 2008, Mr. Noel has served as our Vice President, Technology Management and Business Development. From March 2000 to February 2001, Mr. Noel was employed by GeneLogic, as Vice President of Customer Relations. From January 1998 to February 2000, Mr. Noel was employed by GeneLogic as Senior Director of Program Management. From December 1993 to January 1998, Mr. Noel was employed by the National Cancer Institute s Office of Technology Development (now the NCI Technology Transfer Center), where from July 1997 to January 1998, he served as Acting Deputy Director. From February 1989 to November 1993, Mr. Noel worked as a patent agent at Gist Brocades NV, a supplier of ingredients to the pharmaceutical and food sectors. Mr. Noel holds a B.S. from the University of Maryland.
Changgeng Qian, Ph.D., M.D.	Dr. Qian has served as our Vice President, Discovery and Preclinical Research since September 2006. From May 2005 to September 2006, Dr. Qian served as our Senior Director, Pharmacology. From May 2002 to May 2005, Dr. Qian served as our Director, Pharmacology, and from May 2001 to May 2002, Dr. Qian served as our Associate Director, Pharmacology. From November 1999 to May 2001, Dr. Qian was Senior Scientist II at Millennium Pharmaceuticals, Inc., a biopharmaceutical company. From October 1996 to November 1999, Dr. Qian was Senior Research Scientist III at LeukoSite, Inc., a biopharmaceutical company that was acquired by Millennium Pharmaceuticals in December 1999. From January 1992 to December 1995, Dr. Qian was Head of Pharmacology at CytoMed, Inc., a biopharmaceutical company. Dr. Qian holds a Ph.D. in Pharmacology and an M.D. from the Hunan Medical University in Changsha, China and has served as a professor of the 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, 2007	**High**	**Low**
First Quarter	$ 1.72	$ 1.15
Second Quarter	$ 2.35	$ 1.13
Third Quarter	$ 1.31	$ 0.93
Fourth Quarter	$ 1.20	$ 0.86
Year ended December 31, 2008		
First Quarter	$ 1.63	$ 0.91
Second Quarter	$ 1.58	$ 1.13
Third Quarter	$ 1.94	$ 1.08
Fourth Quarter	$ 1.21	$ 0.68

(b) *Holders*. On February 24, 2009, the last reported sale price of our common stock on the NASDAQ Global Market was $1.26 and there were 301 holders of record of our common stock. The number of record holders may not be representative of the number of beneficial owners because many of the shares of our common stock are held by depositories, brokers or other nominees.

(c) *Dividends*. We have never declared or paid any cash dividends on our common stock. We currently intend to retain earnings, if any, to support our business strategy and do not anticipate paying cash dividends in the foreseeable future. Payment of future dividends, if any, will be at the sole discretion of our board of directors after taking into account various factors, including our financial condition, operating results, capital requirements and any plans for expansion.

(e) *Performance Graph*. The graph below compares the cumulative total stockholder return on the common stock for the period from December 31, 2003 through December 31, 2008, with the cumulative total return on (i) NASDAQ Pharmaceutical Index, (ii) NASDAQ Market Index U.S. Companies and (iii) NASDAQ Biotechnology Index. The comparison assumes investment of $100 on December 31, 2003 in our common stock and in each of the indices and, in each case, assumes reinvestment of all dividends. Prior to August 1, 2000, our common stock was not publicly traded.

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	12/31/03	12/31/04	12/31/05	12/31/06	12/31/07	12/31/08
CURIS INCORPORATED	100.00	116.00	79.11	28.00	21.78	16.67
NASDAQ PHARMACEUTICAL INDEX	100.00	108.08	119.19	119.53	116.69	106.89
NASDAQ MARKET INDEX-U.S. COS.	100.00	109.04	112.97	126.73	138.98	81.17
NASDAQ BIOTECHNOLOGY INDEX	100.00	112.31	131.52	130.42	129.36	122.91

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ITEM 6. SELECTED FINANCIAL DATA

The selected consolidated financial data set forth below have been derived from our consolidated financial statements. These historical results are not necessarily indicative of results to be expected for any future period. You should read the data set forth below in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and the consolidated financial statements and related notes included elsewhere in this report.

	Year Ended December 31,				
	2008	2007	2006	2005	2004
	(in thousands, except per share data)				
Consolidated Statement of Operations Data:					
Revenues:					
Research and development contracts	$ 514	$ 3,262	$ 9,340	$ 10,493	$ 3,407
License and maintenance fees(1)	7,853	13,127	4,324	2,258	242
Substantive milestones(2)			3,000	250	50
Contra-revenues			(1,728)	(6,999)	
Net revenues	8,367	16,389	14,936	6,002	3,699
Costs and expenses:					
Research and development	13,226	14,779	14,590	13,705	12,662
General and administrative	8,260	9,984	10,374	8,090	7,757
Amortization of intangible assets			27	75	75
Total costs and expenses	21,486	24,763	24,991	21,870	20,494
Loss from operations	(13,119)	(8,374)	(10,055)	(15,868)	(16,795)
Other income (expense):					
Interest and other income	1,000	1,495	1,422	1,321	2,131
Interest expense	(4)	(85)	(196)	(308)	(411)
Total other income, net	996	1,410	1,226	1,013	1,720
Net loss applicable to common stockholders	$ (12,123)	$ (6,964)	$ (8,829)	$ (14,855)	$ (15,075)
Basic and diluted net loss per common share	$ (0.19)	$ (0.13)	$ (0.18)	$ (0.31)	$ (0.35)
Weighted average common shares (basic and diluted)	63,378	54,915	49,067	48,074	42,686

	(in thousands) As of December 31,				
	2008	2007	2006	2005	2004
Consolidated Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 28,853	$ 41,459	$ 36,656	$ 44,209	$ 49,514
Working capital	26,748	35,410	32,521	36,010	46,854
Long-term investment restricted	210	210	202	196	193
Total assets	39,982	53,817	52,268	60,914	67,332
Debt and lease obligations		404	1,980	3,227	
Convertible notes payable				2,605	5,710
Accumulated deficit	(707,971)	(695,848)	(688,883)	(680,054)	(665,199)
Total stockholders equity	37,225	46,845	35,897	38,000	48,312

(1) During the year ended December 31, 2008, we recognized $6,000,000 of revenue for contingent cash payments that we received during 2008 under our June 2003 Hedgehog pathway inhibitor collaboration with Genentech. During the year ended December 31, 2007, we recognized $10,509,000 of revenue under this collaboration, which included $7,509,000 in previously deferred revenue and $3,000,000 for a contingent cash payment that we received during 2007.

(2) During the year ended December 31, 2006, we recognized $3,000,000 as substantive milestone revenue under our June 2003 Hedgehog pathway inhibitor collaboration with Genentech. In 2005, we recognized $250,000 under our January 2004 Hedgehog agonist collaboration with Wyeth.

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

The following discussion and analysis of financial condition and results of operations should be read together with Selected Financial Data, and our financial statements and accompanying notes appearing elsewhere in this annual report on Form 10-K. This discussion contains forward-looking statements, based on current expectations and related to future events and our future financial performance, that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many important factors, including those set forth under Item 1A, Risk Factors and elsewhere in this report.

Overview

We are a drug discovery and development company that is committed to leveraging our innovative signaling pathway drug technologies in seeking to develop next generation targeted cancer therapies. In expanding our drug development efforts with respect to these targeted cancer programs, we are building upon our past experiences in targeting signaling pathways, including the Hedgehog pathway. We seek to conduct research programs both internally and through strategic collaborations.

Our most advanced program is a first-in-class orally administered Hedgehog pathway inhibitor program for which our collaborator Genentech is conducting clinical trials on the lead molecule, GDC-0449, including a pivotal Phase II clinical trial in advanced basal cell carcinoma patients as well as Phase II clinical trials in first-line metastatic colorectal cancer and in advanced ovarian cancer patients. We believe that GDC-0449 is the first Hedgehog pathway inhibitor to advance to Phase II clinical testing. The initiation of these clinical trials has provided us with an important source of financing, resulting in a total of $18,000,000, including the $6,000,000 we will receive in the first quarter of 2009 for the initiation of the pivotal Phase II trial. In addition to these three clinical trials, a Phase I clinical trial to treat medulloblastoma patients was initiated by a third-party investigator under a Cooperative Research and Development Agreement (CRADA) between Genentech and the National Cancer Institute (NCI). We anticipate that additional clinical trials will be initiated in the future including Phase II clinical trials in small cell lung and pancreatic cancers, among others. The initiation of trials conducted under the CRADA do not result in cash payments to us. We believe, however, that such trials are important to the overall development of GDC-0449 since they may provide a greater opportunity to generate additional data in tumor types other than those currently under investigation by Genentech.

Our internal drug development efforts are focused on our proprietary targeted cancer programs. 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. These targeted cancer programs primarily consist of several proprietary drug programs that target multiple signaling pathways. 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. Our lead candidate from these programs is CUDC-101, a small molecule that is currently in Phase I clinical testing and is designed to target histone deacetylase (HDAC), epidermal growth factor receptor (EGFR) and epidermal growth factor 2 (Her2). In addition, we expect to file an Investigational Drug Application (IND) for CUDC-305, a Heat Shock Protein 90 (Hsp90) inhibitor, in mid-2009 and provided that we have adequate capital resources, begin clinical testing on this candidate shortly thereafter.

Since our inception, we have funded our operations primarily through license fees, contingent cash payments, research and development funding from our strategic collaborators, the private and public placement of our equity securities and debt financings and the monetization of certain royalty rights. We have never been profitable and have incurred an accumulated deficit of $707,971,000 as of December 31, 2008. We expect to incur significant operating losses for the next several years as we devote substantially all of our resources to our

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research and development programs. We will need to generate significant revenues to achieve profitability and do not expect to achieve profitability in the foreseeable future, if at all. We believe that near term key drivers to our success will include:

- Genentech s ability to continue to successfully advance its clinical trials for GDC-0449;
- our ability to successfully enter into a material license or collaboration agreement for CUDC-305 and/or CUDC-101;
- our ability to continue to successfully enroll and treat patients in our phase I clinical trial for CUDC-101 and achieve the primary and secondary endpoints of the trial;
- our ability to successfully advance CUDC-305 through preclinical IND-enabling studies and file an IND application for this compound in 2009; and
- our ability to advance the preclinical development of other small molecule cancer drug candidates that we are developing under our proprietary pipeline of targeted cancer programs.

In the longer term, a key driver to our success will be our ability, and the ability of any current or future collaborator or licensee, to successfully commercialize drugs based upon our proprietary technologies.

Collaboration Agreements

We are currently a party to a June 2003 collaboration with Genentech relating to our Hedgehog pathway inhibitor technologies and to an April 2005 collaboration with Genentech relating to the Wnt signaling pathway. Our past and current collaborations have generally provided for research, development and commercialization programs to be wholly or majority funded by our collaborators and provide us with the opportunity to receive additional contingent cash payments principally if specified development and regulatory approval objectives are achieved, as well as royalty payments upon the successful commercialization of any products based upon the collaborations. We are currently not receiving any research funding and we do not expect to receive such funding in the future from our current collaborator, Genentech. We currently expect to incur only nominal research and development costs under these collaborations related to the maintenance of licenses. In addition, 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. As of December 31, 2008, we have incurred an aggregate of $600,000 in expenses related to such payments. We also expect to incur general and administrative costs associated with our Hedgehog pathway inhibitor program related to our share of intellectual property costs.

Our current collaboration agreements are summarized as follows:

Genentech Hedgehog Pathway Inhibitor Collaboration. Under the terms of the June 2003 agreement with Genentech, we granted Genentech an exclusive, global, royalty-bearing license, with the right to sublicense, make, use, sell and import small molecule and antibody Hedgehog pathway inhibitors. 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. In November 2008, Genentech granted a license to F. Hoffmann-LaRoche, Ltd (Roche) for ex-U.S. rights to GDC-0449. Roche received this license pursuant to an agreement between Genentech and Roche under which Genentech granted Roche an option to obtain a license to commercialize certain Genentech products in non-U.S. markets. We believe that the collaborative worldwide development activities of Genentech and Roche could expand the potential value of this compound since Roche brings significant additional clinical development and commercialization experience to advance and market GDC-0449 outside of the U.S. Genentech and Roche have primary responsibility for worldwide clinical development, regulatory affairs, manufacturing and supply, formulation and sales and marketing. We are not a party to this agreement between Genentech and Roche but we are eligible to receive cash payments for regulatory filing and approval objectives achieved and future royalties on products developed outside of the U.S., if any, under our June 2003 collaboration agreement with Genentech.

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Pursuant to the collaboration agreement, in June 2003 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 at which time, all research funding ended. We do not expect to receive additional future research funding from Genentech or incur any material research costs related to this program. To date, we have received $12,000,000 in cash payments for the achievement of certain development objectives under the terms of the agreement, and we will receive an additional $6,000,000 during the first quarter of 2009 for the February 2009 initiation of the pivotal Phase II clinical trial in advanced basal cell carcinoma. In addition to these payments, we will be eligible to receive additional future cash payments from Genentech only upon the achievement of additional specified clinical development and regulatory approval objectives as well as royalties on product sales if any Hedgehog pathway inhibitor products are successfully developed and commercialized.

Genentech Wnt Pathway Collaboration. In April 2005, we entered into a collaboration agreement with Genentech for discovery and development of small molecule compounds that modulate the Wnt signaling pathway. Under the terms of the agreement, we granted Genentech an exclusive royalty-bearing license to make, use and sell the small molecule compounds that are modulators of the Wnt pathway. Genentech paid us an up-front license fee of $3,000,000 and funded $5,270,000 for research and development activities during the two-year research term, which ended in March 2007, at which time, Genentech assumed further responsibility for any future development of this program. Genentech has also agreed to make cash payments to us that are contingent upon the successful achievement of certain research, development, clinical and drug approval objectives, as well as royalties on net product sales if product candidates derived from the collaboration are 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 can not predict whether Genentech will continue to pursue the development of drug candidates under the agreement or whether any development objectives for which we may be entitled to a cash payment will be achieved.

Stryker Corporation BMP Assignment and Sale

In December 2007, we sold and assigned our bone morphogenetic protein, or BMP, technologies to Stryker Corporation. Under the agreement, Stryker paid us $1,750,000 in exchange for the sale and assignment of all of our remaining BMP assets. As a result of the transaction, Stryker assumed all future costs subsequent to the December 26, 2007 effective date related to future development activities, as well as to the maintenance and prosecution of the patent portfolio. Under the terms of the agreements, we are entitled to contingent cash payments related to certain clinical development and sales objectives, if achieved. We can not predict whether any development objectives under this agreement for which we may be entitled to a contingent cash payment will be achieved.

Financial Operations Overview

General. Our future operating results will largely depend on the magnitude of payments from our current and potential future corporate collaborators and the progress of drug candidates currently in our research and development pipeline. The results of our operations will vary significantly from year to year and quarter to quarter and depend on, among other factors, the timing of our entry into new collaborations, if any, the timing of the receipt of payments, if any, from new or existing collaborators and the cost and outcome of any preclinical development or clinical trials then being conducted. We anticipate that existing capital resources at December 31, 2008, together with the $6,000,000 we have earned and will receive from Genentech during the first quarter of 2009 for the February 2009 initiation of a pivotal phase II clinical trial in advanced basal cell carcinoma, should

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enable us to maintain current and planned operations into mid-2010. Our ability to continue funding our planned operations is dependent upon the success of our collaborations with Genentech, our ability to control our cash burn rate and our ability to raise additional funds through additional corporate collaborations, equity or debt financings, or from other sources of financing.

In October 2008, we implemented a plan to reduce our spending in various general and administrative and research and development expense areas, particularly costs associated with preclinical research. Spending reductions include decreases in contract medicinal chemistry and biology work that was being performed in China, and in personnel, legal and occupancy costs. As we seek to reduce administrative expenses and our preclinical and discovery research costs, we expect that our expenses associated with the clinical development of CUDC-101 and the IND-enabling studies underway for CUDC-305 will increase, resulting in an overall increase in our research and development expenses for future periods as compared to prior years. We expect that our reductions in general and administrative expenses will result in modest decreases in such expenses in future periods.

A discussion of certain risks and uncertainties that could affect our liquidity, capital requirements and ability to raise additional funds is set forth under Part I, Item 1A Risk Factors.

Revenue. We do not expect to generate any revenue from the sale of products for several years, if ever. Substantially all of our gross revenues to date have been derived from license fees, research and development payments, and other amounts that we have received from our strategic collaborators and licensees. For the year ended December 31, 2008, each of the following parties accounted for a portion of our total revenue as follows: Genentech, $6,282,000, or 75%; Stryker Corporation, $1,750,000, or 21%; and Wyeth, $299,000, or 4%.

We currently have two collaborations, both of which are with Genentech. We currently receive no research funding for our programs under collaboration with Genentech and we do not expect to receive such funding in the future under these collaborations. Accordingly, our only source of revenues and/or cash flows from operations for the foreseeable future will be up-front license payments and funded research and development that we may receive under new collaboration agreements, if any, contingent cash payments for the achievement of development objectives, if any are met, under new collaborations or our existing collaborations with Genentech and royalty payments that are contingent upon the successful commercialization of any products based upon collaborations. The timing of our entrance into any new collaboration agreements and any contingent cash payments under our existing collaboration agreements with Genentech are not assured, cannot be easily predicted and may vary significantly from quarter to quarter. Except for the $6,000,000 we will receive in the first quarter of 2009 under our Hedgehog pathway inhibitor collaboration with Genentech, we do not expect to receive additional contingent cash payments in 2009 under our ongoing collaborations based on our current estimates of these development programs.

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Research and Development. Research and development expense consists of costs incurred to discover, research and develop our drug candidates. These expenses consist primarily of salaries and related expenses for personnel including stock-based compensation expense. Research and development expenses also include the costs of supplies and reagents, outside service costs including clinical research organizations and medicinal chemistry, consulting, and occupancy and depreciation charges. We expense research and development costs as incurred. Although we have historically incurred research and development expenses under our collaborations with Genentech, we are currently incurring only nominal research and development expenses for these programs which are limited to the maintenance of third-party licenses. For each contingent payment, if any, received under our collaborations with Genentech, we would be obligated to make payments to these third parties and recognize the related expense. Our research and development programs, both internal and under collaboration, are summarized in the following table:

Product Candidate	**Primary Indication**	**Collaborator/Licensee**	**Status**
Hedgehog Pathway Inhibitor			
- GDC-0449	Advanced basal cell carcinoma	Genentech	Pivotal Phase II
- GDC-0449	Metastatic colorectal cancer	Genentech	Phase II
- GDC-0449	Advanced ovarian cancer	Genentech	Phase II
Targeted cancer programs			
- CUDC-101 (HDAC, EGFR, Her2 inhibitor)	Cancer	Internal development	Phase I
- CUDC-305 (Hsp90 inhibitor)	Cancer	Internal development	Development candidate
- Other targeted cancer programs	Cancer	Internal development	Preclinical

In the chart above, Pivotal Phase II means that our collaborator Genentech is currently treating human patients in a pivotal Phase II clinical trial, the primary objective of which is a therapeutic response in human patients. The endpoints of this clinical trial, if positive, may serve as the basis for future New Drug Application (NDA) submission by Genentech. Phase II means that our collaborator Genentech is currently treating human patients in a Phase II clinical trial, the primary objective of which is a therapeutic response (i.e., for the metastatic colorectal cancer trial, progression-free survival from randomization to disease progression or death). Phase I means that we are currently treating human patients in a Phase I clinical trial, the principal purpose of which is to evaluate the safety and tolerability of the compound being tested. 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 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.

Because of the early stages of development of these programs, our ability and that of our collaborator to successfully complete preclinical and clinical studies of these drug candidates, and the timing of completion of such programs, is highly uncertain. There are numerous risks and uncertainties associated with developing drugs which may affect our and our collaborators future results, including:

- the scope, quality of data, rate of progress and cost of clinical trials and other research and development activities undertaken by us or our collaborators;
- the results of future preclinical and clinical trials;
- the cost and timing of regulatory approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our drug candidates and any products that we may develop;

the effect of competing technological and market developments; and

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the cost and effectiveness of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

We cannot reasonably estimate or know the nature, timing and estimated costs of the efforts necessary to complete the development of, or the period in which material net cash inflows are expected to commence from any of our drug candidates. Any failure to complete the development of our drug candidates in a timely manner could have a material adverse effect on our operations, financial position and liquidity.

A further discussion of some of the risks and uncertainties associated with completing our research and development programs on schedule, or at all, and some consequences of failing to do so, are set forth above in Part I, Item 1A Risk Factors.

General and Administrative. General and administrative expense consists primarily of salaries, stock-based compensation expense and other related costs for personnel in executive, finance, accounting, business development, legal, information technology, corporate communications and human resource functions. Other costs include facility costs not otherwise included in research and development expense, insurance, and professional fees for legal, patent and accounting services. Patent costs include certain patents covered under collaborations, a portion of which is reimbursed by collaborators and a portion of which is borne by Curis. In October 2008, we extended previously-initiated efforts to reduce our spending in various general and administrative expense areas, including personnel, occupancy and legal services, among others. As a result of these changes, we expect that our general and administration expenses will decline modestly in future periods.

Critical Accounting Policies and Estimates

The preparation of our consolidated financial statements in conformity with accounting principles generally accepted in the United States requires that we make estimates and assumptions that affect the reported amounts and disclosure of certain assets and liabilities at our balance sheet date. Such estimates and judgments include the carrying value of property and equipment and intangible assets, revenue recognition, the value of certain liabilities and stock-based compensation. We base our estimates on historical experience and on various other factors that we believe to be appropriate under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in our consolidated financial statements, we believe that the following accounting policies are critical to understanding the judgments and estimates we use in preparing our financial statements:

Revenue Recognition

Our business strategy includes entering into collaborative license and development agreements with biotechnology and pharmaceutical companies for the development and commercialization of our product candidates. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon achievement of clinical development milestones and royalties on product sales. We follow the provisions of the Securities and Exchange Commission s Staff Accounting Bulletin, or SAB, No. 104, *Revenue Recognition*, Emerging Issues Task Force, or EITF, Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*, EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent*, and EITF Issue No. 01-9, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor s Products)*.

License Fees and Multiple Element Arrangements. Non-refundable license fees are recognized as revenue when we have a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured and we have no further performance obligations under

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the license agreement. Multiple element arrangements, such as license and development arrangements are analyzed to determine whether the deliverables, which often include a license and performance obligations such as research and steering committee services, can be separated or whether they must be accounted for as a single unit of accounting in accordance with EITF 00-21. We recognize up-front license payments as revenue upon delivery of the license only if the license has stand-alone value and the fair value of the undelivered performance obligations, typically including research and/or steering committee services, can be determined. If the fair value of the undelivered performance obligations can be determined, such obligations would then be accounted for separately as performed. If the license is considered to either (i) not have stand-alone value or (ii) have standalone value but the fair value of any of the undelivered performance obligations cannot be determined, the arrangement would then be accounted for as a single unit of accounting and the license payments and payments for performance obligations are recognized as revenue over the estimated period of when the performance obligations are performed.

Whenever we determine that an arrangement should be accounted for as a single unit of accounting, we must determine the period over which the performance obligations will be performed and revenue will be recognized. Revenue will be recognized using either a relative performance or straight-line method. We recognize revenue using the relative performance method provided that we can reasonably estimate the level of effort required to complete our performance obligations under an arrangement and such performance obligations are provided on a best-efforts basis. Direct labor hours or full-time equivalents are typically used as the measure of performance. Revenue recognized under the relative performance method would be determined by multiplying the total payments under the contract, excluding royalties and payments contingent upon achievement of substantive milestones, by the ratio of level of effort incurred to date to estimated total level of effort required to complete our performance obligations under the arrangement. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the relative performance method, as of each reporting period.

If we cannot reasonably estimate the level of effort required to complete our performance obligations under an arrangement, the performance obligations are provided on a best-efforts basis and we can reasonably estimate when the performance obligation ceases or becomes inconsequential, then the total payments under the arrangement, excluding royalties and payments contingent upon achievement of substantive milestones, would be recognized as revenue on a straight-line basis over the period we expect to complete our performance obligations. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the straight-line basis, as of the period ending date.

If we cannot reasonably estimate when our performance obligation either ceases or becomes inconsequential and perfunctory, then revenue is deferred until we can reasonably estimate when the performance obligation ceases or becomes inconsequential and perfunctory. Revenue is then recognized over the remaining estimated period of performance.

Significant management judgment is required in determining the level of effort required under an arrangement and the period over which we are expected to complete our performance obligations under an arrangement. In addition, if we are involved in a steering committee as part of a multiple element arrangement that is accounted for as a single unit of accounting, we assess whether our involvement constitutes a performance obligation or a right to participate. Steering committee services that are not inconsequential or perfunctory and that are determined to be performance obligations are combined with other research services or performance obligations required under an arrangement, if any, in determining the level of effort required in an arrangement and the period over which we expect to complete our aggregate performance obligations.

Substantive Milestone Payments. Our collaboration agreements may also contain substantive milestone payments. Substantive milestone payments are considered to be performance bonuses that are recognized upon achievement of the milestone only if all of the following conditions are met:

- the milestone payments are non-refundable;

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achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement;

substantive effort on our part is involved in achieving the milestone;

the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone; and,

a reasonable amount of time passes between the up-front license payment and the first milestone payment as well as between each subsequent milestone payment.

Determination as to whether a payment meets the aforementioned conditions involves management s judgment. If any of these conditions are not met, the resulting payment would not be considered a substantive milestone, and therefore the resulting payment would be considered part of the consideration for the single unit of accounting and be recognized as revenue as such performance obligations are performed under either the relative performance or straight-line methods, as applicable, and in accordance with these policies as described above. In addition, the determination that one such payment was not a substantive milestone could prevent us from concluding that subsequent milestone payments were substantive milestones and, as a result, any additional milestone payments could also be considered part of the consideration for the single unit of accounting and would be recognized as revenue as such performance obligations are performed under either the relative performance or straight-line methods, as applicable.

Reimbursement of Costs. Reimbursement of costs is recognized as revenue provided the provisions of EITF 99-19 are met, the amounts are determinable, and collection of the related receivable is reasonably assured.

Royalty Revenue. Royalty revenue is recognized upon the sale of the related products, provided that the royalty amounts are fixed or determinable, collection of the related receivable is reasonably assured and we have no remaining performance obligations under the arrangement. If royalties are received when we have remaining performance obligations, the royalty payments would be attributed to the services being provided under the arrangement and therefore would be recognized as such performance obligations are performed under either the relative performance or straight line methods, as applicable, and in accordance with these policies as described above. We did not recognize any royalty revenues for the years ended December 31, 2008, 2007 or 2006.

Payments from Curis as a Vendor to a Collaborator as a Customer. For revenue generating arrangements where we, as a vendor, provide consideration to a licensor or collaborator, as a customer, we apply the provisions of EITF 01-9. EITF 01-9 addresses the accounting for revenue arrangements where both the vendor and the customer make cash payments to each other for services and/or products. A payment to a customer is presumed to be a reduction of the selling price unless we receive an identifiable benefit for the payment and we can reasonably estimate the fair value of the benefit received. Payments to a customer that are deemed a reduction of selling price are recorded first as a reduction of revenue, to the extent of both cumulative revenue recorded to-date and of probable future revenues, which include any unamortized deferred revenue balances, under all arrangements with such customer and then as an expense. Payments that are not deemed to be a reduction of selling price would be recorded as an expense.

Deferred Revenue. Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying consolidated balance sheets. Significant judgments are required in the application of revenue recognition guidance. For example, in connection with our existing and former collaboration agreements, we have historically recorded on our balance sheet short- and long-term deferred revenue based on our best estimate of when such revenue would be recognized. Short-term deferred revenue would consist of amounts that are expected to be recognized as revenue, or applied against future co-development costs, within the next fiscal year. Amounts that we expect will not be recognized in the next fiscal year would be classified as long-term deferred revenue. However, this estimate would be based on our operating plan as of the balance sheet date and on our estimated performance periods under the collaboration in

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which we have recorded deferred revenues. If our operating plan or our estimated performance period would change, we could recognize a different amount of deferred revenue over the reporting period. As of December 31, 2008, we had no remaining short- or long-term deferred revenue related to our collaborations.

The estimate of deferred revenue also reflects management s estimate of the periods of our involvement in certain of our collaborations. Our performance obligations under these collaborations have consisted of participation on steering committees and the performance of other research and development services. In certain instances, the timing of satisfying these obligations can be difficult to estimate. Accordingly, our estimates could change. Such changes to estimates would result in a change in revenue recognition amounts. If these estimates and judgments were to change over the course of these agreements, it could affect the timing and amount of revenue that we would recognize and record in future periods.

Stock-based Compensation

Effective January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123(revised 2004), *Share-Based Payment (SFAS 123(R))* which generally requires that such transactions be accounted for using a fair-value-based method.

We have recorded employee stock-based compensation expense of $2,182,000, $3,105,000 and $3,820,000 for the years ended December 31, 2008, 2007 and 2006, respectively. For the options outstanding as of December 31, 2008, we estimate that we will record approximately $1,200,000 to $1,600,000, in stock-based compensation expense under SFAS 123(R) in 2009. We expect that we will issue additional options in 2009 that will increase the amount of stock-based compensation ultimately recognized. The amount of the incremental employee stock-based compensation expense attributable to 2009 employee stock options will depend primarily on the number of stock options issued to employees in 2009, the fair market value of our common stock at the respective grant dates, and the specific terms of the stock options.

The valuation of employee stock options is an inherently subjective process, since market values are generally not available for long-term, non-transferable employee stock options. Accordingly, an option-pricing model is utilized to derive an estimated fair value. In calculating the estimated fair value of our stock options, we used a Black-Scholes pricing model for a majority of our stock awards and, for a small subset of our awards that contained a market condition, a lattice model. Both of these models require the consideration of the following six variables for purposes of estimating fair value:

- the stock option exercise price
- the expected term of the option
- the grant date price of our common stock
- the expected volatility of our common stock
- the expected dividends on our common stock, which we do not anticipate paying for the foreseeable future, and
- the risk free interest rate for the expected option term

Of the variables above, we believe that the selection of an expected term and expected stock price volatility are the most subjective. In accordance with the transition provisions of SFAS 123(R), the grant date estimates of fair value associated with prior awards have not been changed. The specific valuation assumptions that were utilized for purposes of deriving an estimate of fair value at the time that prior awards were issued are as disclosed in our prior annual reports on Form 10-K, as filed with the SEC.

Upon adoption of SFAS 123(R), we were also required to estimate the level of award forfeitures expected to occur, and record compensation expense only for those awards that we ultimately expect will vest. Accordingly, we performed a historical analysis of option awards that were

forfeited prior to vesting, and recorded total stock

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option expense that reflected this estimated forfeiture rate for each of the quarterly periods in 2008, 2007 and 2006. This analysis is re-evaluated quarterly and the forfeiture rate is adjusted as necessary to reflect the actual forfeitures for the reporting period. Ultimately, the actual expense recognized over the vesting period will only be for those shares that vest.

Fair Value Measurements

Effective January 1, 2008, we adopted the provisions of SFAS (SFAS) No. 157, *Fair Value Measurements* for our financial assets and financial liabilities. The adoption of SFAS No. 157 has not had a material impact on our financial position or results of operations. In accordance with Financial Accounting Standards Board Staff Position (FSP) No. 157-2, *Effective Date of FASB Statement No. 157*, we will delay application of SFAS No. 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis, until January 1, 2009. SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115,* (SFAS No. 159) became effective January 1, 2008 and permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. We did not elect to adopt the fair value option for eligible financial instruments under SFAS No. 159.

SFAS No. 157 provides a framework for measuring fair value under U.S. generally accepted accounting principles and requires expanded disclosures regarding fair value measurements. SFAS No. 157 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Market participants are buyers and sellers in the principal market that are (i) independent, (ii) knowledgeable, (iii) able to transact, and (iv) willing to transact.

SFAS No. 157 requires the use of valuation techniques that are consistent with the market approach, the income approach and/or the cost approach. The market approach uses prices and other relevant information generated by market transactions involving identical or comparable assets and liabilities. The income approach uses valuation techniques to convert future amounts, such as cash flows or earnings, to a single present amount on a discounted basis. The cost approach is based on the amount that currently would be required to replace the service capacity of an asset (replacement cost). Valuation techniques should be consistently applied. SFAS No. 157 also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

Level 1	Quoted prices in active markets for identical assets or liabilities.
Level 2	Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
Level 3	Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Our cash equivalents and marketable securities have been classified as Level 1 assets. We do not hold any asset-backed or auction rate securities. Short-term accounts receivable and accounts payable are reflected in the consolidated financial statements at net realizable value, which approximates fair value due to the short-term nature of these instruments. In general, fair value is based upon quoted market prices, where available. While we believe our valuation methodologies are appropriate and consistent with other market participants, the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different estimate of fair value at the reporting date.

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Long-lived Assets

Long-lived assets consist primarily of property and equipment and goodwill. In the ordinary course of our business, we incur costs that at times have been substantial related to property and equipment. Property and equipment is stated at cost and depreciated over the estimated useful lives of the related assets using the straight-line method. Determining the economic lives of property and equipment requires us to make significant judgments that can materially impact our operating results. If it were determined that the carrying value of our other long-lived assets might not be recoverable based upon the existence of one or more indicators of impairment, we would measure an impairment based on application of SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*.

During 2006, we initiated a realignment of our research programs, shifting our focus on later-stage preclinical drug development programs and de-emphasizing our earlier discovery research programs. As a result, in 2006 we recorded an impairment charge of $148,000 related to certain of our equipment that was no longer used in our discovery or other programs. In addition, we revised our estimates of the depreciable lives on the remaining equipment currently being used in our discovery research programs as a result of the conclusion of two of our discovery screening programs in late 2006 and early 2007.

In March 2007, our BMP-7 small molecule screening agreement with Centocor (a Johnson & Johnson subsidiary) concluded in accordance with the terms of the agreement. The BMP-7 small molecule screening program was the only remaining program utilizing the majority of our existing discovery screening equipment. We determined that we would not fund the BMP small molecule program internally. As a result, during the year ended December 31, 2007, we recorded additional property and equipment impairment charges of $352,000, because this discovery equipment could not be used on other ongoing programs.

We assess the impairment of identifiable long-lived assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. In addition, we perform a goodwill impairment test annually. Since January 1, 2002, we have applied the provisions of Statement of Financial Accounting Standards, or SFAS, No. 142, *Goodwill and Other Intangibles*. SFAS No. 142 requires us to perform an impairment assessment annually or whenever events or changes in circumstances indicate that our goodwill may be impaired. We completed our annual goodwill impairment tests in December 2008, 2007 and 2006, and determined that as of those dates our fair value exceeded the carrying value of our net assets. Accordingly, no goodwill impairment was recognized in 2008, 2007 and 2006.

Our discussion of our critical accounting policies is not intended to be a comprehensive discussion of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by generally accepted accounting principles, with no need for management s judgment in their application. There are also areas in which management s judgment in selecting any available alternative would not produce a materially different result.

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Results of Operations

Years Ended December 31, 2008 and 2007

Revenues

Total revenues are summarized as follows:

	For the Year Ended December 31, 2008	2007	Percentage Increase/ (Decrease)
Revenues:			
Research and development contracts			
Genentech	$ 282,000	$ 962,000	(71%)
Wyeth	196,000	1,529,000	(87%)
Procter & Gamble		636,000	(100%)
Centocor		73,000	(100%)
Other	36,000	62,000	(42%)
Subtotal	514,000	3,262,000	(84%)
License fees			
Genentech	6,000,000	11,446,000	(48%)
Wyeth	103,000	439,000	(77%)
Stryker	1,750,000		100%
Procter & Gamble		1,242,000	(100%)
Subtotal	7,853,000	13,127,000	(40%)
Total Revenues	$ 8,367,000	$ 16,389,000	(49%)

Total revenues decreased by $8,022,000, or 49%, to $8,367,000 for the year ended December 31, 2008 from $16,389,000 for the prior year. Research and development contracts decreased by $2,748,000 because all research funding for programs under collaboration concluded at various times beginning in March 2007, and we currently receive no research funding for our programs under past or current collaborations. We expect that our future research and development contract revenues will be limited to expenses that we incur on behalf of our collaborator, Genentech, for which Genentech is obligated to reimburse us.

In addition, our license revenues decreased by $5,274,000, or 40%, to $7,853,000 for the year ended December 31, 2008 from $13,127,000 for the prior year. The decrease is primarily due to the recognition of $7,509,000 revenue under our June 2003 Hedgehog pathway inhibitor collaboration with Genentech during 2007 resulting from changed facts and circumstances related to our joint steering committee performance obligations. This amount had been previously deferred indefinitely. In addition, we recorded $3,000,000 in license fee revenues received from Genentech as a contingent cash payment during the year ended December 31, 2007, and we recorded $6,000,000 in license fee revenues received from Genentech related to contingent cash payments received during the year ended December 31, 2008. License revenues recognized under our collaborations with Procter & Gamble and Wyeth decreased $1,242,000 and $336,000, respectively, as a result of the conclusion of these collaborations. These decreases were offset by $1,750,000 in license revenue recognized for the sale and assignment of our remaining BMP assets to Stryker Corporation during the year ended December 31, 2008.

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Operating Expenses

Research and development expenses are summarized as follows:

Research and Development Program	Primary Indication	Collaborator	For the Year Ended December 31, 2008	2007	Percentage Increase/ (Decrease)
Hedgehog pathway inhibitor	Cancer	Genentech	$ 457,000	$ 245,000	87%
CUDC-101 (HDAC, EGFR, Her2 inhibitor)	Cancer	Internal	4,002,000	5,056,000	(21%)
CUDC-305 (Hsp90 inhibitor)	Cancer	Internal	2,693,000		100%
Other targeted cancer programs	Cancer	Internal	4,402,000	4,893,000	(10%)
Other targeted programs	Nervous system disorders/ cardiovascular disease	Internal	416,000		100%
Hedgehog small molecule agonist or protein	Nervous system disorders/ cardiovascular disease	Wyeth	199,000	1,593,000	(88%)
Wnt signaling pathway	Cancer	Genentech		638,000	(100%)
Hedgehog small molecule agonist	Hair loss	Procter & Gamble		23,000	(100%)
Discovery research	Various	Various/internal	123,000	1,265,000	(90%)
Net impairment of assets	N/A		191,000	263,000	(27%)
Stock-based compensation	N/A		743,000	803,000	(7%)
Total research and development expense			$ 13,226,000	$ 14,779,000	(11%)

Our research and development expenses decreased by $1,553,000, or 11%, to $13,226,000 for the year ended December 31, 2008, as compared to $14,779,000 for the prior year period. This decrease was due to decreased spending on programs under collaborations offset by increased spending on our targeted programs, specifically CUDC-305, which was selected as a development candidate in July 2008. Spending on our collaborator-funded programs with (i) Genentech for the Wnt signaling pathway; (ii) Wyeth for the Hedgehog agonist; and (iii) Centocor for BMP-7 small molecule agonists decreased by an aggregate amount of $2,472,000 as a result of the conclusion of the research funding for each of these programs at various times between March 2007 and February 2008. Certain of these resources were reallocated across our internal targeted cancer programs. Our lead targeted drug development candidate, CUDC-101, which was selected for clinical development in March 2007 and for which we initiated a phase I clinical trial in August 2008, accounted for a decrease in spending of $1,054,000. Offsetting these decreases, spending on our second development candidate, CUDC-305, accounted for an increase in spending of $2,693,000. We expect that our targeted cancer programs will consist of a majority of our ongoing future research and development expenses for the foreseeable future.

During the year ended December 31, 2008, we also incurred expenses of $457,000, an increase of $212,000 over the same prior year period, related to $300,000 in sublicense payments we were required to make under our Hedgehog pathway inhibitor program as a result of the $6,000,000 in contingent payments received from Genentech for the achievement of clinical development objectives during 2008. During 2007, we incurred sublicense payments of $150,000 related to this program. We expect that future research and development expenses related to our Hedgehog pathway inhibitor program will be nominal.

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General and administrative expenses are summarized as follows:

	For the Year Ended December 31,		Percentage Increase/ (Decrease)
	2008	2007	
Personnel	$ 2,298,000	$ 2,697,000	(15%)
Occupancy and depreciation	376,000	138,000	172%
Legal services	1,672,000	2,220,000	(25%)
Consulting and professional services	1,177,000	1,122,000	5%
Insurance costs	352,000	443,000	(21%)
Other general and administrative expenses	922,000	977,000	(6%)
Stock-based compensation	1,463,000	2,387,000	(39%)
Total general and administrative expenses	$ 8,260,000	$ 9,984,000	(17%)

General and administrative expenses decreased $1,724,000, or 17%, for the year ended December 31, 2008 as compared to 2007 as a result of expense reductions in most cost categories, offset by increases in spending for occupancy-related expenses. Stock-based compensation decreased $924,000 for the year ended December 31, 2008 as a result of the grant of stock options for a smaller number of shares, and related expense, awarded during 2008 compared to the prior year period. In addition, legal services decreased $548,000, primarily due to costs associated with foreign patent applications in the prior year period, and employee costs decreased $399,000. For the year ended December 31, 2007, employee costs related to bonuses and 401(k) matching contribution costs were $260,000. We did not incur such costs during 2008 due to spending reductions taken in an effort to conserve cash. In furtherance of these efforts, our executive officers reduced their respective salaries in October 2008 in exchange for stock options and restricted stock.

Offsetting these decreases, occupancy and depreciation costs increased $238,000 as a result of proceeds received under a settlement agreement entered into with a former subtenant that had defaulted on a sublease of our 61 Moulton Street facility during the year ended December 31, 2007.

Other Income (Expense)

For the year ended December 31, 2008, interest income was $990,000 as compared to $1,609,000 for the year ended December 31, 2007, a decrease of $619,000, or 38%. The decrease in interest income resulted primarily from lower average cash and investment balances as well as lower interest rates for the year ended December 31, 2008 as compared to the year ended December 31, 2007.

For the year ended December 31, 2008, other income was $10,000 as compared to other expense of $114,000 for the year ended December 31, 2007, an increase of $124,000, or 109%. During the year ended December 31, 2007, we wrote down the carrying value of our investment in ES Cell International equity securities, recognizing a charge of $145,000.

For the year ended December 31, 2008, interest expense was $4,000, as compared to $85,000 for the year ended December 31, 2007, a decrease of $81,000, or 95%. The decrease resulted from lower outstanding debt obligations during the year ended December 31, 2008 under our notes with the Boston Private Bank & Trust Company which were fully repaid in April 2008.

Net Loss Applicable to Common Stockholders

As a result of the foregoing, we incurred a net loss applicable to common stockholders of $12,123,000 for the year ended December 31, 2008, as compared to $6,964,000 for the year ended December 31, 2007.

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Years Ended December 31, 2007 and 2006

Revenues

Total revenues are summarized as follows:

	For the Year Ended December 31,		Percentage Increase/ (Decrease)
	2007	2006	
Revenues:			
Research and development contracts			
Genentech	$ 962,000	$ 4,758,000	(80%)
Wyeth	1,529,000	2,299,000	(33%)
Procter & Gamble	636,000	663,000	(4%)
Centocor	73,000	400,000	(82%)
Spinal Muscular Atrophy Foundation		1,191,000	(100%)
Other	62,000	28,000	121%
Subtotal	3,262,000	9,339,000	(65%)
License fees			
Genentech	11,446,000	1,500,000	663%
Wyeth	439,000	306,000	43%
Procter & Gamble	1,242,000	234,000	431%
Micromet		2,284,000	(100%)
Subtotal	13,127,000	4,324,000	204%
Substantive milestones		3,000,000	(100%)
Gross Revenues	16,389,000	16,663,000	(2%)
Contra-revenues from co-development with Genentech		(1,728,000)	(100%)
Net Revenue	$ 16,389,000	$ 14,935,000	10%

Gross revenues decreased by $274,000, or 2%, to $16,389,000 for the year ended December 31, 2007 from $16,663,000 for the prior year. The net decrease was due to decreases in research funding and substantive milestone revenues offset by an increase in license revenues. The decrease in research and development contracts of $6,077,000 was the result of the conclusion of research funding in the fourth quarter of 2006 and first quarter of 2007 under four collaborations, including the conclusion of the research funding portion of our Hedgehog pathway inhibitor and Wnt collaborations with Genentech, a sponsored research agreement with the SMA Foundation and a screening agreement with Centocor. The termination of research funding under these arrangements accounted for $5,314,000 of the decrease in research and development contract revenues. In addition, during the first quarter of 2007 Wyeth decreased from eight to five the number of our researchers supported by Wyeth under our Hedgehog agonist program.

License revenues increased $8,803,000, or 204%, for the year ended December 31, 2007 as compared to the prior year, primarily due to the recognition of $10,509,000 in revenue under our June 2003 Hedgehog pathway inhibitor collaboration with Genentech. Prior to the fourth quarter of 2007, we could not estimate the performance period related to our ongoing joint steering committee obligation under this collaboration and therefore deferred $7,509,000 in payments that we had received from Genentech in prior years. During the fourth quarter of 2007, as a result of changed facts and circumstances, we concluded that our joint steering committee performance obligation had become inconsequential and perfunctory to the agreement. Accordingly, during the fourth quarter of 2007 we recorded as licensing revenues the $7,509,000 in previously deferred revenues as well as $3,000,000 from a contingent cash payment that we received in October 2007. In addition, we accelerated recognition of license fee revenue related to our September 2005 collaboration with Procter & Gamble, since

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Procter & Gamble terminated this collaboration effective November 2007. This termination resulted in a decrease in our estimated performance period under this collaboration, resulting in additional revenue of $1,008,000 for the year ended December 31, 2007 as compared to the year ended December 31, 2006.

The increase in license fee revenues under our June 2003 Hedgehog pathway inhibitor collaboration with Genentech and our September 2005 collaboration with Procter & Gamble were partially offset by decreases in license fee revenues for two of our other research programs. We recorded $937,500 in license revenue during 2007 under our April 2005 Wnt collaboration with Genentech, as compared to $1,500,000 for the prior year period. In addition, during the year ended December 31, 2006, we recognized $2,284,000 in license fee revenue as part of a settlement agreement with a former collaborator, Micromet. We did not record any license fee revenue under this agreement in 2007.

We also recorded $3,000,000 in substantive milestone revenue during the year ended December 31, 2006 under our June 2003 collaboration with Genentech. In addition, we did not record contra-revenues for the year ended December 31, 2007 compared to contra-revenues of $1,728,000 for the year ended December 31, 2006. On August 31, 2006, we ceased our participation in a co-development arrangement with Genentech of a basal cell carcinoma drug candidate pursuant to which we had been recording contra-revenues.

Operating Expenses

Research and development expenses are summarized as follows:

Research and Development Program	Primary Indication	Collaborator	For the Year Ended December 31, 2007	2006	Percentage Increase/ (Decrease)
Hh pathway inhibitor	Cancer	Genentech	$ 245,000	$ 1,695,000	(86%)
CUDC-101 (HDAC, EGFR, Her2 inhibitor)	Cancer	Internal	5,056,000		100%
Single and multi-target inhibitors	Cancer	Internal	4,893,000	2,124,000	130%
Hh small molecule agonist or protein	Nervous system disorders/ cardiovascular disease	Wyeth	1,593,000	2,409,000	(34%)
Wnt signaling pathway	Cancer	Genentech	638,000	2,763,000	(77%)
Hh small molecule agonist	Hair loss	Procter & Gamble	23,000	835,000	(97%)
Discovery research	Various	Various/internal	1,265,000	3,511,000	(64%)
Net impairment of assets	N/A		263,000	148,000	78%
Stock-based compensation	N/A		803,000	1,105,000	(27%)
Total research and development expense			$ 14,779,000	$ 14,590,000	1%

Our research and development expenses increased by $189,000, or 1%, to $14,779,000 for the year ended December 31, 2007 as compared to $14,590,000 for the prior year period. This is due to the result of several offsetting variances within our various programs. We increased spending by $7,825,000 for the internal development of our targeted cancer drug development programs, including CUDC-101, as we shifted spending from several previously funded programs that have concluded. These previously funded programs decreased by $6,633,000 from the prior year period and included (i) the conclusion in the fourth quarter of 2006 and first quarter of 2007 of the research funding under our ongoing Hedgehog pathway inhibitor and our Wnt signaling pathway collaborations with Genentech, (ii) the termination by Procter & Gamble of a September 2005 Hedgehog agonist collaboration agreement for hair loss, and (iii) the conclusion of a sponsored research agreement with the SMA Foundation and a BMP-7 small molecule screening agreement with Centocor, both to conduct discovery research activities.

Spending on our collaborator-funded program with Wyeth decreased $816,000 as a result of fewer researchers supporting the respective program. Funding on this program concluded in February 2008 in accordance with the terms of the agreement.

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Stock-based compensation expense also decreased $302,000 as a result of a decline in the grant date fair value of stock options issued in 2007 as compared to 2006, which resulted in lower compensation expense.

As the research funding concluded on programs under collaboration and as we shifted our research focus, we reallocated certain of these resources to our internal targeted cancer drug development programs, including CUDC-101, which we initiated in the first half of 2006. These programs accounted for $9,949,000, or 67%, of our 2007 research and development expense compared to $2,124,000 for the same prior year period, an increase of $7,825,000.

General and administrative expenses are summarized as follows:

	For the Year Ended December 31,		Percentage Increase/ (Decrease)
	2007	2006	
Personnel	$ 2,697,000	$ 2,758,000	(2%)
Occupancy and depreciation	138,000	678,000	(80%)
Legal services	2,220,000	1,558,000	42%
Consulting and professional services	1,122,000	1,450,000	(23%)
Insurance costs	443,000	451,000	(2%)
Other general and administrative expenses	977,000	822,000	19%
Stock-based compensation	2,387,000	2,657,000	(10%)
Total general and administrative expenses	$ 9,984,000	$ 10,374,000	(4%)

General and administrative expenses decreased $390,000, or 4%, for the year ended December 31, 2007 as compared to 2006 as a result of expense reductions in most cost categories, offset by increases in spending for legal services and other administrative expenses. These decreases included our receipt in 2007 of $262,000 in proceeds under an April 2007 settlement agreement entered into with a former subtenant that had defaulted on a sublease of our 61 Moulton Street facility. We recorded $212,000 of this amount as a reduction of expense. In addition, our lease on our 61 Moulton Street facility concluded on April 30, 2007, which reduced our overall occupancy costs. Professional and consulting services decreased $328,000 as a result of expenses incurred for the restatement of our prior financial statements during the first quarter of 2006 and costs incurred during 2006 associated with the formation of our Chinese subsidiary, including technology evaluations and review of business development opportunities in China. In addition, personnel costs and stock-based compensation decreased $61,000 and $270,000, respectively. Stock-based compensation expense decreased as a result of a decline in the grant date fair value of stock options issued in 2007 as compared to 2006, which resulted in lower compensation expense.

Offsetting these decreases, legal services increased $662,000 as a result of increased spending related to our patent portfolio, including filings related to CUDC-101, other programs under our targeted cancer drug development platform and foreign patent applications. Other general and administrative costs are comprised of travel costs, temporary help, and computer and office supplies. These costs increased $155,000 primarily due to increased travel costs and higher NASDAQ filing fees resulting from our August 2007 private placement.

Other Income (Expense)

For the year ended December 31, 2007, interest income was $1,609,000 as compared to $1,577,000 for the year ended December 31, 2006, an increase of $32,000, or 2%. The increase in interest income resulted primarily from higher interest rates for the year ended December 31, 2007 as compared to the year ended December 31, 2006.

For the year ended December 31, 2007, other expense was $114,000 as compared to $155,000 for the year ended December 31, 2006, a decrease of $41,000, or 26%. During the year ended December 31, 2007, we wrote

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down the carrying value of our investment in ES Cell International equity securities, recognizing a charge of $145,000 compared to a charge of $164,000 from the write down of the carrying value of our investment in Aegera equity securities during the year ended December 31, 2006.

For the year ended December 31, 2007, interest expense was $85,000, as compared to $196,000 for the year ended December 31, 2006, a decrease of $111,000, or 57%. The decrease resulted from lower outstanding debt obligations during the year ended December 31, 2007 under our notes with the Boston Private Bank & Trust Company.

Net Loss Applicable to Common Stockholders

As a result of the foregoing, we incurred a net loss applicable to common stockholders of $6,964,000 for the year ended December 31, 2007, as compared to $8,829,000 for the year ended December 31, 2006.

Liquidity and Capital Resources

We have financed our operations primarily through license fees, contingent cash payments and research and development funding from our collaborators and licensors, the private and public placement of our equity securities, debt financings and the monetization of certain royalty rights.

At December 31, 2008, our principal sources of liquidity consisted of cash, cash equivalents, and marketable securities of $28,853,000, excluding restricted long-term investments of $210,000. Our cash and cash equivalents are highly liquid investments with a maturity of three months or less at date of purchase and consist of time deposits and investments in money market funds with commercial banks and financial institutions, short-term commercial paper, and government obligations. We maintain cash balances with financial institutions in excess of insured limits. While as of the date of this filing, we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents or marketable securities since December 31, 2008, no assurance can be given that further deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or marketable securities or our ability to meet our financing objectives. Further dislocations in the credit market may adversely impact the value and/or liquidity of marketable securities owned by us.

The use of our cash flows for operations has primarily consisted of salaries and wages for our employees, facility and facility-related costs for our office and laboratory, fees paid in connection with preclinical studies, laboratory supplies, consulting fees and legal fees. During the third quarter of 2008, we began incurring clinical costs associated with our phase I trial of CUDC-101. We expect that costs associated with clinical studies will increase in future periods assuming that CUDC-101 advances into further stages of clinical testing and other of our targeted cancer drug candidates reach clinical trials.

To date, the primary source of our cash flows from operations has been payments received from our collaborators and licensors. As a result of the conclusion of all research funding, the majority of our research and development effort and expense has shifted from our programs that were funded under collaborations relating to the Hedgehog pathway and various discovery and preclinical programs to the development of our targeted cancer programs, particularly for our lead targeted cancer drug candidate, CUDC-101, and CUDC-305, which we selected as a development candidate in July 2008 and is currently being evaluated in IND-enabling studies.

While we are seeking a corporate collaborator for one or more of our targeted cancer programs, we are currently progressing the research and development of these programs on our own. We believe that our research and development expenses will increase in future years in connection with our plans to continue phase I clinical testing for CUDC-101 and to progress CUDC-305 in preclinical testing toward an anticipated IND filing in mid-2009. We are actively seeking collaborators for our targeted cancer drug candidates, particularly CUDC-305, but have not reached advanced stages of negotiation with any party. Our intention is to enter into a license

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or collaboration agreement with CUDC-305 prior to initiation of phase I clinical testing. If we are unable to consummate such a transaction, we would consider our further development options for CUDC-305. Our ability to progress CUDC-305 would depend on a number of factors including, our future cash position and the overall financial markets, and phase I data generated by CUDC-101, among others.

In general, our only source of cash flows from operations for the foreseeable future will be up-front license payments and funded research and development that we may receive under new collaboration agreements, if any, contingent cash payments for the achievement of development objectives, if any are met, under new collaborations or our existing collaborations with Genentech and royalty payments that are contingent upon the successful commercialization of any products based upon collaborations. The timing of or entrance into any new collaboration agreements and any contingent cash payments under our existing collaboration agreements with Genentech are not assured, cannot be easily predicted and may vary significantly from quarter to quarter.

Net cash used in operating activities was $12,441,000 for the year ended December 31, 2008, compared to $8,594,000 for the year ended December 31, 2007. Cash used in operating activities during the year ended December 31, 2008 was primarily the result of our net loss for the period of $12,123,000. In addition, changes in certain operating assets and liabilities affected operating cash during the year ended December 31, 2008, including a decrease in deferred revenue of $1,853,000 as a result of the recognition of the $1,750,000 license fee that we received in December 2007 under our BMP transaction with Stryker Corporation and a decrease of $1,961,000 in our accounts payable and accrued liabilities. Offsetting these decreases were noncash items stock-based compensation expense of $2,206,000 and depreciation of $999,000.

Cash used in operating activities during the years ended December 31, 2007 was primarily the result of our net loss for the period of $6,964,000. In addition, changes in certain operating assets and liabilities offset these increases in operating cash during year ended December 31, 2007. Specifically, our deferred revenue decreased $9,034,000 as a result of accelerated license fee amortization under our Genentech and Procter & Gamble collaborations. Offsetting this decrease, our accounts receivables decreased $1,112,000 primarily related to our Microment settlement, and our accounts payable and accrued liabilities increased $1,201,000. Finally, several noncash items further offset our net loss, including stock-based compensation expense of $3,190,000, depreciation of $1,302,000 and impairment of assets of $497,000.

We expect to continue to use cash in operations as we continue to seek to advance our targeted cancer drug programs through preclinical testing and into clinical development. In addition, in the future we may owe royalties and other contingent payments to our licensors based on the achievement of developmental milestones, product sales and other specified objectives.

Investing activities provided cash of $5,316,000 for the year ended December 31, 2008, resulting from $5,376,000 in net investment sales to fund ongoing operations. Investing activities used $5,919,000 of cash for the year ended December 31, 2007, resulting from $6,160,000 in net investment purchases primarily related to investment of funds received from our August 2007 private placement. In addition, for the year ended December 31, 2007, we received $316,000 in net proceeds from the sale of certain of our assets used to pay down our outstanding principal obligations to the Boston Private Bank & Trust Company. We currently do not expect to undertake any significant capital projects during 2009.

Financing activities used cash of approximately $112,000 for the year ended December 31, 2008, resulting from repayment of $401,000 on our notes with the Boston Private Bank & Trust Company, which were canceled in April 2008. This decrease in cash was offset by cash received of $289,000 upon the exercise of stock options and purchases under our employee stock purchase plan. Financing activities provided cash of $13,080,000 for the year ended December 31, 2007, resulting primarily from $14,646,000 received in issuances of common stock, including net proceeds of $14,422,000 from our August 2007 private placement of common stock and $224,000 received upon the exercise of stock options and purchases under our employee stock purchase plan. Offsetting these increases in cash, we repaid $1,565,000 of our term debt with the Boston Private Bank & Trust Company.

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Contractual Obligations

As of December 31, 2008, we had future payments required under contractual obligations and other commitments, including an operating lease related to our facility, research services agreements, consulting agreements, and license agreements, as follows:

	Payment Due By Period (amounts in 000 s)				
	Total	Less than One Year	One to Three Years	Three to Five Years	More than Five Years
Operating lease obligations	$ 1,896	$ 948	$ 948	$	$
Outside service obligations(1)	1,475	1,470	5		
Licensing obligations(2)	230	230			
Total future obligations	$ 3,601	$ 2,648	$ 953	$	$

(1) Outside service obligations consist of agreements we have with outside labs, consultants and various other service organizations.

(2) In the future, we may owe royalties and other contingent payments to our licensees based on the achievement of developmental milestones, product sales and specified other objectives. These potential future obligations are not included in the above table.

We anticipate that existing capital resources at December 31, 2008, together with the $6,000,000 we will receive from Genentech in the first quarter of 2009, should enable us to maintain current and planned operations into mid-2010. We expect to incur substantial additional research and development and other costs, including costs related to preclinical studies and clinical trials, for the foreseeable future. Our ability to continue funding planned operations beyond mid-2010 is dependent upon, among other things, the success of our collaborations, our ability to control our cash burn rate and our ability to raise additional funds through additional corporate collaborations, equity or debt financings, or from other sources of financing. We are seeking additional collaborative arrangements and also anticipate that we will seek to raise funds through one or more financing transactions, if conditions permit. Due to our significant long-term capital requirements, we intend to seek to raise funds through the sale of debt or equity securities when conditions are favorable, even if we do not have an immediate need for additional capital at such time. Our general business strategy may be adversely affected by the recent economic downturn and volatile business environment and continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate further, or do not improve, it may make any necessary debt or equity financing more difficult or impossible, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which would directly affect our ability to attain our operating goals on schedule and on budget. See Part I, Item 1A Risk Factors, for a further discussion of certain risks and uncertainties that could affect our liquidity, capital requirements and ability to raise additional capital.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of December 31, 2008.

Inflation

We believe that inflation has not had a significant impact on our revenue and results of operations since inception.

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New Accounting Pronouncements

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations* (SFAS No. 141(R)). SFAS No. 141(R) establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any noncontrolling interest in the acquiree and the goodwill acquired. SFAS No. 141(R) also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. SFAS No. 141(R) is effective for fiscal years beginning after December 15, 2008. SFAS No. 141(R) will have an impact on our financial statements if we are involved in a business combination that occurs after January 1, 2009.

In December 2007, the EITF issued Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF Issue No. 07-1). This Issue is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, and shall be applied retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date that include a joint operating activity (i.e., co-development) and that are operated as a virtual joint venture. This Issue includes enhanced disclosure requirements regarding the nature and purpose of the arrangement, rights and obligations under the arrangement, accounting policy, amount and income statement classification of collaboration transactions between the parties. This Issue also requires that transactions with third parties (i.e., parties that do not participate in the collaborative arrangement) should be reported in the appropriate line item in each company s financial statement pursuant to the guidance in EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*. We have historically entered into collaborative arrangements in which this Issue would be applicable; however, we do not expect the adoption of EITF 07-1 to have a material impact on our consolidated financial statements as it relates to joint operating activities under current collaborations. Management will have to evaluate the impact of this Issue on future collaborations that we may enter into.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our current cash balances in excess of operating requirements are invested in cash equivalents and short-term marketable securities, which consist of time deposits and investments in money market funds with commercial banks and financial institutions, short-term commercial paper, and government obligations with an average maturity of less than one year. All marketable securities are considered available for sale. The primary objective of our cash investment activities is to preserve principal while at the same time maximizing the income we receive from our invested cash without significantly increasing risk of loss. This objective may be adversely affected by the recent economic downturn and volatile business environment and continued unpredictable and unstable market conditions. Our marketable securities are subject to interest rate risk and will fall in value if market interest rates increase. While as of the date of this filing, we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents or marketable securities since December 31, 2008, no assurance can be given that further deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or marketable securities or our ability to meet our financing objectives. Further dislocations in the credit market may adversely impact the value and/or liquidity of marketable securities owned by us. Our investments are investment grade securities, and deposits are with investment grade financial institutions. We believe that the realization of losses due to changes in credit spreads is unlikely as we currently have the ability to hold our investments for a sufficient period of time to recover the fair value of the investment and there is sufficient evidence to indicate that the fair value of the investment is recoverable. We do not use derivative financial instruments in our investment portfolio. We do not believe that a 10% change in interest rate percentages would have a material impact on the fair value of our investment portfolio or our interest income.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Management s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934, as amended, as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of management and our directors; and

- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of evaluations of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2008. In making this assessment our management used the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO.

Based on our assessment, management concluded that, as of December 31, 2008, our internal control over financial reporting is effective based on the criteria established in *Internal Control Integrated Framework* issued by COSO.

The effectiveness of internal control over financial reporting as of December 31, 2008 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Curis, Inc.:

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations and comprehensive loss, of stockholders equity and of cash flows, present fairly, in all material respects, the financial position of Curis, Inc. and its subsidiaries at December 31, 2008 and 2007, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2008 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company s management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management s Report on Internal Control Over Financial Reporting. Our responsibility is to express opinions on these financial statements and on the Company s internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts

February 26, 2009

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CURIS, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

	December 31, 2008	December 31, 2007
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 10,158,795	$ 17,396,599
Marketable securities	18,694,200	24,062,577
Accounts receivable	107,341	230,467
Prepaid expenses and other current assets	373,373	349,453
Total current assets	29,333,709	42,039,096
Property and equipment, net	1,448,176	2,577,602
Long-term investment restricted	210,007	210,007
Goodwill	8,982,000	8,982,000
Other assets	7,980	7,980
	$ 39,981,872	$ 53,816,685
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Debt, current portion	$	$ 403,832
Accounts payable	1,961,439	3,222,091
Accrued liabilities	624,462	1,150,931
Deferred revenue, current portion		1,852,518
Total current liabilities	2,585,901	6,629,372
Other long-term liabilities	171,375	342,750
Total liabilities	2,757,276	6,972,122
Commitments (Notes 8 and 9)		
Stockholders Equity:		
Common stock, $0.01 par value 125,000,000 shares authorized; 64,701,405 and 63,653,698 shares issued and outstanding, respectively, at December 31, 2008 and 64,288,793 and 63,241,086 shares issued and outstanding, respectively, at December 31, 2007	647,014	642,888
Additional paid-in capital	745,360,736	742,903,399
Treasury stock (at cost, 1,047,707 shares)	(891,274)	(891,274)
Deferred compensation	(12,550)	(46,286)
Accumulated deficit	(707,970,836)	(695,847,738)
Accumulated other comprehensive income	91,506	83,574
Total stockholders equity	37,224,596	46,844,563
	$ 39,981,872	$ 53,816,685

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

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CURIS, INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Loss

	Years Ended December 31,		
	2008	2007	2006
Revenues:			
Research and development contracts	$ 514,099	$ 3,261,643	$ 9,339,191
License fees	7,852,518	13,126,911	4,324,173
Substantive milestones			3,000,000
Gross revenues	8,366,617	16,388,554	16,663,364
Contra-revenues from co-development with Genentech			(1,727,727)
Net revenues	8,366,617	16,388,554	14,935,637
Costs and Expenses:			
Research and development	13,226,449	14,779,184	14,589,647
General and administrative	8,259,812	9,983,931	10,373,883
Amortization related to intangible assets			27,050
Total costs and expenses	21,486,261	24,763,115	24,990,580
Loss from operations	(13,119,644)	(8,374,561)	(10,054,943)
Other Income (Expense):			
Interest income	990,263	1,608,805	1,576,949
Other income (expense)	10,137	(113,644)	(155,124)
Interest expense	(3,854)	(84,843)	(196,204)
Total other income	996,546	1,410,318	1,225,621
Net loss applicable to common stockholders	$ (12,123,098)	$ (6,964,243)	$ (8,829,322)
Net Loss per Common Share (Basic and Diluted)	$ (0.19)	$ (0.13)	$ (0.18)
Weighted Average Common Shares (Basic and Diluted)	63,378,159	54,914,666	49,066,680
Net Loss	$ (12,123,098)	$ (6,964,243)	$ (8,829,322)
Unrealized Gain on Marketable Securities	7,932	75,780	47,196
Comprehensive loss	$ (12,115,166)	$ (6,888,463)	$ (8,782,126)

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

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CURIS, INC. AND SUBSIDIARIES

Consolidated Statements of Stockholders Equity

	Common Stock							
	Shares	Amount	Additional Paid-in Capital	Treasury Stock	Deferred Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders Equity
Balance, December 31, 2005	49,374,345	$ 493,743	$ 718,732,982	$ (891,274)	$ (242,297)	$ (680,054,173)	$ (39,402)	$ 37,999,579
Issuance of common stock in connection with conversion of note payable to Becton Dickinson (Note 8)	669,656	6,697	2,598,583					2,605,280
Other issuances of common stock	337,560	3,376	309,015					312,391
Issuance of stock options to non-employees for services			61,320					61,320
Recognition of employee stock-based compensation under SFAS 123(R)			3,814,516					3,814,516
Mark-to-market on stock options to non-employees			(244,728)		244,728			
Amortization of deferred compensation					(113,821)			(113,821)
Unrealized gain on marketable securities							47,196	47,196
Net loss						(8,829,322)		(8,829,322)
Balance, December 31, 2006	50,381,561	503,816	725,271,688	(891,274)	(111,390)	(688,883,495)	7,794	35,897,139
Issuance of common stock and warrants, net of issuance costs of $78,000	13,631,022	136,310	14,285,472					14,421,782
Other issuances of common stock	270,210	2,702	221,048					223,750
Issuance of stock to non-employees for services	6,000	60						60
Recognition of employee stock-based compensation under SFAS 123(R)			3,110,071					3,110,071
Mark-to-market on stock options to non-employees			15,120		(15,120)			
Amortization of deferred compensation					80,224			80,224
Unrealized gain on marketable securities							75,780	75,780
Net loss						(6,964,243)		(6,964,243)
Balance, December 31, 2007	64,288,793	642,888	742,903,399	(891,274)	(46,286)	(695,847,738)	83,574	46,844,563
Issuances of common stock	412,612	4,126	284,601					288,727
Recognition of employee stock-based compensation under SFAS 123(R)			2,182,100					2,182,100
Mark-to-market on stock options to non-employees			(9,364)		9,364			
Amortization of deferred compensation					24,372			24,372
Unrealized gain on marketable securities							7,932	7,932
Net loss						(12,123,098)		(12,123,098)
Balance, December 31, 2008	64,701,405	$ 647,014	$ 745,360,736	$ (891,274)	$ (12,550)	$ (707,970,836)	$ 91,506	$ 37,224,596

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

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CURIS, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

	Years Ended December 31,		
	2008	**2007**	**2006**
Cash Flows from Operating Activities:			
Net loss	$ (12,123,098)	$ (6,964,243)	$ (8,829,322)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	998,596	1,302,102	1,407,620
Stock-based compensation expense	2,206,472	3,190,295	3,762,015
Reserve on loss of subtenant income			98,000
Amortization of intangible assets			27,050
Impairment on property and equipment	191,376	352,009	147,531
Gain on sale of assets		(87,761)	
Impairment of investment		145,000	164,020
Unrealized foreign currency exchange gain		(26,935)	(40,280)
Changes in operating assets and liabilities:			
Accounts receivable	123,126	1,111,880	(272,621)
Prepaid expenses and other assets	(23,920)	216,953	266,327
Accounts payable and accrued and other liabilities	(1,961,115)	1,200,778	(1,603,100)
Deferred revenue	(1,852,518)	(9,034,315)	(1,106,851)
Total adjustments	(317,983)	(1,629,994)	2,849,711
Net cash used in operating activities	(12,441,081)	(8,594,237)	(5,979,611)
Cash Flows from Investing Activities:			
Purchase of marketable securities	(35,377,459)	(37,558,691)	(47,076,284)
Sale of marketable securities	40,753,768	31,398,569	51,195,829
Increase in restricted cash/restricted long-term investments		(8,163)	(5,846)
Expenditures for property and equipment	(60,546)	(66,469)	(694,111)
Net proceeds from sale of assets		316,121	
Net cash provided by (used in) investing activities	5,315,763	(5,918,633)	3,419,588
Cash Flows from Financing Activities:			
Proceeds from issuance of common stock, net of issuance costs		14,421,782	
Proceeds from other issuances of common stock	288,727	223,810	312,391
Repayments of notes payable and capital leases	(401,213)	(1,565,455)	(1,233,334)
Net cash provided by (used in) financing activities	(112,486)	13,080,137	(920,943)
Net decrease in Cash and Cash Equivalents	(7,237,804)	(1,432,733)	(3,480,966)
Cash and Cash Equivalents, beginning of period	17,396,599	18,829,332	22,310,298
Cash and Cash Equivalents, end of period	$ 10,158,795	$ 17,396,599	$ 18,829,332
Supplemental cash flow data			
Cash paid during the year for:			
Interest	$ 6,365	$ 95,080	$ 209,086
Supplemental Disclosure of Noncash Investing and Financing Activities:			

Issuance of common stock in connection with conversion of note payable to Becton Dickinson (Note 8)	$	$	$ 2,605,280

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

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CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

(1) OPERATIONS

Curis, Inc. (the Company or Curis) is a drug discovery and development company that is committed to leveraging its innovative signaling pathway drug technologies in seeking to develop next generation targeted cancer therapies. In expanding the Company s drug development efforts with respect to these targeted cancer programs, Curis is building upon its past experiences in targeting signaling pathways, including the Hedgehog pathway. Curis seeks to conduct research programs both internally and through strategic collaborations.

The Company operates in a single reportable segment, which is the research and development of innovative cancer therapeutics. The Company expects that any successful products would be used in the health care industry and would be regulated in the United States by the U.S. Food and Drug Administration, or FDA, and in overseas markets by similar regulatory agencies.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, development by its competitors of new or better technological innovations, dependence on key personnel, its ability to protect proprietary technology, its ability to successfully advance discovery and preclinical stage drug candidates in its internally funded programs, unproven technologies and drug development approaches, reliance on corporate collaborators and licensors to successfully research, develop and commercialize products based on the Company s technologies, its ability to comply with FDA government regulations and approval requirements as well as its ability to execute on its business strategies and obtain adequate financing to fund its operations through corporate collaborations, sales of equity or otherwise.

The Company s future operating results will largely depend on the magnitude of payments from its current and potential future corporate collaborators and the progress of drug candidates currently in its research and development pipeline. The results of the Company s operations will vary significantly from year to year and quarter to quarter and depend on, among other factors, the timing of its entry into new collaborations, if any, the timing of the receipt of payments from new or existing collaborators and the cost and outcome of any preclinical development or clinical trials then being conducted. The Company anticipates that existing capital resources at December 31, 2008, together with the $6,000,000 to be received from Genentech in the first quarter of 2009 for the initiation of the pivotal phase II clinical trial in advanced basal cell carcinoma (see Note 16), should enable it to maintain current and planned operations into mid-2010. The Company s ability to continue funding its planned operations is dependent upon, among other things, the success of its collaborations with Genentech, its ability to control the cash burn rate and its ability to raise additional funds through equity, debt, entry into new collaborations or other sources of financing.

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

(a) USE OF ESTIMATES

The preparation of the Company s consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts and disclosure of revenue and certain assets and liabilities at the balance sheet date. Such estimates include the performance obligations under the Company s collaboration agreements, the collectibility of receivables, the carrying value of property and equipment and intangible assets and the value of certain investments and liabilities. Actual results may differ from such estimates.

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CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements Continued

(b) CONSOLIDATION

The accompanying consolidated financial statements include the Company and its wholly owned subsidiaries, Curis Securities Corporation, Inc. and Curis Pharmaceuticals (Shanghai) Co., Ltd., or Curis Shanghai.

(c) REVENUE RECOGNITION

The Company s business strategy includes entering into collaborative license and development agreements with biotechnology and pharmaceutical companies for the development and commercialization of the Company s product candidates. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon achievement of clinical development milestones and royalties on product sales. The Company follows the provisions of the Securities and Exchange Commission s Staff Accounting Bulletin (SAB) No. 104 (SAB No. 104), *Revenue Recognition*, Emerging Issues Task Force (EITF) Issue No. 00-21 (EITF 00-21), *Accounting for Revenue Arrangements with Multiple Deliverables,* EITF Issue No. 99-19 (EITF 99-19), *Reporting Revenue Gross as a Principal Versus Net as an Agent,* and EITF Issue No. 01-9 (EITF 01-9), *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor s Products).*

License Fees and Multiple Element Arrangements.

Non-refundable license fees are recognized as revenue when the Company has a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured and the Company has no further performance obligations under the license agreement. Multiple element arrangements, such as license and development arrangements are analyzed to determine whether the deliverables, which often include a license and performance obligations such as research and steering committee services, can be separated or whether they must be accounted for as a single unit of accounting in accordance with EITF 00-21. The Company recognizes up-front license payments as revenue upon delivery of the license only if the license has stand-alone value and the fair value of the undelivered performance obligations, typically including research and/or steering committee services, can be determined. If the fair value of the undelivered performance obligations can be determined, such obligations would then be accounted for separately as performed. If the license is considered to either (i) not have stand-alone value or (ii) have stand-alone value but the fair value of any of the undelivered performance obligations cannot be determined, the arrangement would then be accounted for as a single unit of accounting and the license payments and payments for performance obligations are recognized as revenue over the estimated period of when the performance obligations are performed.

If the Company is involved in a steering committee as part of a multiple element arrangement that is accounted for as a single unit of accounting, the Company assesses whether its involvement constitutes a performance obligation or a right to participate. Steering committee services that are determined to be performance obligations are combined with other research services or performance obligations required under an arrangement, if any, in determining the level of effort required in an arrangement and the period over which the Company expects to complete its aggregate performance obligations.

Whenever the Company determines that an arrangement should be accounted for as a single unit of accounting, it must determine the period over which the performance obligations will be performed and revenue will be recognized. Revenue will be recognized using either a relative performance or straight-line method. The Company recognizes revenue using the relative performance method provided that

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CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements Continued

the Company can reasonably estimate the level of effort required to complete its performance obligations under an arrangement and such performance obligations are provided on a best-efforts basis. Direct labor hours or full-time equivalents are typically used as the measure of performance. Revenue recognized under the relative performance method would be determined by multiplying the total payments under the contract, excluding royalties and payments contingent upon achievement of substantive milestones, by the ratio of level of effort incurred to date to estimated total level of effort required to complete the Company s performance obligations under the arrangement. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the relative performance method, as of each reporting period.

If the Company cannot reasonably estimate the level of effort required to complete its performance obligations under an arrangement, the performance obligations are provided on a best-efforts basis and the Company can reasonably estimate when the performance obligation ceases or the remaining obligations become inconsequential and perfunctory, then the total payments under the arrangement, excluding royalties and payments contingent upon achievement of substantive milestones, would be recognized as revenue on a straight-line basis over the period the Company expects to complete its performance obligations. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the straight-line basis, as of the period ending date.

If the Company cannot reasonably estimate when its performance obligation either ceases or becomes inconsequential and perfunctory, then revenue is deferred until the Company can reasonably estimate when the performance obligation ceases or becomes inconsequential. Revenue is then recognized over the remaining estimated period of performance.

Significant management judgment is required in determining the level of effort required under an arrangement and the period over which the Company is expected to complete its performance obligations under an arrangement.

Substantive Milestone Payments.

Collaboration agreements may also contain substantive milestone payments. Substantive milestone payments are considered to be performance bonuses that are recognized upon achievement of the milestone only if all of the following conditions are met:

- the milestone payments are non-refundable;
- achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement;
- substantive Company effort is involved in achieving the milestone;
- the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone; and,
- a reasonable amount of time passes between the up-front license payment and the first milestone payment as well as between each subsequent milestone payment.

Determination as to whether a payment meets the aforementioned conditions involves management s judgment. If any of these conditions are not met, the resulting payment would not be considered a substantive milestone, and therefore the resulting payment would be considered part of the consideration for the single unit of accounting and would be recognized as revenue as such performance obligations are performed under either the relative performance or straight-line methods,

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CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements Continued

as applicable, and in accordance with these policies as described above. In addition, the determination that one such payment was not a substantive milestone could prevent the Company from concluding that subsequent milestone payments were substantive milestones and, as a result, any additional milestone payments could also be considered part of the consideration for the single unit of accounting and would be recognized as revenue as such performance obligations are performed under either the relative performance or straight-line methods, as applicable.

Reimbursement of Costs.

Reimbursement of costs is recognized as revenue provided the provisions of EITF 99-19 are met, the amounts are determinable and collection of the related receivable is reasonably assured.

Royalty Revenue.

Royalty revenue is recognized upon the sale of the related products, provided that the royalty amounts are fixed or determinable, collection of the related receivable is reasonably assured and the Company has no remaining performance obligations under the arrangement. If royalties are received when the Company has remaining performance obligations, the royalty payments would be attributed to the services being provided under the arrangement and therefore would be recognized as such performance obligations are performed under either the relative performance or straight line methods, as applicable, and in accordance with these policies as described above.

Payments by Curis as a Vendor to a Collaborator as a Customer.

For revenue-generating arrangements where the Company, as a vendor, provides consideration to a licensor or collaborator, as a customer, the Company applies the provisions of EITF 01-9. A payment to a customer is presumed to be a reduction of the selling price unless the Company receives an identifiable benefit for the payment and the Company can reasonably estimate the fair value of the benefit received. Payments to a customer that are deemed a reduction of selling price are recorded first as a reduction of revenue, to the extent of both cumulative revenue recorded to-date and of probable future revenues, which include any unamortized deferred revenue balances, under all arrangements with such customer and then as an expense. Payments that are not deemed to be a reduction of selling price would be recorded as an expense.

Deferred Revenue.

Amounts received prior to satisfying the above revenue recognition criteria would be recorded as deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized during the year ending December 31, 2008 would be classified as long-term deferred revenue. As of December 31, 2008, the Company had no remaining short- or long-term deferred revenue.

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CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements Continued

Summary.

During the years ended December 31, 2008, 2007 and 2006, total gross revenues from major customers as a percent of total gross revenues of the Company were as follows:

	Year Ended December 31,		
	2008	2007	2006
Genentech	75%	76%	56%
Wyeth Pharmaceuticals	4%	12%	16%
Stryker Corporation	21%	%	%
Spinal Muscular Atrophy Foundation	%	%	7%
Procter & Gamble	%	11%	5%
Micromet AG	%	%	14%
Centocor	%	%	2%

(d) RESEARCH AND DEVELOPMENT

Research and development costs, including internal and external costs, are charged to operations as incurred. Research and development costs include personnel costs, lab supplies, outside services including clinical research organizations, medicinal chemistry, consulting agreements, allocations of facility costs and fringe benefits, and other costs.

(e) CASH EQUIVALENTS, MARKETABLE SECURITIES AND LONG-TERM INVESTMENTS

Cash equivalents consist of short-term, highly liquid investments purchased with maturities of three months or less. All other liquid investments are classified as marketable securities. In accordance with Statement of Financial Accounting Standards (SFAS) No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, all of the Company s marketable securities have been designated as available-for-sale and are stated at market value with any unrealized holding gains or losses included as a component of stockholders equity and any realized gains and losses recorded in the statement of operations in the period the securities are sold.

The amortized cost, unrealized gains and fair value of marketable securities available-for-sale as of December 31, 2008, with maturity dates ranging between one and twelve months and with a weighted average maturity of 3.3 months are as follows:

	Amortized Cost	Unrealized Gain	Fair Value
U.S. Government obligations	$ 9,449,000	$ 50,000	$ 9,499,000
Corporate bonds and notes	9,157,000	38,000	9,195,000
Total marketable securities	$ 18,606,000	$ 88,000	$ 18,694,000

The amortized cost, unrealized gains and fair value of marketable securities available-for-sale as of December 31, 2007, with maturity dates ranging between one and 12 months and with a weighted average maturity of 3.8 months are as follows:

	Amortized Cost	Unrealized Gain	Fair Value
Corporate bonds and notes	$ 23,979,000	$ 84,000	$ 24,063,000
Total marketable securities	$ 23,979,000	$ 84,000	$ 24,063,000

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CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements Continued

The Company has a restricted long-term investment in the amount of $210,000 at December 31, 2008 and 2007. This restricted long-term investment is comprised of a certificate of deposit pledged as collateral in connection with a facility lease agreement. The restriction expires on December 31, 2010 unless the Company elects to extend its lease. The Company had no other long-term investments as of December 31, 2008 or 2007.

(f) FAIR VALUE OF FINANCIAL INSTRUMENTS

On January 1, 2008, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 157, *Fair Value Measurements,* (SFAS No. 157) for its financial assets and liabilities. The adoption of SFAS No. 157 has not had a material impact on the Company s financial position or results of operations. As permitted by FASB Staff Position No. FAS 157-2, *Effective Date of FASB Statement No. 157*, the Company elected to defer the adoption of SFAS No. 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis, until January 1, 2009. SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115,* (SFAS No. 159) became effective January 1, 2008 and permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. The Company did not elect to adopt the fair value option for eligible financial instruments under SFAS No. 159.

SFAS No. 157 provides a framework for measuring fair value under U.S. GAAP and requires expanded disclosures regarding fair value measurements. SFAS No. 157 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Market participants are buyers and sellers in the principal market that are (i) independent, (ii) knowledgeable, (iii) able to transact, and (iv) willing to transact.

SFAS No. 157 requires the use of valuation techniques that are consistent with the market approach, the income approach and/or the cost approach. The market approach uses prices and other relevant information generated by market transactions involving identical or comparable assets and liabilities. The income approach uses valuation techniques to convert future amounts, such as cash flows or earnings, to a single present amount on a discounted basis. The cost approach is based on the amount that currently would be required to replace the service capacity of an asset (replacement cost). Valuation techniques should be consistently applied. SFAS No. 157 also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

Level 1 Quoted prices in active markets for identical assets or liabilities. The Company s Level 1 assets include cash and cash equivalents, investments in marketable securities, and a long-term restricted investment. As of December 31, 2008, the Company held cash equivalents and marketable securities of $8,967,000 and $18,694,000, respectively. The Company s marketable securities are investments with expected maturities of greater than three months, but less than twelve months, and consist of commercial paper, corporate debt securities, and government obligations. These amounts are invested directly in commercial paper of financial institutions and corporations with A-/Aa3 or better long-term ratings and A-1/P-1 short term debt ratings, U.S. Treasury securities, U.S. Treasury money market funds and interest bearing bank accounts.

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CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements Continued

Level 2 Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. The Company has no Level 2 assets or liabilities at December 31, 2008.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. The Company has no material Level 3 assets or liabilities at December 31, 2008.

(g) LONG-LIVED ASSETS OTHER THAN GOODWILL

Long-lived assets other than goodwill consist of property and equipment and long-term deposits. The aggregate balances for these long-lived assets were $1,666,000 and $2,796,000 as of December 31, 2008 and 2007, respectively. The Company applies SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. If it were determined that the carrying value of the Company s other long-lived assets might not be recoverable based upon the existence of one or more indicators of impairment, the Company would measure an impairment based on application of SFAS No. 144 (see Note 6). During the years ended December 31, 2008, 2007 and 2006, the Company recognized an impairment charge of $191,000, $352,000 and $148,000, respectively, related to certain equipment with no current or planned future use.

Purchased equipment is recorded at cost. The Company does not currently hold any leased equipment. Depreciation and amortization are provided on the straight-line method over the estimated useful lives of the related assets or the remaining terms of the leases, whichever is shorter, as follows:

Asset Classification	Estimated Useful Life
Laboratory equipment, computers and software	3-5 years
Leasehold improvements	Lesser of life of the lease or the life of the asset
Office furniture and equipment	5 years

(h) GOODWILL

As of December 31, 2008 and 2007, the Company had recorded goodwill of $8,982,000. Effective January 1, 2002, the Company applied the provisions of SFAS No. 142, *Goodwill and Other Intangible Assets*. During each of December 2008, 2007 and 2006, the Company completed its annual goodwill impairment tests and determined that the Company represented a single reporting unit under SFAS 142 and as of those dates the fair value of the Company exceeded the carrying value of its net assets. Accordingly, no goodwill impairment was recognized for the years ended December 31, 2008, 2007 and 2006.

(i) TREASURY STOCK

On May 31, 2002, the Company announced that its Board of Directors had approved the repurchase of up to $3,000,000 of the Company s common stock. Such purchases can be made from time to time, at the discretion of certain members of the Company s management. The Company accounts for its common stock repurchases as treasury stock under the cost method. The repurchased stock provides the Company with treasury shares for general corporate purposes, such as stock to be issued under employee stock option and stock purchase plans. In 2002, the Company repurchased 1,047,707 shares of its common stock at a cost of $891,000 pursuant to this repurchase program. The Company has not purchased any shares since 2002.

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CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements Continued

(j) BASIC AND DILUTED LOSS PER COMMON SHARE

The Company applies SFAS No. 128, *Earnings per Share*, which establishes standards for computing and presenting earnings per share. Basic and diluted net losses per share were determined by dividing net loss by the weighted average common shares outstanding during the period. Diluted net loss per common share is the same as basic net loss per common share for all periods presented, as the effect of the potential common stock equivalents is antidilutive due to the Company s net loss position for all periods presented. Antidilutive securities consist of stock options, warrants and shares issuable under the Company s 2000 Employee Stock Purchase Plan; all of which are weighted based on the number of days outstanding during the respective reporting period. Antidilutive securities were 15,887,602, 15,371,793 and 9,561,899 as of December 31, 2008, 2007 and 2006, respectively, consisting of the following:

	For the years ended December 31,		
	2008	2007	2006
Stock options outstanding	9,861,811	8,969,102	7,913,407
Warrants outstanding	5,987,338	6,399,271	1,630,976
Shares issuable under ESPP	38,453	3,420	17,516
Total antidilutive securities	15,887,602	15,371,793	9,561,899

(k) STOCK-BASED COMPENSATION

On January 1, 2006, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 123 (revised 2004), *Share-Based Payment* (SFAS 123(R)), which establishes standards for the accounting of transactions in which an entity exchanges its equity instruments for goods or services. SFAS 123(R) focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions. SFAS 123(R) requires that the fair value of such equity instruments be recognized as an expense in the financial statements as services are performed.

The Company adopted SFAS 123(R) using the modified-prospective-transition method. Under that transition method, compensation cost recognized for the years ended December 31, 2008, 2007 and 2006 includes (i) compensation cost for all share-based payments granted prior to January 1, 2006, but not yet vested at that date, based on the grant-date fair value estimated in accordance with the original provisions of SFAS 123; and (ii) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123(R).

(l) OPERATING LEASES

As of December 31, 2008, the Company has one facility located at 45 Moulton Street in Cambridge, Massachusetts under a noncancellable operating lease agreement for office and laboratory space. The rent payments for this facility escalate over the lease term and the Company expenses its obligations under this lease agreement on a straight-line basis over the term of the lease (see Note 9(a)).

(m) NEW ACCOUNTING PRONOUNCEMENTS

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations* (SFAS No. 141(R)). SFAS No. 141(R) establishes principles and requirements for how an acquirer recognizes

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and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any noncontrolling interest in the acquiree and the goodwill acquired. SFAS No. 141(R) also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. SFAS No. 141(R) is effective for fiscal years beginning after December 15, 2008. SFAS No. 141(R) will have an impact on the Company s financial statements if it is involved in a business combination that occurs after January 1, 2009.

In December 2007, the EITF issued Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF Issue No. 07-1). This Issue is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, and shall be applied retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date that include a joint operating activity (i.e., co-development) and that are operated as a virtual joint venture. This Issue includes enhanced disclosure requirements regarding the nature and purpose of the arrangement, rights and obligations under the arrangement, accounting policy, amount and income statement classification of collaboration transactions between the parties. This Issue also requires that transactions with third parties (i.e., parties that do not participate in the collaborative arrangement) should be reported in the appropriate line item in each company s financial statement pursuant to the guidance in EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*. The Company has historically entered into collaborative arrangements in which this Issue would be applicable; however, the Company does not expect the adoption of EITF 07-1 to have a material impact on its consolidated financial statements as it relates to joint operating activities under current collaborations. The Company will have to evaluate the impact of this Issue on future collaborations that the Company may enter into.

(3) RESEARCH AND DEVELOPMENT COLLABORATIONS

(a) GENENTECH, INC. JUNE 2003 COLLABORATION

(i) Agreement Summary

In June 2003, the Company licensed its proprietary Hedgehog pathway technologies to Genentech for human therapeutic use. The primary focus of the collaborative research plan has been to develop molecules that inhibit the Hedgehog pathway for the treatment of various cancers. The collaboration consists of two programs: the development of a small molecule Hedgehog pathway inhibitor formulated for the topical treatment for basal cell carcinoma; and the development of systemically administered small molecule and antibody Hedgehog pathway inhibitors for the treatment of certain other solid tumor cancers. Under this second program, Genentech is currently conducting three clinical trials with GDC-0449, the lead molecule from the systemically administered Hedgehog pathway inhibitor program.

Pursuant to the agreement, Genentech made an up-front payment of $8,500,000, which consisted of a $3,509,000 non-refundable license fee payment and $4,991,000 in exchange for shares of the Company s common stock. Genentech also made license maintenance fee payments totaling $4,000,000 over the first two years of the collaboration and agreed to pay additional contingent cash, assuming specified clinical development and regulatory approval objectives are met. To date, the Company has received a total of $12,000,000 in such contingent cash payments for the achievement of development objectives under the agreement (see Note 16). In addition, Genentech agreed to pay a royalty on potential future net product sales, which increases with increasing sales volume.

As a result of its licensing agreements with various universities, the Company is obligated to make payments to these university licensors when certain payments are received from Genentech. As of

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December 31, 2008, we have incurred aggregate expenses of $600,000 in connection with the Company s receipt of contingent cash payments from Genentech related to such licensing agreements.

The collaboration agreement provides the Company with the option to co-develop topically administered Hedgehog pathway inhibitor products in the field of basal cell carcinoma in the U.S. In January 2005, the Company exercised this co-development option and, until August 31, 2006, the Company shared equally in the U.S. development costs of this product candidate. Development of this topically administered basal cell carcinoma product candidate was governed by a co-development steering committee. The co-development steering committee terminated when the parties ended the co-development arrangement. In July 2006, the Company and Genentech elected to halt clinical development of this product candidate. Effective August 31, 2006, the Company elected to cease its co-development participation and Genentech became solely responsible for all future costs and development decisions regarding this program. Since the termination of its co-development participation, the Company has not incurred any additional co-development or internal costs for a topically administered basal cell carcinoma product candidate. Should Genentech determine to develop a topically administered Hedgehog pathway inhibitor for the treatment of basal cell carcinoma, the Company would be eligible for cash payments on the achievement of certain future clinical development objectives as well as a royalty on future product sales, if any.

In addition to the co-development of a topically administered Hedgehog pathway inhibitor product in the field of basal cell carcinoma, the collaboration provides for the development of systemically administered small molecule and antibody Hedgehog pathway inhibitors for the treatment of cancer. The development of these programs is governed by a joint steering committee which is comprised of an equal number of representatives from both the Company and Genentech to oversee the research, development and commercialization and other efforts around these programs. Each member of the joint steering committee receives the right to cast one vote, but Genentech has the final decision making authority in most matters. The joint steering committee was required to meet on at least a quarterly basis until the filing of the first investigational new drug, or IND, application for a Hedgehog pathway inhibitor product candidate, which occurred in October 2006. After such filing, the joint steering committee shall meet as often as it deems necessary or at least semi-annually and shall exist as long as any compound under the collaboration is being developed or commercialized in accordance with the contract terms.

Unless terminated earlier, the agreement shall expire six months after the later of the expiration of Genentech s obligation to pay royalties to the Company under the agreement or such time as no activities have occurred under the agreement for a period of twelve months. Early termination provisions are as follows:

(i) Either the Company or Genentech may terminate the agreement upon sixty days written notice for cause upon either the occurrence of bankruptcy, insolvency, dissolution, winding up, or upon the breach of any material provision of this agreement by the other party, provided such breach is not cured by the other party within the sixty day period following written notice of termination by the other party.

(ii) If Genentech terminates the agreement for cause, all licenses granted by Genentech to the Company automatically terminate and revert to Genentech and specified licenses granted by Curis to Genentech shall survive so long as Genentech is not then in breach under the Agreement. The consideration for any product that the Company shares gross profits and losses with Genentech through a co-development structure (i.e., the basal cell carcinoma product candidate) will be modified so that the Company will no longer receive its share of gross profits and losses. The Company will instead receive clinical development and drug approval milestones and royalties on product sales for such product.

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(iii) If the Company terminates the agreement for cause or Genentech terminates the agreement without cause, all licenses granted by the Company to Genentech automatically terminate and revert to the Company and specified licenses granted by Genentech to the Company shall survive so long as the Company is not then in breach under the Agreement. At the time of such termination, Genentech shall 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.

(ii) Accounting Summary

The Company considers its June 2003 arrangement with Genentech to be a revenue arrangement with multiple deliverables. The Company s deliverables under this collaboration include an exclusive license to its Hedgehog pathway inhibitor technologies, research and development services for the first two years of the collaboration, and participation on both the joint steering committee and the co-development steering committee. The Company applied the provisions of EITF 00-21 to determine whether the performance obligations under this collaboration could be accounted for separately or should be accounted for as a single unit of accounting. The Company determined that the deliverables, specifically, the license, research and development services and steering committee participation, represented a single unit of accounting because the Company believes that the license, although delivered at the inception of the arrangement, did not have stand-alone value to Genentech without the Company s research and development services and steering committee participation. In addition, objective and reliable evidence of the fair value of the Company s research and development services and steering committee participation could not be determined.

The Company attributed the $3,509,000 up-front fee and the $4,000,000 of maintenance fees to the undelivered research and development services and steering committee participation. The Company did not consider the $4,000,000 in maintenance fees to be substantive milestone payments because receipt of the maintenance fee payments did not meet each of the criteria set forth in the Company s revenue recognition policy related to substantive milestones (see Note 2(c)).

As of December 31, 2006, the Company had completed the delivery of (i) the license, (ii) the research and development services and (iii) its participation on the co-development steering committee. Therefore, as of December 31, 2006, the Company s sole remaining performance obligation under this collaboration consisted of participation on the joint steering committee. The agreement provides that the joint steering committee shall exist for so long as any compound subject to this collaboration is being developed or commercialized by either of the parties. As of December 31, 2006, the Company had deferred the $7,509,000 in up-front license fee and maintenance fee payments because, at that time, it could not reasonably estimate the period of performance of its steering committee obligation or when the steering committee obligation would become inconsequential or perfunctory.

Since submission of the IND application in October 2006, Genentech has independently pursued further clinical development of a lead compound and has not sought to involve the Company in the development of the systemically administered small molecule and antibody Hedgehog pathway inhibitor research and development efforts, all of which are being conducted exclusively by Genentech. Further, the Company terminated all internal research activities involving Hedgehog pathway inhibitors immediately upon the conclusion of the research funding in December 2006. Genentech manages all aspects of research and development of Hedgehog pathway inhibitors covered by this collaboration. Genentech designed, enrolled and continues to manage all aspects of the ongoing clinical trials of GDC-0449. The Company has not been involved in the development of this program subsequent to the IND submission in October 2006 and expects that it will not be involved in the development plans in the future.

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During the fourth quarter of 2007, in consideration of Genentech s development progress without assistance from the Company, including limited participation by either party on the joint steering committee in 2007, the Company reassessed its participation on the joint steering committee. As a result of this reassessment, the Company concluded that its participation in the joint steering committee had become inconsequential and perfunctory. Specifically, the Company believes that its participation on the joint steering committee is no longer essential to the current or future development of Hedgehog pathway inhibitor compounds under collaboration with Genentech, and the fair value or cost, if any, of completing the Company s obligation is insignificant in relation to the non-refundable up-front license fee and maintenance payments received from Genentech that have been allocated to the single unit of accounting. As a result, the Company recorded the $7,509,000 in up-front license fee and maintenance fee payments as license revenues for the year ended December 31, 2007.

In October 2006, Genentech filed an IND application with the FDA to initiate Phase I clinical testing of GDC-0449 for the treatment of cancer, which triggered a contingent cash payment of $3,000,000 by Genentech. The Company has recorded this amount as revenue in Substantive milestones in the Revenues section of its Consolidated Statement of Operations for the year ended December 31, 2006 since the successful achievement of these objectives met each of the criteria set forth in the Company s revenue recognition policy related to substantive milestones.

In 2007, the Company received a payment of $3,000,000 from Genentech and, in 2008, the Company received additional payments totaling $6,000,000 from Genentech upon the achievement of Phase II clinical development objectives under the agreement. These payments did not meet the criteria to be classified as substantive milestones, and, therefore, the Company has recorded these amounts as revenue within License Fees in the Revenues section of its Consolidated Statement of Operations for the years ended December 31, 2008 and 2007, respectively as the Company did not have any further performance obligations under the collaboration. During the years ended December 31, 2008, 2007 and 2006, the Company also recorded revenue within Research and development contracts of $282,000, $322,000 and $202,000, respectively, as revenue related to expenses incurred on behalf of Genentech that were paid by the Company and for which Genentech is obligated to reimburse the Company. The Company will continue to recognize revenue for expense reimbursement as such reimbursable expenses are incurred, provided that the provisions of EITF 99-19 are met. As of December 31, 2008, the Company had recorded $104,000 as amounts receivable from Genentech under this collaboration in Accounts receivable in the Company s Current Assets section of its Consolidated Balance Sheets.

The Company s right to co-develop the Hedgehog pathway inhibitor products in the field of basal cell carcinoma was not considered a deliverable under EITF 00-21, was exercisable only at the Company s option and, therefore, did not impact the initial accounting for this arrangement. As a result of the Company s decision to exercise its right to co-development the basal cell carcinoma product candidate, the Company made significant cash payments to Genentech through August 31, 2006, which is the date the Company ceased its participation in co-development. As of August 31, 2006, Genentech is solely responsible for all future costs and development decisions regarding the basal cell carcinoma program. The Company has recorded $1,728,000 in co-development payments to Genentech for the year ended December 31, 2006 as contra-revenues in its Consolidated Statement of Operations. The Company does not expect to incur any additional costs related to co-development of this drug candidate.

(b) GENENTECH, INC. APRIL 2005 AGREEMENT

(i) Agreement Summary

Effective April 11, 2005, the Company entered into a second amendment to its June 2003 agreement with Genentech. Under the terms of the amendment, Genentech agreed to provide the Company with

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up to $2,000,000 of funding to continue development of therapeutics to treat solid tumor cancers, and the research term was extended from June 11, 2005 to December 11, 2005, at which time the $2,000,000 was paid. At Genentech s option, the research term would be extended for an additional six-month period to June 11, 2006, upon written notice delivered to the Company by October 2005. Genentech notified the Company in October 2005 of its decision to extend the research term, and agreed to fund up to ten Curis full-time equivalents through June 11, 2006. Genentech paid the Company $1,250,000 in June 2006. Other than the change to the period of the research term and payments associated with such research, the amendment did not change the terms of the June 2003 agreement, which remains in full force and effect.

(ii) Accounting Summary

The Company considered the provisions of EITF 00-21 and determined that this agreement is a separate contract from its June 2003 agreement, and a previous amendment entered into between the Company and Genentech in December 2004, since it was not contemplated at the time of the June 2003 arrangement, was separately negotiated in order to increase the number of full-time equivalent providing research and development services and to provide xenograft tumor samples to Genentech, and was not entered into at or near the time of the June 2003 agreement. The Company s performance obligations under this agreement were to provide research services and xenograft tumor samples to Genentech through June 11, 2006. Since Genentech elected to exercise its option and extend the research services, the Company s performance obligations extended for an additional period from December 2005 through June 2006. The Company has applied the provisions of SAB No. 104 and recognized the research funding as revenues under this collaboration as such research services were performed. The amount payable to the Company and, accordingly, the amount of revenue recognized was based on the actual number of full-time equivalents providing research services under this agreement through June 2006. During the year ended December 31, 2006, the Company recorded $898,000 related to its research and development services under this agreement as revenue in Research and development contracts in the Company s Revenues section of its Consolidated Statement of Operations. No revenues were recognized under this agreement with Genentech in 2007 or 2008. As of December 31, 2008, the Company had no amounts receivable from Genentech under this collaboration in Accounts receivable in the Company s Current Assets section of its Consolidated Balance Sheets.

(c) GENENTECH, INC. MAY 2006 AGREEMENT

(i) Agreement Summary

In May 2006, the Company entered into a third amendment to its June 2003 agreement with Genentech. The May 2006 amendment, effective from June 12, 2006 to December 11, 2006, provided for up to seven of the Company s full-time equivalent researchers to provide research and development services, in exchange for up to an additional $918,750, payable quarterly in advance. The agreement also provided Genentech with the option to request that the Company provide up to seven full-time equivalent researchers to perform research services during the period of December 12, 2006 until June 11, 2007. Genentech did not exercise this option, and funding for research services on this program ceased on December 11, 2006.

(ii) Accounting Summary

The Company considered the provisions of EITF 00-21 and determined that this agreement is a separate contract from its June 2003 agreement, and previous amendments entered into between the

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Company and Genentech in December 2004 and April 2005, since it was not contemplated at the time of the June 2003 arrangement, was separately negotiated in order to extend the term in which full-time equivalents would provide research and development services and to provide xenograft tumor samples to Genentech, and was not entered into at or near the time of the June 2003 agreement. The Company s performance obligations under this agreement were to provide research services and xenograft tumor samples to Genentech through December 11, 2006. The Company applied the provisions of SAB No. 104 and recognized the research funding as revenues under this collaboration as such research services were performed. The amount payable to the Company and, accordingly, the amount of revenue recognized was based on the actual number of full-time equivalents providing research services under this agreement through December 2006. During the year ended December 31, 2006, the Company recorded $842,000 related to its research and development services under this agreement as revenue in Research and development contracts in the Company s Revenues section of its Consolidated Statement of Operations. No revenues were recognized under this agreement with Genentech in 2008 or 2007. As of December 31, 2008, the Company had no amounts receivable from Genentech under this collaboration.

(d) GENENTECH APRIL 2005 WNT DRUG DISCOVERY COLLABORATION

(i) Collaboration Summary

On April 1, 2005, the Company entered into a drug discovery collaboration agreement with Genentech for the discovery and development of small molecule compounds that modulate the Wnt signaling pathway. This pathway is believed to play an important role in cell proliferation and is a regulator of tissue formation and repair, the abnormal activation of which is associated with certain cancers. Under the terms of the agreement, the Company has granted Genentech an exclusive, royalty-bearing license to make, use and sell the small molecule compounds that are modulators of the pathway. Curis has retained the rights for ex vivo cell therapy, except in the areas of oncology and hematopoiesis.

Under the terms of the agreement, the Company had primary responsibility for research and development activities through March 2007 and Genentech is primarily responsible for clinical development, manufacturing, and commercialization of products that may result from the collaboration. Genentech paid the Company an up-front license fee of $3,000,000 and paid the Company $5,270,000 for research and development activities during the initial two-year research term. Genentech will also make cash payments to the Company that are contingent upon the successful achievement of certain preclinical and clinical development objectives and drug approval objectives. Genentech had an option to extend the initial two-year research term for up to two additional years in one-year increments. In January 2007, Genentech informed the Company that it would not extend the research term beyond the initial two-year term ending on March 31, 2007. Genentech will also pay the Company royalties on net product sales if product candidates derived from the collaboration are successfully developed. If Genentech does not advance drug candidates generated under this collaboration beyond the discovery research stage, the Company is not entitled to receive any future cash payments under this collaboration. The Company can not predict whether Genentech will pursue the further development of drug candidates under the agreement and/or whether any development objectives for which the Company may be entitled to a cash payment will be achieved.

(ii) Accounting Summary

The Company considers this arrangement with Genentech to be a revenue arrangement with multiple deliverables. The Company s deliverables under this collaboration include an exclusive license to its technologies in this signaling pathway and certain performance obligations, including research services

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for at least two years and participation on a steering committee. The Company applied the provisions of EITF 00-21 to determine whether the performance obligations under this collaboration can be accounted for separately or as a single unit or multiple units of accounting. The Company determined that these deliverables represented a single unit of accounting, since the Company believes that the license does not have stand-alone value to Genentech without the Company s research services and steering committee participation during certain phases of research and because objective and reliable evidence of the fair value of the Company s research and steering committee participation could not be determined.

The Company s performance obligations under this collaboration consist of participation on a steering committee and the performance of research services. Because the Company believed that it could reasonably estimate its level of effort over the term of the arrangement, the Company accounted for the arrangement under the relative performance method. In developing its original estimate of the Company s level of effort required to complete its performance obligations, the Company estimated that Genentech would elect twice to extend the research service period and related funding, each in one-year increments, although there was no assurance Genentech would make such an election. The Company originally estimated that it would provide an equal number of full-time equivalents for the four-year research and development service term. In developing this estimate, the Company assumed that Genentech would maintain its initially elected number of twelve full-time equivalent researchers throughout the four-year period. The steering committee effort was also expected to be consistent over the four-year period. The $3,000,000 up-front fee plus $12,000,000**,** the total amount of research funding which the Company would be entitled to for providing twelve full-time equivalents at $250,000 each over four years, was being attributed to the research services.

As a result of Genentech s decision not to extend the research term, the Company s estimated performance period was changed during the fourth quarter of 2006 to coincide with the March 31, 2007 research term end date, and the Company accelerated amortization of the unamortized up-front license fee and the remaining amount of research funding to which the Company was entitled. Revenue for the period April 1, 2005 through September 30, 2006 was being recognized as the research services were provided assuming a four-year term through March 2009 at a rate of $312,500 per full-time equivalent. Revenue for the period October 1, 2006 through March 31, 2007 was recognized as the research services were provided at a rate of $562,500 per full-time equivalent, which includes the effects of accelerating the unamortized up-front license fee.

The Company recorded revenue under this collaboration of $1,577,000 and $4,316,000 during the years ended December 31, 2007 and 2006, respectively. Of this amount, approximately $938,000 and $1,500,000 was attributed to the amortization of the up-front license fee and is included in License fees within the Revenue section of the Company s Consolidated Statement of Operations for the years ended December 31, 2007 and 2006, respectively. In addition, the Company recorded $639,000 and $2,811,000 related to research services performed by the Company s full-time equivalent researchers for the years ended December 31, 2007 and 2006, respectively, and is included within Research and development contracts within the Revenues section of the Company s Consolidated Statement of Operations. During the year ended December 31, 2006, the Company also recorded revenue within Research and development contracts of $5,000 as revenue related to expenses incurred on behalf of Genentech that were paid by the Company and for which Genentech is obligated to reimburse the Company. No revenues were recognized under this agreement with Genentech in 2008.

The Company believes that contingent payments tied to preclinical, clinical development and drug approval objectives under this collaboration would not constitute substantive milestones since the successful achievement of these objectives would not meet each of the criteria set forth in the

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Company s revenue recognition policy related to substantive milestones. For any future contingent payments received by the Company, the Company would have no future deliverables under the agreement because its performance period ended on March 31, 2007. The Company therefore expects that it would record any such contingent payments as revenue in License Fees in the Company s Revenues section of its Consolidated Statement of Operations when the milestones are met.

As of December 31, 2006, the Company had provided cash consideration to Genentech in the form of co-development payments for the Company s equal share of U.S. development costs of a basal cell carcinoma product candidate that is being developed under a separate collaboration with Genentech. Effective August 31, 2006, the Company elected to cease its participation in the co-development of this drug candidate and, as of August 31, 2006, Genentech will be solely responsible for all future costs and development decisions regarding the basal cell carcinoma program. As of December 31, 2008, the Company had no amounts receivable from Genentech under this collaboration.

(e) STRYKER

On December 27, 2007, the Company completed a transaction with Stryker, under the terms of which Stryker paid the Company $1,750,000 in cash in exchange for the sale and assignment of all of the Company s remaining BMP assets. As a result of the transaction, Stryker assumed all future costs subsequent to the December 27, 2007 effective date related to maintenance and prosecution of the patent portfolio. As of December 31, 2007, the Company recorded the $1,750,000 received as short-term deferred revenue because the Company had not delivered all of the assets to Stryker as required by the agreement as of that date. The Company completed the transfer of all assets during the first quarter of 2008, at which time no material ongoing performance obligations remained under the agreement. Accordingly, the Company recorded $1,750,000 as license revenue within the Revenues section of the Consolidated Statement of Operations for the year ended December 31, 2008.

Under the terms of the agreement, the Company is entitled to contingent cash payments related to certain clinical development and sales objectives, if achieved. The Company believes that these contingent payments would not constitute substantive milestones since the successful achievement of these objectives would not meet each of the criteria set forth in the Company s revenue recognition policy related to substantive milestones. Accordingly, the Company would recognize such contingent payments as revenue in License Fees in the Company s Revenues section of its Consolidated Statement of Operations when the milestones are met because the Company would has no future deliverables under the agreement.

In connection with its transaction with Stryker, the Company entered into a separate agreement in December 2007 with a former collaborator, to which the Company had previously licensed a portion of its BMP technology. In exchange for the rights to transfer the licensed technology to Stryker and to place previously agreed-upon financial consideration under such transfer, the Company was obligated to make a one-time payment of $750,000 to the former collaborator, which has been recorded in Research and Development line item of the Costs and Expenses section of the Company s Consolidated Statement of Operations for the year ended December 31, 2007. In connection with its receipt of any contingent payments from Stryker, the Company would also be required to make payments of up to $14,000,000 to this former third-party collaborator if such payments are made for product candidates or products that are designed to treat certain indications affecting chronic kidney disease patients.

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(4) FORMER COLLABORATIONS

(a) WYETH PHARMACEUTICALS

(i) Agreement Summary

On January 12, 2004, the Company licensed its Hedgehog proteins and small molecule Hedgehog pathway agonists to Wyeth Pharmaceuticals, or Wyeth, for therapeutic applications in the treatment of neurological and other disorders. Pursuant to the collaboration agreement, Wyeth agreed to make specified cash payments, including up-front payments of $3,000,000, which consisted of a $1,362,000 non-refundable license fee payment and $1,638,000 in exchange for 315,524 shares of the Company s common stock.

On May 6, 2008 the agreement terminated. On the termination date, the licenses granted by the Company to Wyeth terminated and all terminated license rights reverted to the Company.

In addition, as part of a termination agreement entered into between the Company and Elan Corporation, the Company paid Elan royalty payments related to any revenues in excess of the first $1,500,000 received by the Company from Wyeth, other than revenues received as direct reimbursement for research, development and other expenses that the Company receive from Wyeth. The Company was also obligated to make payments to various university licensors when certain payments were received from Wyeth. These obligations totaled $163,000 in payments to Elan and university licensors for the up-front license fee and substantive milestone payment received through December 31, 2008.

(ii) Accounting Summary

The Company considered its arrangement with Wyeth to be a revenue arrangement with multiple deliverables, or performance obligations. The Company s performance obligations under this collaboration included an exclusive license to its Hedgehog agonist technologies and performing services, including research and development services for at least two years and participation on a steering committee. The Company applied the provisions of EITF 00-21 to determine whether the performance obligations under this collaboration could be accounted for separately or as a single unit or multiple units of accounting. The Company determined that these performance obligations represented a single unit of accounting, research and steering committee services, since the Company believed that the license did not have stand-alone value to Wyeth without its research services and steering committee participation and because objective and reliable evidence of the fair value of the Company s research and steering committee participation could not be determined.

The Company s ongoing performance obligations under this collaboration consisted of participation on a steering committee and the performance of research services. Because the Company believed that it could reasonably estimate its level of effort over the term of the arrangement, the Company accounted for the arrangement under the relative performance method. In developing its original estimate of the Company s level of effort required to complete its performance obligations, the Company estimated that Wyeth would elect twice to extend the research and development service period and related funding, each in one-year increments, for a total of four years. The agreement provided for a one-year evaluation period immediately following the end of the research term, during which time the Company could have been obligated to serve on the steering committee and could have been required, at Wyeth s expense, to perform additional research and development services. The Company originally estimated that it would provide an equal number of full-time equivalents for the four-year research and development service term plus the one-year evaluation period. In developing this estimate, the

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Company assumed that Wyeth would maintain its initially elected number of eight full-time equivalents throughout the five-year period. The steering committee effort was also expected to be consistent over the five-year period. On November 3, 2006, Wyeth agreed to extend the research funding term by one year through February 9, 2008 but elected to fund only five researchers working on the program through the research term. Accordingly, the Company revised its estimated level of effort over the remaining performance period. In December 2007, Wyeth informed the Company that it would not extend the current contractual research funding term beyond February 2008. As a result, the Company changed its estimated performance period to coincide with the conclusion of the research term from its original estimate of February 2009. On March 7, 2008, Wyeth provided notice that it was terminating the agreement.

The $1,362,000 up-front license fee plus $7,250,000**,** the total amount of research funding which the Company will be entitled to for providing an average of 7.25 full-time equivalents over the four-year performance period at a rate of $250,000 each (eight full-time equivalents over the first three years and five full-time equivalents over the last year), is therefore being attributed to the research services. Revenue was recognized as the research services were provided over the remaining performance period through February 2008 at a rate of $297,000 per full-time equivalent.

During the years ended December 31, 2008, 2007 and 2006, the Company recorded revenue of $299,000, $1,968,000 and $2,604,000, respectively, related to the Company s research efforts under the Wyeth arrangement, of which $103,000, $439,000 and $306,000, respectively, were recorded in License Fees and $196,000, $1,332,000 and $2,298,000, respectively, were recorded in Research and development contracts in the Company s Revenues section of its Consolidated Statement of Operations. Included within Research and development contracts , the Company recorded $62,000, $197,000 and $298,000 for the years ended December 31, 2008, 2007 and 2006, respectively, as revenue related to expenses incurred on behalf of Wyeth that were paid by the Company and for which Wyeth is obligated to reimburse the Company. As of December 31, 2008, the Company had no amounts recorded as amounts receivable from Wyeth.

As of December 31, 2008, the Company has not provided any consideration to Wyeth.

(b) PROCTER & GAMBLE

On September 18, 2005, the Company entered into a collaboration, research and license agreement with Procter & Gamble to evaluate and seek to develop potential treatments for hair growth regulation and skin disorders utilizing the Company s Hedgehog agonist technology.

Under the terms of the agreement, the Company granted Procter & Gamble an exclusive, worldwide, royalty-bearing license for the development and commercialization of topical dermatological and hair growth products that incorporate the Company s Hedgehog agonist technology. In accordance with the terms of the agreement, the parties agreed to jointly undertake a research program with the goal of identifying one or more compounds to be developed and commercialized by Procter & Gamble. Under the agreement, Procter & Gamble paid the Company an up-front license fee of $500,000 and agreed to fund up to $600,000 for two Curis full-time equivalents providing research and development activities during the initial one-year research term, subject to its termination rights. Procter & Gamble had an option to extend the initial one-year research term for up to three additional years in one-year increments, and, in September 2006, Procter & Gamble exercised the option to extend research funding through September 2007 for one-third of a full-time equivalent for $83,000.

On May 9, 2007, Procter & Gamble notified the Company of Procter & Gamble s decision to terminate the collaboration effective November 9, 2007.

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The Company recorded revenue under this collaboration of $1,878,000 and $898,000 during the years ended December 31, 2007 and 2006, respectively. Of these amounts, $1,242,000 and $235,000 were attributed to the amortization of (i) the up-front license fee and (ii) a contingent cash payment that did not constitute a substantive milestone since the successful achievement of these objectives did not meet each of the criteria set forth in the Company s revenue recognition policy related to substantive milestones. These amounts are included in the License fees line item within the Revenues section of the Company s Consolidated Statement of Operations for the years ended December 31, 2007 and 2006. Of the remaining amounts, $548,000 and $107,000 were related to research services performed by the Company s two full-time equivalents for the years ended December 31, 2007 and 2006, respectively, and $88,000 and $556,000 for the years ended December 31, 2007 and 2006, respectively, related to expenses incurred on behalf of Procter & Gamble by the Company for which Procter & Gamble is obligated to reimburse the Company, and for which the Company believes that the revenue recognition provisions of EITF 99-19 have been met. These amounts are included within the Research and development contracts line item within the Revenues section of the Company s Consolidated Statement of Operations. The Company did not record any revenues under this agreement for the year ended December 31, 2008. As of December 31, 2008, the Company had no amounts receivable from Procter & Gamble.

As of December 31, 2008, the Company has not provided any consideration, such as payments under co-development arrangements, to Procter & Gamble.

(c) SPINAL MUSCULAR ATROPHY FOUNDATION

(i) Agreement Summary

Effective September 7, 2004, the Company entered into a sponsored research agreement with the Spinal Muscular Atrophy, or SMA, Foundation. Under the agreement, the SMA Foundation had committed to grant the Company up to $5,364,000 over a three-year period for the identification of therapeutic compounds to treat spinal muscular atrophy, a neurological disease. The sponsored research agreement was terminated by both parties on November 30, 2006, and the Company has no remaining performance obligations under this grant.

(ii) Accounting Summary

The Company s sole deliverable under this sponsored research agreement was to provide research services. The Company has applied the provisions of SAB No. 104 for recognizing revenue under this collaboration. The Company recognized revenues under this collaboration as the services were performed, since payment was reasonably assured under the terms of the grant. For the year ended December 31, 2006, the Company recognized $1,191,000 related to its research and development efforts under this sponsored research agreement. These amounts are included in Research and development contracts in the Company s Revenues section of its Consolidated Statement of Operations. The Company did not record any revenues under this agreement for the years ended December 31, 2008 or 2007.

(d) MICROMET AG

In 2001, the Company entered into three agreements with Micromet including: (i) a purchase and sale agreement pursuant to which the Company assigned its single-chain-polypeptide technology to Micromet in exchange for up-front consideration of $12,146,000, consisting of $8,000,000 in cash,

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$3,460,000 in a euro-denominated note receivable, and equity valued by the Company at $686,000, (ii) a product development agreement and (iii) a target research and license agreement. The note receivable received under the purchase and sale agreement bore interest at 7% and was due and payable in full on the earlier of (i) the closing date of an initial public offering of Micromet s shares or (ii) June 30, 2005. At maturity, the Company had the option to receive either cash or shares of Micromet common stock. Further, under these agreements, the Company was entitled to receive royalties on Micromet s revenues, if any, arising out of the assigned technology, rights to jointly develop and commercialize future product discoveries, if any, arising out of the product development agreement and access to other technologies. The product development agreement provided the Company with the right to (i) jointly fund research to develop antibodies on up to four potential targets through the proof of principle stage and (ii) jointly fund the development of two such antibody targets from the proof of principle stage through the completion of Phase I clinical trials.

On October 21, 2004, the Company amended its note receivable with Micromet, and, under the amended note, Micromet was obligated to pay the Company a total amount of 4,500,000, subject to certain conditions. As a result of Micromet s financing in October 2004, the Company received a 1,250,000 payment in 2004, resulting in a gain of $1,604,000 based on the EURO-to-US dollar foreign exchange rate on the date of payment. The gain was recorded in other income as it related to a recovery of previously written-off interest income and foreign exchange gains related to the note.

As a result of completing additional financings in 2005, Micromet made a second payment of 1,250,000 on October 27, 2005, which resulted in a gain of $1,500,000 based on the EUR-to-US dollar foreign exchange rate on such date. $1,400,000 of the gain was recorded as license fee revenue for the year ended December 31, 2005 because it represented the recovery of a previously written-off note that the Company had received from Micromet in exchange for the assignment of technology. The remaining $100,000 was recorded in other income as it is related to a recovery of previously written-off interest income and foreign exchange gains related to the note.

In March 2006, the Company asserted that the conditions precedent to the payment of the remaining 2,000,000 due under the note receivable had been achieved through Micromet s merger with CancerVax, a claim that Micromet disputed. In September 2006, the Company agreed to a court-proposed settlement agreement with Micromet, pursuant to which Micromet was required to repay the note receivable in two installments of 1,000,000, on each of November 1, 2006 and May 31, 2007. Under the terms of the settlement agreement, if Micromet made the second payment on or before April 30, 2007, the second payment would decrease to 800,000. The Company believed that it was probable that Micromet would honor its obligation under the court ruling and pay Curis 1,000,000 by November 1, 2006 and 800,000 by April 30, 2007, to take advantage of the 30-day discount term. As a result of this recovery of amounts owed under the note, the Company recorded license fee revenues of $2,284,000 during the year ended December 31, 2006 based on the then Euro-to-U.S. dollar exchange rate. The first payment of 1,000,000, or $1,252,000, was received on October 17, 2006, and the second payment of 800,000, or $1,082,000, was received on April 20, 2007. Accordingly, no additional amounts are due under this note.

(5) STOCK PLANS AND STOCK BASED COMPENSATION

2000 Stock Incentive Plan

In March 2000, the Board of Directors adopted and, in June 2000, the stockholders approved, the 2000 Stock Incentive Plan (the 2000 Plan), which permits the grant of incentive and non-qualified options to purchase the Company s common stock as well as the issuance of restricted shares of common stock.

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Beginning on January 1, 2001 and continuing through January 1, 2010, the number of shares of common stock reserved for issuance under the 2000 Plan is automatically increased by the lesser of 1,000,000 shares or 4% of outstanding stock on January 1 of each year. As of December 31, 2008, the number of shares of common stock reserved for issuance under the 2000 Plan is 18,000,000 and 4,331,856 shares are available for grant under the 2000 Plan.

The 2000 Plan permits the granting of incentive and non-qualified stock options and stock awards to employees, officers, directors, and consultants of the Company and its subsidiaries at prices determined by the Company s Board of Directors. Awards of stock may be made to consultants, directors, employees or officers of the Company and its subsidiaries, and direct purchases of stock may be made by such individuals also at prices determined by the Board of Directors. Options become exercisable as determined by the Board of Directors and expire up to 10 years from the date of grant. Awards issued under the 2000 Plan have generally consisted of stock options that typically vest over a four-year period and that are issued with exercise prices equal to the closing market price of the Company s common stock on the NASDAQ Global Market on the grant date. The Company has, however, also issued stock options that vest over shorter periods, stock options with performance conditions, as well as restricted stock and unrestricted stock awards.

During the year ended December 31, 2008, the Company s Board of Directors granted stock options to purchase 1,826,000 shares of common stock to the Company s employees, executive officers and non-employee directors under the 2000 Plan. Of these stock options, 1,211,000 shares of common stock will vest over a four-year period. Stock options to purchase 204,000 shares of common stock were issued to non-officer employees of the Company with a performance condition and will vest on April 24, 2014 or upon the consummation of a collaboration, licensing or other similar agreement regarding programs under the Company s targeted cancer programs that includes an up-front cash payment of at least $10,000,000 excluding any equity investment in the Company, whichever occurs first, subject to the employee s continued employment. In consideration for the reduction of annual base salaries of the Company s executive officers, the Board of Directors granted stock options to purchase 296,000 shares of common stock to three of the Company s four executive officers, which will vest monthly over a twelve-month period beginning November 24, 2008, subject to the executive officer s continued employment. The remaining stock options to purchase 115,000 shares of common stock were issued to the Company s non-employee directors and vested on the date of grant. All of these stock options were issued with exercise prices equal to the closing market price of the Company s common stock on the NASDAQ Global Market on the respective grant dates.

On October 24, 2008, in consideration for the reduction of his annual base salary, the Board of Directors granted to the Chief Operating and Chief Financial Officer a restricted stock award under the 2000 Plan for 79,113 shares of common stock at a purchase price of $0.01 per share which will vest monthly over a twelve-month period beginning November 24, 2008. The only substantive restriction on the award relates to a one-year service condition to achieve full vesting of the award. The restricted common stock is subject to a right of repurchase by the Company, which lapses after this one-year period, or October 24, 2009. The Company does not intend to exercise its repurchase right to these shares. The closing price of the common stock on October 24, 2008 was $0.79 per share, which is also the weighted average grant date fair value of the restricted stock. Accordingly, the Company will recognize $62,000 in compensation expense over a one-year period, assuming a 0% forfeiture rate. For the year ended December 31, 2008, the Company recognized $10,000 related to this award and 65,928 of the 79,113 shares of common stock granted remained unvested at December 31, 2008.

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2000 Director Stock Option Plan

In March 2000, the Board of Directors adopted and, in June 2000, the shareholders approved the 2000 Director Stock Option Plan (the 2000 Director Plan). The 2000 Director Plan provides for the grant of non-qualified options to non-employee directors as follows: (i) upon his or her initial election, each non-employee director receives an option to purchase 25,000 shares of the Company s common stock that vests over a four-year period and that is issued with an exercise price that is equal to the closing price of the Company s common stock on the grant date; and (ii) each director receives an annual grant of a stock option to purchase 5,000 shares of the Company s common stock that vests and becomes exercisable upon the grant date and that is issued with an exercise price that is equal to the closing price of the Company s common stock on the grant date.

During the year ended December 31, 2008, the Company s Board of Directors granted options to its Board of Directors to purchase 35,000 shares of common stock under the 2000 Director Plan, which fully vested on the grant date of January 25, 2008. The exercise price of each of these options is equal to the closing market price of the Company s common stock on the NASDAQ Global Market on the date of grant. As of December 31, 2008, the number of shares of common stock subject to issuance under the 2000 Director Plan is 500,000 and there are 45,000 shares available for grant.

2000 Employee Stock Purchase Plan

In March 2000, the Board of Directors adopted and, in June 2000, the stockholders approved, the 2000 Employee Stock Purchase Plan (the ESPP). The Company has reserved 1,000,000 of its shares of common stock for issuance under the ESPP. Eligible employees may purchase shares at 85% of the lower closing market price at the beginning or ending date of the purchase period, as defined. The Company has two six-month purchase periods per year. During the year ended December 31, 2008, 224,424 shares were issued under the ESPP and there are 192,677 shares available for future purchase under the ESPP.

A summary of stock option activity under the 2000 Plan and the 2000 Director Plan is summarized as follows:

	Number of Shares	Weighted Average Exercise Price per Share
Outstanding, December 31, 2007 (6,207,111 exercisable at weighted average price of $3.51 per share)	9,240,966	$ 2.93
Granted employees	1,861,000	1.25
Exercised	(109,075)	1.00
Cancelled	(542,132)	2.60
Outstanding, December 31, 2008 (7,218,825 exercisable at weighted average price of $3.23 per share)	10,450,759	$ 2.67
Vested and unvested expected to vest	10,253,375	$ 2.69

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The table below summarizes options outstanding and exercisable at December 31, 2008:

	Options Outstanding			Options Exercisable	
Exercise Price Range	Number of Shares	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price per Share	Number of Shares	Weighted Average Exercise Price per Share
$0.56 - $1.35	1,264,844	7.62	$ 1.04	520,075	$ 1.10
1.39 - 1.39	1,832,875	8.43	1.39	770,999	1.39
1.43 - 1.50	1,780,907	6.97	1.46	798,907	1.49
1.57 - 2.43	2,423,126	6.11	1.96	2,076,499	2.02
2.48 - 4.03	1,750,086	4.39	3.74	1,654,049	3.72
4.05 - 29.26	1,398,921	3.83	7.23	1,398,296	7.23
	10,450,759	6.25	$ 2.67	7,218,825	$ 3.23

The aggregate intrinsic value of options outstanding at December 31, 2008 was $6,000, of which all related to exercisable options, and the weighted average remaining contractual life of vested stock options at December 31, 2008 was 6.04 years. The weighted average grant-date fair values of stock options granted during the years ended December 31, 2008, 2007 and 2006 were $0.91, $1.10 and $1.62, respectively. As of December 31, 2008, there was approximately $2,991,000, including the impact of estimated forfeitures, of unrecognized compensation cost related to unvested employee stock option awards outstanding under the 2000 Plan and 2000 Director Plan that is expected to be recognized as expense over a weighted average period of 2.7 years. The intrinsic value of employee stock options exercised during the years ended December 31, 2008, 2007 and 2006 were $38,000, $13,000 and $45,000, respectively. The total fair value of vested stock options for the years ended December 31, 2008, 2007 and 2006 were $2,003,000, $3,300,000 and $3,423,000, respectively.

In determining the fair value of stock options, the Company generally uses the Black-Scholes option pricing model. As discussed below, for employee stock options with a market performance condition, the Company uses a lattice-based option valuation model. The Black-Scholes option pricing model employs the following key assumptions for employee option grants issued in each of the following years:

	For the Year Ended December 31,		
	2008	2007	2006
Expected term (years) Employees	3.0-6.0	5.5-7.0	5.5-6.25
Expected term (years) Directors	7.0	7.0	5.0
Risk-free interest rate	1.7-3.4%	3.6-4.9%	4.5-5.2%
Expected volatility	71-93%	90-97%	95-102%
Expected dividend yield	None	None	None

For the years ended December 31, 2007 and 2006, the expected terms of the options granted were calculated using the simplified approach, as outlined in Staff Accounting Bulletin (SAB) No. 107, *Share-Based Payments*. Using this approach, for grants issued during the years ended December 31, 2007 and 2006, the Company assigned an expected term of 6.25 years for grants with four-year graded vesting and 5.5 years for grants with one-and two-year vesting. As of January 1, 2008, the simplified approach could no longer be used for estimating expected terms.

The expected volatility is based on the annualized daily historical volatility of the Company s stock price through the end of the reporting period for a time period consistent with the expected term of a grant. Management believes that the historical volatility of the Company s stock price best represents

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the volatility of the stock price. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant. The Company does not anticipate declaring dividends in the foreseeable future.

The stock price volatility and expected terms utilized in the calculation involve management s best estimates at that time, both of which impact the fair value of the option calculated under the Black-Scholes methodology and, ultimately, the expense that will be recognized over the life of the option. SFAS 123(R) also requires that the Company recognize compensation expense for only the portion of options that are expected to vest. Therefore, management calculated an estimated annual pre-vesting forfeiture rate that is derived from historical employee termination behavior since the inception of the Company, as adjusted. If the actual number of forfeitures differs from those estimated by management, additional adjustments to compensation expense may be required in future periods. The Company does not have a policy to repurchase shares of its common stock upon employee stock option exercises. Further, no such repurchases have been made.

Under SFAS 123(R), the lattice-based model was used to value a limited number of stock options issued in June 2002 that remained unvested as of January 1, 2006, and that contain a market condition. These awards accounted for $40,000 and $70,000 of the employee stock-based compensation expense recorded by the Company for the years ended December 31, 2007 and 2006, respectively. The lattice model utilized assumptions including a 7-year expected life, 2.10% risk-free rate, 116% volatility, and a 0% dividend rate. These awards became fully vested during 2007 and no additional expense related to these options was recognized in subsequent periods.

For the years ended December 31, 2008, 2007 and 2006, the Company recorded compensation expense related to its ESPP and calculated the fair value of shares expected to be purchased under the ESPP using the Black-Scholes model with the following assumptions:

	For the Year Ended December 31,		
	2008	2007	2006
Compensation expense recognized under ESPP	$ 73,000	$ 64,000	$ 80,000
Expected term	6 months	6 months	6 months
Risk-free interest rate	0-1.9%	3.3-5.0%	4.6-5.3%
Volatility	75-86%	64-71%	70-85%
Dividends	None	None	None

Stock-based compensation for employees for the years ended December 31, 2008, 2007 and 2006 of $2,182,000, $3,105,000 and $3,820,000, respectively, was calculated using the above valuation models and has been included in the Company s results of operations. No income tax benefit has been recorded as the Company has recorded a full valuation allowance and management has concluded that it is not likely that the net deferred tax asset will be realized (see Note 12). Based on basic and diluted weighted average shares outstanding of 63,378,159, 54,914,666 and 49,066,680 for the years ended December 31, 2008, 2007 and 2006, respectively, the effect on the Company s net loss per share of stock-based compensation expense recorded under SFAS 123(R) was approximately $0.03, $0.06 and $0.08 per share.

Non-Employee Grants

During the years ended December 31, 2007 and 2006, the Company granted stock options and unrestricted stock awards to consultants for services. The options were issued at or above their fair market value on the date of grant and have various vesting dates from date of grant, ranging from 9 months to 4 years. In addition, certain non-employee options vested only upon the achievement of performance objectives. Should the Company terminate the consulting agreements, any unvested

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options will be cancelled. Options issued to non-employees are marked-to-market liabilities, which means that as the Company s stock price fluctuates, the liability and related expense either increases or decreases. The Company recognized expense of $24,000 and $85,000 related to non-employee stock options and stock awards for the years ended December 31, 2008 and 2007, respectively. The Company reversed expense of $58,000 related to non-employee stock options for the year ended December 31, 2006 as a result of a decline in the Company s stock price throughout 2006. As of December 31, 2008, the Company had recorded $13,000 in deferred compensation related to unvested non-employee options.

For the years ended December 31, 2008, 2007 and 2006, the Company recorded employee and non-employee stock-based compensation expense to the following line items in its Costs and Expenses section of the Consolidated Statements of Operations and Comprehensive Loss:

	For the Year ended December 31,		
	2008	2007	2006
Research and development expenses	$ 743,000	$ 803,000	$ 1,105,000
General and administrative expenses	1,463,000	2,387,000	2,657,000
Total stock-based compensation expense	$ 2,206,000	$ 3,190,000	$ 3,762,000

(6) PROPERTY AND EQUIPMENT

Property and equipment consist of the following:

	December 31,	
	2008	2007
Laboratory equipment, computers and software	$ 3,971,000	$ 3,647,000
Laboratory equipment and computers under notes payable		777,000
Leasehold improvements	6,254,000	4,619,000
Leasehold improvements under notes payable		1,623,000
Office furniture and equipment	380,000	368,000
	10,605,000	11,034,000
Less Accumulated depreciation and amortization	(9,157,000)	(8,456,000)
Total	$ 1,448,000	$ 2,578,000

The Company recorded depreciation and amortization expense of $999,000, $1,302,000 and $1,408,000 for the years ended December 31, 2008, 2007 and 2006, respectively.

In the fourth quarter of 2006, the Company initiated a realignment of its research programs, focusing on later-stage preclinical drug development programs and de-emphasizing its earlier discovery research programs. The Company revised its estimates of the depreciable lives on the remaining equipment currently being used in its discovery research programs as a result of two of the Company s discovery programs ending: the sponsored research agreement with the SMA Foundation, which ended in the fourth quarter of 2006, and the April 2005 drug discovery collaboration with Genentech, which ended in the first quarter of 2007. During the year ended December 31, 2006, the Company recorded property and equipment impairment charges of $148,000 related to the impairment of assets that had been used in the Company s discovery

research programs.

During the year ended December 31, 2007, the Company s BMP-7 small molecule screening agreement with Centocor (a Johnson & Johnson subsidiary) concluded in accordance with the terms of

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the contract and was the only remaining discovery research program. The Company determined that it would not fund the program internally and, as a result, during the year ended December 31, 2007, recorded property and equipment impairment charges of $352,000, net of estimated proceeds from the sale of these assets, because this discovery equipment could not be used on other ongoing programs. These impairment charges have been reported within the Research and development line item within the Expenses section of the Company s Consolidated Statement of Operations for the years ended December 31, 2007 and 2006.

The Company will continue to review its estimate of remaining useful lives related to assets currently being used on the Company s remaining programs. Any future changes to the estimated useful lives of the Company s assets could have a material impact on its financial statements.

(7) ACCRUED LIABILITIES

Accrued liabilities consist of the following:

	December 31,	
	2008	**2007**
Accrued compensation	$ 111,000	$ 708,000
Professional fees	137,000	73,000
Facility-related costs	262,000	192,000
Other	114,000	178,000
Total	$ 624,000	$ 1,151,000

(8) DEBT OBLIGATIONS

Boston Private Bank & Trust Company. Short-term debt, including accrued interest, was $404,000 at December 31, 2007. This debt related to two separate 36-month term notes that the Company entered into loan agreements with the Boston Private Bank & Trust Company, one for $2,250,000 at a fixed rate of 7.36% and the other for $1,450,000 at a fixed rate of 7.95% for the respective repayment periods. On April 1, 2008, the Company made the final repayments related to these notes and the Company has no further obligations under these notes.

Becton Dickinson. On June 26, 2001, the Company received $2,000,000 from Becton Dickinson under a convertible subordinated note payable in connection with the exercise of an option to negotiate a collaboration agreement. The note payable was repayable at the option of the Company in either cash or issuance of the Company s common stock, also at the option of the Company, at any time up to its maturity date of June 26, 2006. On January 20, 2006, the Company elected to prepay the then-outstanding principal and interest due under the note in the amount of $2,639,000 by issuing to Becton Dickinson 669,656 shares of the Company s common stock, based on a 10-day trailing average of the Company s closing stock prices resulting in a conversion price of $3.94 per share. The Company has no further obligations under this convertible note payable.

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(9) COMMITMENTS

(a) OPERATING LEASES

The Company has noncancellable operating lease agreements for office and laboratory space. The Company s remaining operating lease commitments for all leased facilities with an initial or remaining term of at least one year are as follows:

Year Ending December 31,	
2009	$ 948,000
2010	948,000
Thereafter	
Total minimum payments	$ 1,896,000

Rent expense for all operating leases was $776,000, $541,000 and $863,000 for the years ended December 31, 2008, 2007 and 2006, respectively, net of settlement proceeds received during 2007 and facility sublease income of $262,000 and $185,000 in 2007 and 2006, respectively.

(b) LICENSE AGREEMENTS

The Company licenses a significant portion of its technology from several universities and foundations. In exchange for the right to use licensed technology in its research and development efforts, the Company has entered into various license agreements. These agreements generally stipulate that the Company pays an annual license fee and is obligated to pay royalties on future revenues, if any, resulting from use of the underlying licensed technology. Such revenues may include, for example, up-front license fees, development milestones and royalties. In addition, some of the agreements commit the Company to make contractually defined payments upon the attainment of scientific or clinical milestones. The Company expenses license fee payments as incurred and expects to expense royalty payments as related future product sales, if any, are recorded. The Company accrues expenses for scientific and clinical milestones over the period that the work required to meet the milestone is completed, provided that the Company believes that the achievement of the milestone is probable. The Company incurred license fee expenses of $165,000, $199,000 and $295,000 for the years ended December 31, 2008, 2007 and 2006, respectively.

(10) WARRANTS

The Company has warrants to purchase an aggregate of 5,322,361 shares of its common stock outstanding as of December 31, 2008. These warrants are summarized as follows:

(a) In connection with the private placement of 13,631,022 shares of its common stock on August 8, 2007, the Company issued warrants to purchase 4,770,859 shares of its common stock at an exercise price of $1.02 per share all of which has been accounted for as equity in accordance with EITF 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock*.

The warrants are exercisable for cash until August 8, 2012. In the event that the closing price of the Company s common stock as listed on NASDAQ equals or exceeds $2.50 per share for thirty consecutive days, then for a period of thirty days thereafter the Company may require the mandatory exercise of the warrants by providing at least twenty business days prior written notice to the holder; provided that the Company

simultaneously requires the mandatory exercise of all warrants then outstanding under this private placement. As of December 31, 2008, none of these warrants have been exercised.

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(b) In connection with the registered direct offering of 5,476,559 shares of its common stock on October 14, 2004, the Company issued warrants to purchase 547,656 shares of its common at an exercise price of $4.59 per share. The warrants expire on October 14, 2009. As of December 31, 2008, none of these warrants have been exercised.

(c) At December 31, 2008, other warrants to purchase 3,846 shares of common stock at an exercise price of $19.51 per share are outstanding. These warrants expire at various dates, ranging from September 2009 until December 2009.

(11) CURIS SHANGHAI

In August 2006, the Company established a wholly-owned subsidiary in Shanghai, China called Curis Pharmaceuticals (Shanghai) Co., Ltd., or Curis Shanghai. Upon establishment of the subsidiary, the Company was required by the Chinese government to contribute $2,100,000 to Curis Shanghai, of which the first contribution of $420,000 was made in November 2006. The Company converted $140,000 of this initial contribution into local currency and this amount will therefore be affected by foreign currency fluctuations. The remaining $280,000 initial investment was in a U.S. dollar-denominated bank account in China. During 2007, the Chinese government approved the Company s request to decrease its capital requirement to $140,000, and $280,000 of the initial investment made in China was returned to the Company in July 2007.

As of December 31, 2008, Curis Shanghai was not operational. There were only nominal transactions related to administrative expenses at Curis Shanghai for the years ended December 31, 2008, 2007 and 2006. There were no intercompany transactions during the years ended December 31, 2008, 2007 and 2006. Curis Shanghai currently has no employees and the Company does not plan to hire any subsidiary employees for the foreseeable future. The Company currently expects that certain operational aspects, including oversight of the third party chemistry provider, will be managed from the Company s Cambridge, Massachusetts location.

(12) INCOME TAXES

For the years ended December 31, 2008, 2007 and 2006, the Company did not record any federal or state tax expense given its continued net operating loss position.

The provision for income taxes for continuing operations was at rates different from the U.S. federal statutory income tax rate for the following reasons:

	For the Year Ended December 31,		
	2008	2007	2006
Statutory federal income tax rate	34.0%	34.0%	34.0%
State income taxes, net of federal benefit	5.7%	5.2%	5.0%
Research and development tax credits	3.3%	7.4%	9.0%
Deferred compensation	(3.2%)	(6.9%)	(6.5%)
NOL expirations	(53.7%)	(70.3%)	(19.5%)
Other	(2.6%)	(0.2%)	(0.6%)
Net increase (decrease) in valuation allowance	16.5%	30.8%	(21.4%)
Effective income tax rate	%	%	%

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Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using future expected enacted rates. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized.

The principle components of the Company s deferred tax assets at December 31, 2008 and 2007, respectively are as follows:

	December 31,	
	2008	2007
Deferred Tax Assets:		
Net operating loss carryforwards	$ 69,826,000	$ 71,296,000
Research and development tax credit carryforwards	9,814,000	9,586,000
Depreciation and amortization	1,819,000	2,663,000
Capitalized research and development expenditures	24,295,000	23,725,000
Deferred revenue		746,000
Impairment of investments	124,000	124,000
Stock options	1,864,000	1,482,000
Accrued expenses and other	140,000	257,000
Total Gross Deferred Tax Asset	107,882,000	109,879,000
Valuation Allowance	(107,882,000)	(109,879,000)
Net Deferred Tax Asset	$	$

The classification of the above deferred tax assets is as follows:

	December 31,	
	2008	2007
Deferred Tax Assets:		
Current deferred tax assets	$ 127,000	$ 996,000
Non-current deferred tax assets	107,755,000	108,883,000
Valuation Allowance	(107,882,000)	(109,879,000)
Net Deferred Tax Asset	$	$

As of December 31, 2008, the Company had federal and state net operating losses (NOLs) of $195,974,000 and $50,952,000, respectively, and federal and state research and experimentation credit carryforwards of approximately $8,028,000 and $2,706,000, respectively, which will expire at various dates starting in 2009 through 2028. The Company had $17,355,000 of federal net operating losses generated in 1993 and $9,631,000 of Massachusetts net operating losses generated in 2003 that expired in 2008. As required by SFAS No. 109, the Company s management has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, and has determined that it is not more likely than not that the Company will recognize the benefits of the deferred tax assets. Accordingly, a valuation allowance of approximately $107,882,000 has been established at December 31, 2008. The benefit of deductions from the exercise of stock options is included in the NOL carryforwards. The benefit from these deductions will be recorded as a credit to additional paid-in capital if and when realized through a reduction of cash taxes.

Utilization of the NOL and R&D credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership change limitations that have

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CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements Continued

occurred previously or that could occur in the future. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. The Company has not completed a study to assess whether a change of control has occurred or whether there have been multiple changes of control since the Company s formation because the Company continues to maintain a full valuation allowance on its NOL and R&D credit carryforwards. In addition, there could be additional ownership changes in the future, which may result in additional limitations in the utilization of the carryforward NOLs and credits, and the Company does not expect to have any taxable income for the foreseeable future.

In June 2006, the FASB issued Interpretation No. 48, Accounting for Uncertainty in Income Taxes, an interpretation of FAS 109 (FIN 48). This statement clarifies the criteria that an individual tax position must satisfy for some or all of the benefits of that position to be recognized in a company s financial statements. The Company adopted FIN No. 48 on January 1, 2007. The implementation of FIN No. 48 did not have a material impact on the Company s consolidated financial statements, results of operations or cash flows. At the adoption date of January 1, 2007, and also at December 31, 2008, the Company had no unrecognized tax benefits. The Company has not, as yet, conducted a study of its research and development credit carryforwards. This study may result in an adjustment to the Company s research and development credit carryforwards, however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position under FIN 48. A full valuation allowance has been provided against the Company s research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the consolidated balance sheet or statement of operations if an adjustment were required.

The tax years 1994 through 2007 remain open to examination by major taxing jurisdictions to which the Company is subject, which are primarily in the United States (U.S.), as carryforward attributes generated in years past may still be adjusted upon examination by the Internal Revenue Service (IRS) or state tax authorities if they have or will be used in a future period. The Company is currently not under examination by the Internal Revenue Service or any other jurisdictions for any tax years. The Company recognizes both accrued interest and penalties related to unrecognized benefits in income tax expense. The Company has not recorded any interest and penalties on any unrecognized tax benefits since its inception.

(13) RETIREMENT SAVINGS PLAN

The Company has a 401(k) retirement savings plan covering substantially all of the Company s employees. Matching Company contributions are at the discretion of the Board of Directors. For the years ended December 31, 2007 and 2006, the Board of Directors authorized matching contributions of $129,000 and $139,000, respectively. The Board of Directors did not authorize matching contributions for the year ended December 31, 2008 as the Company continues to reduce costs.

(14) RELATED PARTY TRANSACTIONS

The Company and Joseph M. Davie, Ph.D., M.D., a member of the Company s Board of Directors, entered into a consulting agreement, which was approved by the Board of Directors on August 23, 2006 with an effective date of June 19, 2006, the date on which Dr. Davie commenced the performance of consulting services for the Company as the Interim Chief Scientific Officer, as amended on October 30, 2006. This agreement expired on June 19, 2007 in accordance with its terms. In consideration for the services rendered by Dr. Davie to the Company, the Company agreed to pay Dr. Davie compensation in the amount of $4,000 per day for each day of consulting work, or $500 per

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CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements Continued

hour for portions thereof. For the years ended December 31, 2007 and 2006, the Company had incurred $8,000 and $53,000, respectively, in related consulting expenses in its Consolidated Statement of Operations.

On September 14, 2006, the Company and Dr. Davie entered into a Scientific Advisory and Consulting Agreement pursuant to which Dr. Davie agreed to serve as Chairman of the Company s Scientific Advisory Board. The term of this agreement is for a period of five years. Either party may terminate this agreement by providing thirty days written notice to the other party. In consideration for the services rendered by Dr. Davie to the Company, the Company agreed to pay Dr. Davie an annual retainer of $25,000. Such retainer became effective upon the expiration of the consulting agreement for services as interim Chief Scientific Officer on June 19, 2007. For the years ended December 31, 2008 and 2007, the Company incurred $25,000 and $13,000, respectively, in Scientific Advisory Board services provided by Dr. Davie. As of December 31, 2008, $6,000 was included in Accounts payable in the Company s Consolidated Balance Sheet. For the year ended December 31, 2006, the Company did not incur costs for Dr. Davie in his role as Chairman of the Scientific Advisory Board because this retainer did not become effective until June 19, 2007.

In connection with the Scientific Advisory Board agreement, the Board also granted to Dr. Davie an option, pursuant to the 2000 Plan, to purchase 35,000 shares of common stock of the Company at an exercise price equal to $1.72, which was the closing price of the common stock of the Company on the NASDAQ Global Market on September 14, 2006, the date of grant. These options will vest quarterly over a four-year period.

(15) SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

The following are selected quarterly financial data for the years ended December 31, 2008 and 2007:

	Quarter Ended			
	March 31, 2008	**June 30, 2008**	**September 30, 2008**	**December 31, 2008**
Revenues	$ 2,067,583	$ 3,107,810	$ 86,721	$ 3,104,503
Loss from operations	(3,823,723)	(2,217,682)	(4,775,516)	(2,302,723)
Loss applicable to common stockholders	(3,430,667)	(1,964,556)	(4,571,451)	(2,156,424)
Basic and diluted net loss per share	$ (0.05)	$ (0.03)	$ (0.07)	$ (0.03)
Shares used in computing basic and diluted net loss per share	63,245,538	63,337,647	63,435,070	63,492,498

	March 31, 2007	**June 30, 2007**	**September 30, 2007**	**December 31, 2007**
Revenues	$ 2,362,786	$ 1,228,724	$ 1,312,202	$ 11,484,842
Income (loss) from operations	(3,884,414)	(4,177,286)	(4,122,660)	3,809,799
Net income (loss) applicable to common stockholders	(3,540,773)	(3,997,544)	(3,718,300)	4,292,374
Basic net income (loss) per share	$ (0.07)	$ (0.08)	$ (0.06)	$ 0.07
Diluted net income (loss) per share	$ (0.07)	$ (0.08)	$ (0.06)	$ 0.07
Shares used in computing basic net income (loss) per share	49,354,125	49,408,100	57,534,767	63,180,451
Shares used in computing diluted net income (loss) per share	49,354,125	49,408,100	57,534,767	63,206,837

The net loss amounts presented above for the quarter ending December 31, 2008 include $3,000,000 of license revenue recognized under the Genentech June 2003 collaboration.

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CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements Continued

The net loss amounts presented above for the quarter ending December 31, 2007 include $10,509,000 of revenue recognized under the Genentech June 2003 collaboration, which includes $3,000,000 for a contingent cash payment that the Company received in October 2007 (see Note 3(a)).

(16) Subsequent Events

In February 2009, Genentech notified the Company that it had initiated a pivotal Phase II clinical trial of GDC-0449, an orally-administered small molecule Hedgehog pathway inhibitor, as a single-agent therapy for patients with metastatic or locally advanced basal cell carcinoma. As a result, the Company will receive a $6,000,000 cash payment from Genentech under the parties June 2003 collaboration agreement during the first quarter of 2009. Genentech is obligated to make the payment because it determined that the pivotal classification satisfied the criteria for a Phase III clinical trial under the parties collaboration agreement.

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ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls & Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2008. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2008, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management s report on internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, is included in Item 8 of this annual report on Form 10-K and is incorporated herein by reference.

Changes in Internal Control Over Financial Reporting

No changes in our internal control over financial reporting occurred during the year ended December 31, 2008 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

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PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information concerning directors that is required by this Item 10 is set forth in our proxy statement for our 2009 annual meeting of stockholders under the headings Directors and Nominees for Director, Board Committees and Section 16(a) Beneficial Ownership Reporting Compliance, which information is incorporated herein by reference. The information concerning our code of ethics is set forth in our proxy statement under the heading Code of Business Conduct and Ethics. The name, age, and position of each of our executive officers is set forth under the heading Executive Officers of the Registrant in Part I of this Annual Report on Form 10-K, which information is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

Information required by this Item 11 is set forth in our proxy statement for our 2009 annual meeting of stockholders under the headings Executive and Director Compensation and Related Matters, Compensation Committee Interlocks and Insider Participation and Compensation Committee Report which information is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Information required by this Item 12 is set forth in our proxy statement for our 2009 annual meeting of stockholders under the headings Securities Authorized for Issuance Under Equity Compensation Plans and Security Ownership of Certain Beneficial Owners and Management, which information is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Information required by this Item 13 is set forth in our proxy statement for our 2009 annual meeting of stockholders under the headings Policies and Procedures for Related Person Transactions, Determination of Independence and Board Committees which information is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Information required by this Item 14 is set forth in our proxy statement for our 2009 annual meeting of stockholders under the heading Independent Registered Public Accounting Firm s Fees and Other Matters, which information is incorporated herein by reference.

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PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) *Financial Statements.*

(a)(2) *Financial Statement Schedules.*

All schedules are omitted because they are not applicable or the required information is shown in the Financial Statement or Notes thereto.

(a)(3) *List of Exhibits*. The list of Exhibits filed as a part of this annual report on Form 10-K is set forth on the Exhibit Index immediately preceding such Exhibits, and is incorporated herein by reference.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CURIS, INC.

By: /s/ DANIEL R. PASSERI
Daniel R. Passeri
President and Chief Executive Officer

Date: February 26, 2009

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ DANIEL R. PASSERI **Daniel R. Passeri**	President, Chief Executive Officer and Director (Principal Executive Officer)	February 26, 2009
/s/ MICHAEL P. GRAY **Michael P. Gray**	Chief Operating Officer and Chief Financial Officer (Principal Financial and Accounting Officer)	February 26, 2009
/s/ JAMES R. MCNAB, JR. **James R. McNab, Jr.**	Chairman of the Board of Directors	February 26, 2009
/s/ SUSAN B. BAYH **Susan B. Bayh**	Director	February 26, 2009
/s/ JOSEPH M. DAVIE **Joseph M. Davie**	Director	February 26, 2009
/s/ MARTYN D. GREENACRE **Martyn D. Greenacre**	Director	February 26, 2009
/s/ KENNETH I. KAITIN **Kenneth I. Kaitin**	Director	February 26, 2009
/s/ JAMES R. TOBIN **James R. Tobin**	Director	February 26, 2009

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EXHIBIT INDEX

Exhibit No.	Description	Incorporated by Reference			Filed with this 10-K
		Form	SEC Filing Date	Exhibit Number	
	Articles of Incorporation and By-laws				
3.1	Restated Certificate of Incorporation of Curis, Inc.	S-4/A (333-32446)	06/19/00	3.3	
3.2	Certificate of Designations of Curis, Inc.	S-3 (333-50906)	08/10/01	3.2	
3.3	Amended and Restated By-laws of Curis, Inc.	S-1 (333-50906)	11/29/00	3.2	
3.4	Amendment to Amended and Restated By-laws of Curis, Inc.	8-K	09/24/07	3.1	
	Instruments defining the rights of security holders, including indentures				
4.1	Form of Curis Common Stock Certificate	10-K	03/01/04	4.1	
	Material contracts Management Contracts and Compensatory Plans				
#10.1	Employment Agreement, dated as of September 18, 2007, between Curis and Daniel R. Passeri	8-K	09/24/07	10.1	
#10.2	Amendment to Employment Agreement, dated as of October 31, 2006, to the employment agreement dated September 20, 2001, by and between Curis and Daniel R. Passeri	8-K	11/02/06	10.2	
#10.3	Amendment to Employment Agreement, dated as of October 27, 2008, to the employment agreement dated September 18, 2007, by and between Curis and Daniel R. Passeri	10-Q	10/28/08	10.1	
#10.4	Offer Letter, dated as December 10, 2003, between Curis and Michael P. Gray	10-K	03/01/04	10.4	
#10.5	Amendment to Offer Letter, dated as of October 31, 2006, to the offer letter dated December 10, 2003, by and between Curis and Michael P. Gray	8-K	11/02/06	10.3	
#10.6	Amendment to Offer Letter, dated as of October 27, 2008, to the offer letter dated December 10, 2003, by and between Curis and Michael P. Gray	10-Q	10/28/08	10.2	
#10.7	Offer Letter, dated May 2, 2001, by and between Curis and Changgeng Qian	10-K	3/14/08	10.5	
#10.8	Amendment to Offer Letter, dated as of May 10, 2002, to the offer letter dated May 2, 2001, by and between Curis and Changgeng Qian	10-K	3/14/08	10.6	
#10.9	Amendment to Offer Letter, dated as of December 14, 2006, to the offer letter dated May 2, 2001, as amended on May 10, 2002, by and between Curis and Changgeng Qian	10-K	3/14/08	10.7	

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Exhibit No.	Description	Incorporated by Reference			Filed with this 10-K
		Form	SEC Filing Date	Exhibit Number	
#10.10	Amendment to Offer Letter, dated as of October 27, 2008, to the offer letter dated May 2, 2001, by and between Curis and Changgeng Qian	10-Q	10/28/08	10.3	
#10.11	Offer Letter, dated January 11, 2001, by and between Curis and Mark W. Noel	10-K	03/02/07	10.6	
#10.12	Amendment to Offer Letter, dated as of October 31, 2006, to the offer letter dated January 11, 2001, by and between Curis and Mark W. Noel	8-K	11/02/06	10.4	
#10.13	Amendment to Offer Letter, dated as of October 27, 2008, to the offer letter dated January 11, 2001, by and between Curis and Mark W. Noel	10-Q	10/28/08	10.4	
#10.14	Offer Letter, dated as of July 25, 2002, between Curis and Mary Elizabeth Potthoff	10-K	03/01/04	10.5	
#10.15	Amendment to Offer Letter, dated as of October 31, 2006, to the offer letter dated July 25, 2002, by and between Curis and Mary Elizabeth Potthoff	8-K	11/02/06	10.5	
#10.16	Agreement and General Release, dated as of June 25, 2007, by and between Curis and Mary Elizabeth Potthoff	10-Q	07/31/07	10.1	
#10.17	Consulting Agreement dated June 19, 2006 by and between Curis and Joseph M. Davie, Ph. D., M.D.	8-K	08/29/06	10.1	
#10.18	First Amendment to Consulting Agreement, dated as of October 30, 2006, between Curis and Joseph M. Davie, Ph.D., M.D.	8-K	11/02/06	10.1	
#10.19	Scientific Advisory Agreement dated September 14, 2006 by and between Curis and Joseph M. Davie, Ph. D., M.D.	8-K	09/19/06	10.2	
#10.20	Agreement for Service as Chairman of the Board of Directors, between Curis, Inc. and James McNab, dated as of June 1, 2005	8-K	06/07/05	10.1	
#10.21	Form of Indemnification Agreement, between Curis, Inc. and each member of the Board of Directors named on Schedule I thereto	10-Q	08/09/05	10.5	
#10.22	Indemnification Agreement between Curis, Inc. and Dr. Stephen Carter, dated January 29, 2008	8-K	1/31/08	10.1	
#10.23	Consulting Agreement dated May 11, 2007 by and between Curis and Dr. Stephen Carter.	10-K	3/14/08	10.19	
#10.24	Curis 2000 Stock Incentive Plan	S-4/A (333-32446)	05/31/00	10.71	
#10.25	Curis 2000 Director Stock Option Plan	S-4/A (333-32446)	05/31/00	10.72	

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Exhibit No.	Description	Incorporated by Reference			Filed with this 10-K
		Form	SEC Filing Date	Exhibit Number	
#10.26	Curis 2000 Employee Stock Purchase Plan	S-4/A (333-32446)	05/31/00	10.73	
#10.27	Form of Incentive Stock Option Agreement granted to directors and named executive officers under Curis 2000 Stock Incentive Plan	10-Q	10/26/04	10.2	
#10.28	Form of Non-statutory Stock Option Agreement granted to directors and named executive officers under Curis 2000 Stock Incentive Plan	10-Q	10/26/04	10.3	
#10.29	Form of Non-statutory Stock Option Agreement granted to non-employee directors under Curis 2000 Director Stock Option Plan	10-Q	10/26/04	10.4	
	Material contracts Leases				
10.30	Lease, dated November 16, 1995, as amended, between Ontogeny, Inc., Moulton Realty Corporation and the trustees of Moulton Realty Trust relating to the premises at 33 and 45 Moulton Street, Cambridge, Massachusetts	S-4 (333-32446)	03/14/00	10.42	
10.31	Lease, dated March 15, 2001, between Curis and Moulton Realty Company relating to the premises at 61 Moulton Street, Cambridge, Massachusetts	10-K	03/30/01	10.3	
10.32	Amendment to Lease, dated August 9, 2002, between Curis and FPRP Moulton LLC relating to the premises at 25, 27, 33, 45 and 61 Moulton Street, Cambridge, Massachusetts	10-Q	11/12/02	10.1	
10.33	Second Amendment to Leases, dated August 17, 2004, between Curis and FPRP Moulton LLC relating to the premises at 25, 27, 33, 45 and 61 Moulton Street, Cambridge, Massachusetts	10-Q	10/26/04	10.1	
	Material contracts Financing Agreements				
10.34	Line of Credit Agreement for the Acquisition of Equipment and Leasehold Improvements, restated on September 23, 2004, between Curis and Boston Private Bank & Trust Company	10-K	03/15/05	10.18	
10.35	Security Agreement, dated restated on September 23, 2004, between Curis and Boston Private Bank & Trust Company	10-K	03/15/05	10.19	
10.36	Secured Non-Revolving Time Note, dated restated on September 23, 2004, made by Curis in favor of Boston Private Bank & Trust Company	10-K	03/15/05	10.20	
10.37	Line of Credit Agreement for the Acquisition of Equipment and Leasehold Improvements, between Curis, Inc. and Boston Private Bank & Trust Company, dated as of June 9, 2005	8-K	06/15/05	10.1	

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Exhibit No.	Description	Incorporated by Reference Form	SEC Filing Date	Exhibit Number	Filed with this 10-K
10.38	Secured Non-Revolving Time Note, issued by Curis, Inc. to Boston Private Bank & Trust Company, dated June 9, 2005	8-K	06/15/05	10.2	
10.39	Security Agreement (Equipment), between Curis, Inc. and Boston Private Bank & Trust Company, dated June 9, 2005	8-K	06/15/05	10.3	
	Material contracts License and Collaboration Agreements				
10.40	License Agreement, dated as of February 12, 1996, between Curis and Leland Stanford Junior University	S-4/A (333-32446)	06/02/00	10.43	
10.41	License Agreement, dated as of January 1, 1995 as amended on July 19, 1995 and August 30, 1996, between Ontogeny and The Trustees of Columbia University in the City of New York	S-4/A (333-32446)	04/03/00	10.45	
10.42	Amended and Restated License Agreement, dated June 1, 2003, between Curis, The Johns Hopkins University and University of Washington School of Medicine	10-K	03/01/04	10.23	
10.43	Amended and Restated License Agreement (2000), dated June 10, 2003, between Curis and the President and Fellows of Harvard University	10-K	03/01/04	10.24	
10.44	Amended and Restated License Agreement (1995), dated June 10, 2003, between Curis and the President and Fellows of Harvard University	10-K	03/01/04	10.25	
10.45	Agreement, dated as of November 27, 2002, by and between Curis and Ortho Biotech Products, L.P.	8-K	12/09/02	10.1	
10.46	Collaborative Research, Development and License Agreement, dated June 11, 2003, between Curis and Genentech, Inc.	8-K	07/10/03	10.1	
10.47	First Amendment to Collaborative Research, Development and License Agreement, effective December 10, 2004, between Curis and Genentech, Inc.	10-K	03/15/05	10.33	
10.48	Second Amendment to Collaborative Research, Development and License Agreement between Curis and Genentech effective as of April 11, 2005	8-K	04/19/05	99.1	
10.49	Drug Discovery and Collaboration Agreement dated April 1, 2005 by and between Curis, Inc. and Genentech, Inc.	10-Q	4/29/05	10.1	
10.50	Collaboration, Research and License Agreement, dated January 12, 2004, between Curis and Wyeth	10-K	03/01/04	10.29	

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Exhibit No.	Description	Incorporated by Reference			Filed with this 10-K
		Form	SEC Filing Date	Exhibit Number	
10.51	Collaboration, Research and License Agreement dated September 18, 2005 by and between Curis, Inc. and Procter & Gamble Company	10-Q	11/14/05	10.1	
	Material contracts Miscellaneous				
10.52	Termination Agreement and Amendments to Finance Documents, dated May 16, 2003, between Elan Corporation, PLC, Neuralab Limited, Elan International Services, LTD, Elan Pharma International Limited, Curis, Inc. and Curis Newco, LTD	8-K	06/03/03	10.1	
10.53	Registration Rights Agreement, dated June 13, 2003, between Curis and Genentech, Inc.	8-K	07/10/03	10.3	
10.54	Common Stock Purchase Agreement, dated June 11, 2003, between Curis and Genentech, Inc.	8-K	07/10/03	10.2	
10.55	Common Stock Purchase and Registration Rights Agreement, dated January 9, 2004, between Curis and Wyeth	10-K	03/01/04	10.34	
10.56	Form of Common Stock and Warrant Purchase Agreement, dated August 11, 2003, entered into by Curis and certain investors, together with a schedule of such investors and the material details of each such agreement	10-Q	11/12/03	10.1	
10.57	Form of Stock Purchase Agreement, dated as of October 12, 2004, entered into by Curis and each of the purchasers, together with a schedule of purchasers who are parties thereto	8-K	10/14/04	10.1	
10.58	Common Stock Purchase Agreement, dated as of August 6, 2007, by and among the Company and the Purchasers (as defined therein), as amended by Amendment to Common Stock Purchase Agreement and Waiver, dated August 7, 2007	8-K	08/09/07	10.1	
10.59	Common Stock Purchase Agreement, dated as of August 7, 2007, by and among the Company and the Purchasers (as defined therein)	8-K	08/09/07	10.2	
10.60	Registration Rights Agreement, dated as of August 6, 2007, by and among the Company and the Purchasers (as defined therein), as amended by Amendment to Registration Rights Agreement, dated August 7, 2007	8-K	08/09/07	10.3	
10.61	Form of Warrant, dated August 8, 2007, issued pursuant to the Common Stock Purchase Agreement, dated as of August 6, 2007, as amended on August 7, 2007	8-K	08/09/07	10.4	
10.62	Form of Warrant, dated August 8, 2007, issued pursuant to the Common Stock Purchase Agreement, dated as of August 7, 2007	8-K	08/09/07	10.5	
	Code of Conduct				
14	Code of Business Conduct and Ethics	10-K	03/01/04	14	

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Exhibit No.	Description	Incorporated by Reference Form	SEC Filing Date	Exhibit Number	Filed with this 10-K
	Additional Exhibits				
21	Subsidiaries of Curis				X
23.1	Consent of PricewaterhouseCoopers LLP				X
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act/15d-14(a) of the Exchange Act				X
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) of the Exchange Act/15d-14(a) of the Exchange Act				X
32.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(b)/15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350				X
32.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(b)/15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350				X

# Indicates management contract or compensatory plan or arrangement.

Confidential treatment has been requested as to certain portions, which portions have been separately filed with the Securities and Exchange Commission.