

CURIS INC  
Form 10-K  
March 14, 2008  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

(Mark one)

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

OR

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

Commission File Number 000-30347

**CURIS, INC.**

(Exact Name of Registrant as Specified in Its Charter)

**DELAWARE**  
(State or other jurisdiction of  
incorporation or organization)

45 Moulton Street

**04-3505116**  
(I.R.S. Employer  
Identification No.)

Edgar Filing: CURIS INC - Form 10-K

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

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

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  No

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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

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

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

**DOCUMENTS INCORPORATED BY REFERENCE**

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



**Table of Contents**

**CURIS, INC.**

**TABLE OF CONTENTS**

**Form 10-K**

**PART I**

|         |  |    |
|---------|--|----|
| ITEM 1. | <u>BUSINESS</u>  | 1  |
| ITEM 2. | <u>PROPERTIES</u>  | 33 |
| ITEM 3. | <u>LEGAL PROCEEDINGS</u>                                   | 33 |
| ITEM 4. | <u>SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS</u> | 34 |

**PART II**

|         |  |     |
|---------|--|-----|
| ITEM 5. | <u>MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDERS MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u> | 36  |
| ITEM 6. | <u>SELECTED FINANCIAL DATA</u>   | 38  |
| ITEM 7. | <u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>                         | 39  |
| ITEM 8. | <u>FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>   | 60  |
| ITEM 9. | <u>CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>                          | 102 |

**PART III**

|          |   |     |
|----------|---|-----|
| ITEM 10. | <u>DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</u>   | 103 |
| ITEM 11. | <u>EXECUTIVE COMPENSATION</u>   | 103 |
| ITEM 12. | <u>SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u> | 103 |
| ITEM 13. | <u>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE</u>                      | 103 |
| ITEM 14. | <u>PRINCIPAL ACCOUNTANT FEES AND SERVICES</u>   | 103 |

**PART IV**

|          |   |     |
|----------|---|-----|
| ITEM 15. | <u>EXHIBITS AND FINANCIAL STATEMENT SCHEDULES</u> | 104 |
|          | <u>SIGNATURES</u>                                 | 105 |

---

**Table of Contents**

**PART I**

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

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

**ITEM 1. BUSINESS**

**Overview**

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

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

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

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

## Table of Contents

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

### Recent Developments

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

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

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

### Product Development Programs

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

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

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

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

---

## **Table of Contents**

In the chart above, Phase I expansion cohort means that our collaborator is currently treating human patients in an expanded Phase I clinical trial, the principal purpose of which is to evaluate the safety and biological activity of the compound being tested in a specific solid tumor type.

Development candidate means that from our testing in several preclinical models of human disease of various compounds from a particular compound class, we have selected a single lead candidate for potential future clinical development and are seeking to complete the relevant safety, toxicology, and other data required to submit an investigational new drug, or IND, application with the FDA seeking to commence a Phase I clinical trial. Preclinical means we are seeking to obtain evidence of therapeutic efficacy in preclinical models of human disease of one or more compounds within a particular class of drug candidates.

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

### **Hedgehog Systemic Antagonist Programs**

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

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

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

### ***Small Molecule Hedgehog Antagonist Program***

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

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

---

**Table of Contents**

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

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

***Antibody Hedgehog Antagonist Program***

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

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

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

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



---

## **Table of Contents**

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

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

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

### **Targeted Cancer Drug Development Platform**

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

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

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

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

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

---

## **Table of Contents**

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

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

### ***CUDC-101***

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

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

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

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

### ***Other Targeted Cancer Programs***

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

## **Table of Contents**

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

### **Other Research Programs**

#### *Wnt Signaling Pathway*

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

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

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

### **Hedgehog Agonist**

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

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

## **Table of Contents**

### **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](http://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](http://www.sec.gov), that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. The public may read and copy any materials we file with the Securities and Exchange Commission at the SEC's Public Reference Room at 110 F Street, N.E., Washington, D.C. 20549. In addition, we provide paper copies of our filings free of charge upon request. We also make available on our website our corporate governance guidelines, the charters for our audit committee, compensation committee and nominating and corporate governance committee, and our code of business conduct and ethics, and such information is available in print to any stockholder of Curis who requests it.

### **Intellectual Property**

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

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

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

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

---

## **Table of Contents**

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

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

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

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

## **Research Program**

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

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

## **Regulatory Matters**

### *FDA Requirements for New Drug Compounds*

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

## **Table of Contents**

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

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

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

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

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

---

**Table of Contents**

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

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

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

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

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

## **Table of Contents**

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

### *New Legislation*

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

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

### *Foreign Regulation of New Drug Compounds*

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

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

### *Hazardous Materials*

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

## **Competition**

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



## **Table of Contents**

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

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

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

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

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

## **Manufacturing**

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

**Table of Contents**

**Sales and Marketing**

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

**Scientific Governance**

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

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

| Name                                    | Position/Institutional Affiliation  |
|---|---|
| Joseph M. Davie, Ph.D., M.D. (Chairman) | Director, Curis, Inc.<br><br>Director, CV Therapeutics, Inc.<br><br>Director, Keel Pharmaceuticals, Inc.<br><br>Director, GENTIAE Clinical Research, Inc.<br><br>Director, Ocera, Inc.<br><br>Director, Stratatech Corporation<br><br>Director, Targeted Genetics, Inc.<br><br>Director, BG Medicine<br><br>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<br><br>Director, Translational Medicine Committee of the Southwest Oncology Group (SWOG)<br><br>Principal investigator, The University of Michigan's SPORE (Specialized Program of Research Excellence) in prostate cancer awarded from the National Cancer Institute |
| George Vande Woude, Ph.D.               | Director, Van Andel Research Institute Co-editor, <i>Advances in Cancer Research</i>  |

**Table of Contents**

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

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

**Employees**

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

---

**Table of Contents**

**ITEM 1A. RISK FACTORS**

**RISKS RELATING TO OUR FINANCIAL RESULTS AND NEED FOR FINANCING**

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

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

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

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

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

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

support our research and development activities for CUDC-101 and other small molecule multi-targeted inhibitors that we are seeking to develop under our targeted cancer drug development platform;

fund our general and administrative costs and expenses; and

potentially expand our infrastructure.

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

**Table of Contents**

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

unanticipated costs in our research and development programs;

the timing and cost of obtaining regulatory approvals for our product candidates;

the cost of additional facility requirements;

the timing, receipt and amount of research funding and contingent cash payments, license, royalty and other payments, if any, from current and potential future collaborators;

the timing, payment and amount of research funding and contingent cash payments, license, royalty and other payments due to licensors of patent rights and technology used in our product candidates;

the timing, receipt and amount of sales revenues and/or royalties, if any, that we may receive in the future if any of our product candidates are successfully developed and commercialized; and

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

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

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

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

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

the cost of research and development that we engage in;

the timing, receipt and amount of research funding and contingent cash payments, license, royalty and other payments, if any, from current and potential future collaborators;

the entry into, or termination of, collaboration agreements;

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

the scope, duration and effectiveness of our collaborative arrangements;

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

costs to comply with changes in government regulations;

changes in management and reductions or additions of personnel;

changes in accounting estimates, policies or principles; and

the introduction of competitive products and technologies by third parties.

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

---

**Table of Contents**

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

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

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

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

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

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

---

**Table of Contents**

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

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

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

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

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

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

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

**RISKS RELATING TO COLLABORATIONS**

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

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



---

**Table of Contents**

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

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

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

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

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

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

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

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

**RISKS RELATED TO OUR BUSINESS, INDUSTRY, STRATEGY AND OPERATIONS**

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

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

---

**Table of Contents**

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

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

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

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

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

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

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

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

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

---

**Table of Contents**

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

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

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

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

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

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

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

a diversion of management from our existing operations;

increased operating complexity of our business, requiring greater personnel and resources;

significant additional cash expenditures to expand our operations and acquire and integrate new businesses and technologies;

---

**Table of Contents**

incurrence of debt, other liabilities and contingent liabilities; and

dilutive stock issuances.

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

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

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

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

**RISKS RELATING TO OUR INTELLECTUAL PROPERTY**

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

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

---

## **Table of Contents**

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

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

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

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

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

obtain patents to protect our technologies and discoveries;

protect trade secrets from disclosure to third-party competitors;

operate without infringing upon the proprietary rights of others; and

prevent others from infringing on our proprietary rights.

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

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

---

**Table of Contents**

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

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

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

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

initiation of litigation or other proceedings against third parties to enforce our patent rights;

initiation of litigation or other proceedings against third parties to seek to invalidate the patents held by these third parties or to obtain a judgment that our product candidates do not infringe the third parties' patents;

participation in interference proceedings to determine the priority of invention if our competitors file U.S. patent applications that claim technology also claimed by us;

initiation of foreign opposition proceedings by third parties that seek to limit or eliminate the scope of our patent protection in a foreign jurisdiction;

initiation of litigation by third parties claiming that our processes or product candidates or the intended use of our product candidates infringe their patent or other intellectual property rights; and

initiation of litigation by us or third parties seeking to enforce contract rights relating to intellectual property that may be important to our business.

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

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

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



---

## **Table of Contents**

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

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

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

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

### **RISKS RELATING TO PRECLINICAL, CLINICAL AND REGULATORY MATTERS**

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

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

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

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

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

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





---

**Table of Contents**

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

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

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

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

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

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

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

---

**Table of Contents**

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

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

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

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

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

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

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

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

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

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

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

---

**Table of Contents**

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

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

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

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

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

**RISKS RELATING TO MANUFACTURING AND SALES**

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

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

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

---

**Table of Contents**

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

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

we and any collaborators may not be able to initiate or continue certain preclinical and/or clinical trials of products that are under development;

we and any collaborators may be delayed in submitting applications for regulatory approvals for our product candidates; and

we and any collaborators may not be able to meet commercial demands for any approved products.

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

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

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

we may not be able to attract and build a significant and skilled marketing staff or sales force;

the cost of establishing a marketing staff or sales force may not be justifiable in light of the revenues generated by any particular product; and

our direct sales and marketing efforts may not be successful.

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

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

government health administration authorities;

---

**Table of Contents**

private health insurers;

health maintenance organizations;

health maintenance organizations;

pharmacy benefit management companies; and

other healthcare-related organizations.

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

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

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

**RISKS RELATED TO OUR COMMON STOCK**

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

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

**Table of Contents**

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

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

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

announcements regarding new technologies by us or our competitors;

market conditions in the biotechnology and pharmaceutical sectors;

rumors relating to us or our competitors;

litigation or public concern about the safety of our potential products;

actual or anticipated variations in our quarterly operating results and any subsequent restatement of such results;

actual or anticipated changes to our research and development plans;

deviations in our operating results from the estimates of securities analysts;

entering into new collaboration agreements or termination of existing collaboration agreements;

adverse results or delays in clinical trials being conducted by us or any collaborators;

any intellectual property or other lawsuits involving us;

third-party sales of large blocks of our common stock;

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



## Edgar Filing: CURIS INC - Form 10-K

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

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

FDA or international regulatory actions; and

general market conditions.

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

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

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

---

## **Table of Contents**

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

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

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

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

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

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

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

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

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

### **ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

### **ITEM 2. PROPERTIES**

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

**ITEM 3. LEGAL PROCEEDINGS**

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

**Table of Contents****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:

| <b>Name</b>                   | <b>Age</b> | <b>Position</b>   |
|-------------------------------|------------|---|
| Daniel R. Passeri, MSc., J.D. | 47         | President and Chief Executive Officer   |
| Michael P. Gray               | 37         | Chief Operating Officer and Chief Financial Officer   |
| Mark W. Noel                  | 49         | Vice President, Technology Management and Business Development  |
| Changgeng Qian, Ph.D., M.D.   | 52         | Vice President, Discovery and Preclinical Research  |
| Daniel R. Passeri, MSc., J.D. |            | Mr. Passeri has served as our President and Chief 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.   |

**Table of Contents**

Mark W. Noel

Mr. Noel has served as our Vice President, Technology Management and Business Development since March 2001. 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 Technology Transfer Branch of the NCI Office of Technology and Industrial Relations), 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.

**Table of Contents****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<br>Common Stock |         |
|-------------------------------------|-----------------------|---------|
|                                     | High                  | Low     |
| <b>Year ended December 31, 2006</b> |                       |         |
| First Quarter                       | \$ 4.10               | \$ 2.28 |
| Second Quarter                      | \$ 2.43               | \$ 1.21 |
| Third Quarter                       | \$ 1.98               | \$ 0.91 |
| Fourth Quarter                      | \$ 1.95               | \$ 1.11 |
| <b>Year ended December 31, 2007</b> |                       |         |
| First Quarter                       | \$ 1.72               | \$ 1.15 |
| Second Quarter                      | \$ 2.35               | \$ 1.13 |
| Third Quarter                       | \$ 1.31               | \$ 0.93 |
| Fourth Quarter                      | \$ 1.20               | \$ 0.86 |

(b) *Holders.* On March 12, 2008, the last reported sale price of our common stock on the NASDAQ Global Market was \$1.17 and there were 302 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, 2002 through December 31, 2007, with the cumulative total return on (i) NASDAQ Market Index U.S. Companies, (ii) NASDAQ Pharmaceutical Index and (iii) NASDAQ Biotechnology Index. The comparison assumes investment of \$100 on December 31, 2002 in our common stock and in each of the indices and, in each case, assumes reinvestment of all dividends.

**Table of Contents**

|                               | 12/31/02 | 12/31/03 | 12/31/04 | 12/31/05 | 12/31/06 | 12/31/07 |
|-------------------------------|----------|----------|----------|----------|----------|----------|
| CURIS, INC.                   | 100.00   | 436.89   | 506.80   | 345.63   | 122.33   | 95.15    |
| NASDAQ PHARMACEUTICAL INDEX   | 100.00   | 144.26   | 155.92   | 171.94   | 172.43   | 168.33   |
| NASDAQ MARKET INDEX-U.S. COS. | 100.00   | 152.01   | 165.75   | 171.72   | 192.65   | 211.26   |
| NASDAQ BIOTECHNOLOGY INDEX    | 100.00   | 146.47   | 160.84   | 188.04   | 185.31   | 183.07   |

**Table of Contents****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.

|   | 2007              | Year Ended December 31, |                    |                    | 2003               |
|---|-------------------|-------------------------|--------------------|--------------------|--------------------|
|   |                   | 2006                    | 2005               | 2004               |                    |
| (in thousands, except per share data)                     |                   |                         |                    |                    |                    |
| <b>Consolidated Statement of Operations Data:</b>         |                   |                         |                    |                    |                    |
| Revenues:   |                   |                         |                    |                    |                    |
| Research and development contracts and government grants  | \$ 3,262          | \$ 9,340                | \$ 10,493          | \$ 3,407           | \$ 1,629           |
| License and maintenance fees(1)                           | 13,127            | 4,324                   | 2,258              | 242                | 8,749              |
| Substantive milestones(2)                                 |                   | 3,000                   | 250                | 50                 |                    |
| Contra-revenues   |                   | (1,728)                 | (6,999)            |                    |                    |
| <b>Net revenues</b>                                       | <b>16,389</b>     | <b>14,936</b>           | <b>6,002</b>       | <b>3,699</b>       | <b>10,378</b>      |
| Costs and expenses:                                       |                   |                         |                    |                    |                    |
| Research and development                                  | 14,779            | 14,590                  | 13,705             | 12,662             | 14,388             |
| General and administrative                                | 9,984             | 10,374                  | 8,090              | 7,757              | 6,883              |
| Amortization of intangible assets                         |                   | 27                      | 75                 | 75                 | 75                 |
| <b>Total costs and expenses</b>                           | <b>24,763</b>     | <b>24,991</b>           | <b>21,870</b>      | <b>20,494</b>      | <b>21,346</b>      |
| <b>Loss from operations</b>                               | <b>(8,374)</b>    | <b>(10,055)</b>         | <b>(15,868)</b>    | <b>(16,795)</b>    | <b>(10,968)</b>    |
| Other income (expense):                                   |                   |                         |                    |                    |                    |
| Interest and other income (expense)                       | 1,495             | 1,422                   | 1,321              | 2,131              | (1,017)            |
| Interest expense  | (85)              | (196)                   | (308)              | (411)              | (694)              |
| <b>Total other income (expense), net</b>                  | <b>1,410</b>      | <b>1,226</b>            | <b>1,013</b>       | <b>1,720</b>       | <b>(1,711)</b>     |
| <b>Net loss</b>   | <b>(6,964)</b>    | <b>(8,829)</b>          | <b>(14,855)</b>    | <b>(15,075)</b>    | <b>(12,679)</b>    |
| <b>Accretion on Series A Redeemable Preferred Stock</b>   |                   |                         |                    |                    | <b>(271)</b>       |
| <b>Net loss applicable to common stockholders</b>         | <b>\$ (6,964)</b> | <b>\$ (8,829)</b>       | <b>\$ (14,855)</b> | <b>\$ (15,075)</b> | <b>\$ (12,950)</b> |
| <b>Basic and diluted net loss per common share</b>        | <b>\$ (0.13)</b>  | <b>\$ (0.18)</b>        | <b>\$ (0.31)</b>   | <b>\$ (0.35)</b>   | <b>\$ (0.36)</b>   |
| <b>Weighted average common shares (basic and diluted)</b> | <b>54,915</b>     | <b>49,067</b>           | <b>48,074</b>      | <b>42,686</b>      | <b>36,016</b>      |

|  | 2007          | 2006          | (in thousands)     |               | 2003          |
|--|---------------|---------------|--------------------|---------------|---------------|
|  |               |               | As of December 31, |               |               |
|  |               |               | 2005               | 2004          |               |
| <b>Consolidated Balance Sheet Data:</b>          |               |               |                    |               |               |
| Cash, cash equivalents and marketable securities | \$ 41,459     | \$ 36,656     | \$ 44,209          | \$ 49,514     | \$ 35,148     |
| Working capital                                  | 35,410        | 32,521        | 36,010             | 46,854        | 33,376        |
| Long-term investment restricted                  | 210           | 202           | 196                | 193           | 191           |
| <b>Total assets</b>                              | <b>53,817</b> | <b>52,268</b> | <b>60,914</b>      | <b>67,332</b> | <b>51,450</b> |
| Debt and lease obligations                       | 404           | 1,980         | 3,227              |               |               |
| Convertible notes payable                        |               |               | 2,605              | 5,710         | 5,334         |



## Edgar Filing: CURIS INC - Form 10-K

|                            |           |           |           |           |           |
|----------------------------|-----------|-----------|-----------|-----------|-----------|
| Accumulated deficit        | (695,848) | (688,883) | (680,054) | (665,199) | (650,124) |
| Total stockholders' equity | 46,845    | 35,897    | 38,000    | 48,312    | 39,300    |

- (1) During the year ended December 31, 2007, we recognized \$10,509,000 of revenue recognized under the Genentech June 2003 collaboration, which includes \$7,509,000 in previously deferred revenue and \$3,000,000 for a contingent cash payment that we received in October 2007.
- (2) During the years ended December 31, 2006, we recognized \$3,000,000 as substantive milestone revenue under our June 2003 Hedgehog antagonist collaboration with Genentech. In 2005, we recognized \$250,000 under our January 2004 Hedgehog agonist collaboration with Wyeth.

**Table of Contents****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 create new medicines, primarily for cancer. In expanding our drug development efforts in the field of cancer through our targeted cancer drug development platform, we are building upon our past experiences in targeting signaling pathways in the areas of cancer, neurological disease and cardiovascular disease.

We seek to conduct research programs both internally and through strategic collaborations. Our most advanced program is our Hedgehog antagonist program that is under collaboration with Genentech. In January 2007, Genentech began a phase I clinical trial to test GDC-0449, a systemically administered Hedgehog antagonist, in cancers. The primary objectives of the phase I clinical trial are to evaluate the safety and tolerability of escalating doses of GDC-0449 and to establish the maximum tolerated dose and dose limiting toxicities. In October 2007, Genentech notified us that these initial objectives were achieved and that Genentech had initiated a Phase I clinical trial expansion cohort to enroll additional patients with advanced basal cell carcinoma to assess preliminary signs of biological activity as well as to continue the accumulation of phase I safety data. Genentech has indicated that it expects to present more comprehensive phase I data at an upcoming scientific conference. Genentech also has indicated that it plans to initiate three phase II clinical trials of GDC-0449 in 2008, which include a phase II trial in metastatic colorectal cancer during the first quarter of 2008 and trials in advanced basal cell carcinoma and in an undisclosed advanced solid tumor of epithelial origin during the second half of 2008.

Our internal drug development efforts are focused on our proprietary targeted cancer drug development platform. This platform focuses on the development of single agent drug candidates targeting one or more molecular components within the signaling pathways associated with certain cancers. These programs are primarily focused on developing a number of proprietary, small molecule, single agent, multi-targeted inhibitor drug compounds, including CUDC-101, the first drug candidate selected as a development candidate from this platform. Each proprietary compound is being designed to inhibit validated cancer targets, including the epidermal growth factor receptor (EGFR), vascular endothelial growth factor receptor (VEGFR), heat shock protein 90 (Hsp90), epidermal growth factor 2 (Her2) and in combination with inhibition of histone deacetylase, or HDAC, which is a validated non-kinase cancer target. We are also seeking to use this platform to develop proprietary single agent, single target drug candidates for cancer indications, including an Hsp90 inhibitor. CUDC-101, our lead drug candidate under internal development, is being designed as a first-in-class therapeutic to inhibit HDAC, EGFR and Her2. In preclinical studies, we have demonstrated that CUDC-101 inhibits 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. We have been actively working toward our goal of filing an IND for CUDC-101, and expect to do so early in the second quarter of 2008.

In furtherance of the development of our targeted cancer drug development platform, since May 2006, we have outsourced certain medicinal chemistry-based research functions to a leading provider of such services in Shanghai, China. More recently, we have engaged another provider in Beijing, China to perform certain biology-based research functions. We have developed these relationships with Chinese providers to support our U.S. operations and we are currently engaging a total of 27 chemists and six biologists in China.

---

## Table of Contents

Since our inception, we have funded our operations primarily through license fees, research and development funding from our strategic collaborators, the private and public placement of our equity securities, debt financings and the monetization of certain royalty rights. We have never been profitable and have incurred an accumulated deficit of \$695,848,000 as of December 31, 2007. We expect to incur significant operating losses for the next several years as we devote substantially all of our resources to our 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 key drivers to our success will include our ability to:

successfully file an IND and advance CUDC-101 into clinical testing in 2008;

advance the preclinical development of other small molecule cancer drug candidates that we are developing under our targeted cancer drug development platform;

commence and complete clinical trials, both for our internally developed programs, our Hedgehog small molecule antagonist program being studied in phase I clinical trials by our collaborator, Genentech, and any future programs we may pursue in collaboration with others in the future; and

successfully commercialize products on the basis of our and any current or planned collaborators' drug development programs. Going forward, we intend to add clinical development and regulatory capacities in 2008 and we will seek to advance one or more of our proprietary multi-targeted cancer programs into early stages of clinical testing. We also plan to continue to seek corporate collaborators for the further development and commercialization of at least one of our multi-targeted cancer programs from our targeted cancer drug development platform. When evaluating potential collaborative opportunities, we plan to seek to retain significant rights and involvement or control in at least the early stages of clinical development.

### *Strategic Collaborations*

Since inception, substantially all of our revenues have been derived from collaborations and other research and development arrangements with third parties. We are currently a party to a June 2003 collaboration with Genentech relating to our Hedgehog signaling pathway antagonist technologies and to an April 2005 collaboration with Genentech relating to the Wnt signaling pathway.

Our current collaboration agreements are summarized as follows:

*Genentech Hedgehog Antagonist Collaboration.* In June 2003, we established a collaboration with Genentech that included continued development of our systemically administered Hedgehog antagonist drug candidates for the treatment of cancer. Genentech is a biotechnology company with broad expertise in the development of cancer therapeutics. Under the terms of the agreement, we granted Genentech an exclusive, royalty-bearing license, with the right to sublicense, to make, use, sell and import, small molecule and antibody inhibitors of the Hedgehog signaling pathway, for applications in cancer therapy. We had responsibilities to perform certain funded preclinical research activities and, to the extent relevant, co-fund clinical development costs for certain products. Genentech has primary responsibility for clinical development, regulatory affairs, manufacturing and supply, formulation and sales and marketing.

Pursuant to the collaboration agreement, Genentech made up-front payments of \$8,500,000, which consisted of a \$3,509,000 non-refundable license fee payment and a payment of \$4,991,000 in exchange for 1,323,835 shares of our common stock. Genentech also made license maintenance fee payments totaling \$4,000,000 over the first two years of the collaboration. We have entered into three amendments to the June 2003 collaboration agreement. Pursuant to the amendments, Genentech increased its funded research commitment and extended its funding obligation through December 2006. As part of these amendments, Genentech provided us with \$5,846,000 in incremental research funding over the period from December 2004 to December 2006. All

---

**Table of Contents**

research funding ended in December 2006, and we do not expect to receive additional future research funding from Genentech or incur any material research costs related to this program. In October 2006, Genentech filed an IND application for which we received a \$3,000,000 cash payment. Assuming that Genentech proceeds with three Phase II clinical trials in 2008 as planned, in connection with the treatment of the first patient in the Phase II colorectal cancer trial, we have the right to receive a \$3,000,000 cash payment from Genentech. We also have the right to receive an additional \$3,000,000 cash payment upon initiation of the Phase II testing of the undisclosed advanced epithelial solid tumor. We have already received a \$3,000,000 cash payment for the initiation of Phase II testing in advanced basal cell carcinoma. Genentech had determined that it was obligated to make this payment since the Phase I clinical trial expansion cohort in advanced basal cell carcinoma, which was initiated in October 2007, satisfied the criteria for a Phase II clinical trial under the parties' collaboration agreement. We are eligible to receive additional payments upon the achievement of further development milestones in this indication. In addition to these payments, we will be eligible to receive cash payments from Genentech only upon the achievement of additional specified clinical development objectives as well as royalties on product sales if any Hedgehog systemic antagonist products are successfully developed and commercialized. Should the current drug candidate successfully continue its development into subsequent stages of clinical testing and regulatory approval, we would be eligible to receive additional cash milestone payments.

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

*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 has also funded \$5,270,000 for research and development activities during the two-year research term, which ended in March 2007. Beginning April 2007, 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. Genentech has also agreed to pay us 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 will assume 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.

*Recent Development Wyeth Pharmaceuticals*

On March 10, 2008, we announced that Wyeth Pharmaceuticals has decided that it will no longer pursue its development efforts on our Hedgehog agonist program and will terminate its January 2004 collaboration

---

## **Table of Contents**

agreement with us. Pursuant to the collaboration agreement, we had licensed our Hedgehog protein and novel small molecule Hedgehog pathway agonists to Wyeth. Wyeth paid us an up-front license fee and provided research funding through February 2008. Research efforts under the collaboration focused on the preclinical development of small molecule and protein Hedgehog agonists, primarily for stroke and cardiovascular indications. Pursuant to the agreement, the collaboration will terminate on May 6, 2008. We intend to pursue other opportunities to enter into a new collaboration or licensing relationship with a third party relating to this technology.

### **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 other product 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, the timing of the receipt of payments from collaborators and the cost and outcome of any clinical trials then being conducted. We anticipate that existing capital resources at December 31, 2007, should enable us to maintain current and planned operations into the second half of 2009. Our ability to continue funding our planned operations is dependent upon the success of our current collaborations with Genentech, our ability to successfully enter into one or more additional collaborations for our technologies, our ability to control our cash burn rate and our ability to raise additional funds through equity, debt or other sources of financing. 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 II, 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, 2007, each of the following collaborators or former collaborators accounted for a portion of our total revenue as follows: Genentech, \$12,408,000, or 76%; Wyeth, \$1,968,000, or 12%; and Procter & Gamble, \$1,878,000, or 11%.

Wyeth's funding of five of our researchers concluded on February 9, 2008, and we currently have no third-party funded research. Accordingly, for the majority of our programs under collaboration, our future revenues are limited to:

the amortization of previously received license payments from Wyeth and Strkyer,

research funding from Wyeth through the February 2008 research term,

potential future cash payments, if any, that are contingent upon the successful completion principally of contractually defined development and regulatory approval objectives, and

royalty payments upon the successful commercialization of any products based upon the collaboration.

In the future, we will seek to generate revenues from a combination of license fees, research and development funding, milestone payments and royalties resulting from strategic collaborations relating to the development of products that incorporate our intellectual property, and from sales of any products that we successfully develop and commercialize, either alone or in collaboration. We expect that any revenues we generate will fluctuate from quarter to quarter as a result of the timing and amount of payments, if any, to be received under our existing and any future strategic collaborations and license arrangements, and the amount and timing of payments that we receive upon the sale of our products, to the extent that any are successfully commercialized.

**Table of Contents**

**Research and Development.** Research and development expense consists of costs incurred to discover, research and develop our product candidates. These expenses consist primarily of salaries and related expenses for personnel including stock-based compensation expense for employee share-based payments beginning January 1, 2006. Research and development expenses also include the costs of supplies and reagents, outside service costs including medicinal chemistry, consulting, and occupancy and depreciation charges. We expense research and development costs as incurred. We believe that our research and development expenses will increase in 2008 as compared to prior years as we continue to progress our drug product candidates under our targeted cancer drug development platform into clinical trials.

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

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

In the chart above, Phase I expansion cohort means that our collaborator is currently treating human patients in an expanded Phase I clinical trial, the principal purpose of which is to evaluate the safety and biological activity of the compound being tested in a specific solid tumor type.

Development candidate means that from our testing in several preclinical models of human disease of various compounds from a particular compound class, we have selected a single lead candidate for potential future clinical development and are seeking to complete the relevant safety, toxicology, and other data required to submit an 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 any collaborators and licensors to successfully complete preclinical and clinical studies of these drug product 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 any 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 any collaborators;

the results of future preclinical and clinical trials;

the terms and timing of any collaborative, licensing and other arrangements that we may establish;

the cost and timing of regulatory approvals;

the cost and timing of establishing sales, marketing and distribution capabilities;

## Edgar Filing: CURIS INC - Form 10-K

the cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop;

the effect of competing technological and market developments; and

---

## **Table of Contents**

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 product candidates. Any failure to complete the development of our product 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 and other related costs for personnel in executive, finance, accounting, business development, legal, information technology, corporate communications and human resource functions. These expenses include stock-based compensation expense for employee share-based payments beginning January 1, 2006. Other costs include facility costs not otherwise included in research and development expense, insurance, and professional fees for legal, patent and accounting services.

### **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 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



---

**Table of Contents**

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;

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

substantive effort is involved in achieving the milestone;

---

**Table of Contents**

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.

*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 collaboration agreements, we have recorded on our balance sheet short- and long-term deferred revenue based on our best estimate of when such revenue will be recognized. Short-term deferred revenue consists of amounts that are expected to be recognized as revenue, or applied against future co-development costs, by December 31, 2008. Amounts that we expect will not be recognized prior to December 31, 2008 are classified as long-term deferred revenue. However, this estimate is based on our operating plan as of December 31, 2007 and on our estimated performance periods under the collaboration in which we have recorded deferred revenues. If our operating plan or our estimated performance period should change in the future, we may recognize a different amount of deferred revenue over the twelve-month period from January 1, 2008 through December 31, 2008. As of December 31, 2007, we have short-term deferred revenue of \$1,853,000 related to our collaborations. As of December 31, 2007, we have no remaining long-term deferred revenue related to our collaborations.

---

## **Table of Contents**

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 consist 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 may change in the future. Such changes to estimates would result in a change in revenue recognition amounts. If these estimates and judgments change over the course of these agreements, it may affect the timing and amount of revenue that we 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))*. Prior to the adoption of SFAS 123(R), we followed Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, (APB 25) and related interpretations in accounting for share-based payments and had elected the disclosure-only alternative under SFAS 123, *Accounting for Stock-Based Compensation*. Accordingly, when options granted to employees had an exercise price equal to the market value of the stock on the date of grant, no compensation expense was recognized in our financial statements. SFAS 123(R) eliminates the ability to account for share-based compensation transactions using APB 25, and generally requires that such transactions be accounted for using a fair-value-based method. We also adopted the modified prospective transition method for recognizing expense.

We have recorded employee stock-based compensation expense of \$3,105,000 and \$3,820,000 for the years ended December 31, 2007 and 2006, respectively. Employee stock-based compensation expense of \$7,000 for the year ended December 31, 2005 was recorded applying APB 25. For the options outstanding as of December 31, 2007, we estimate that we will record approximately \$1,500,000 to \$2,000,000, in stock-based compensation expense under SFAS 123(R) in 2008. We expect that we will issue additional options in 2008 that will increase the amount of stock-based compensation ultimately recognized. The amount of the incremental employee stock-based compensation expense attributable to 2008 employee stock options will depend primarily on the number of stock options issued to employees in 2008, 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. Approximately 56% of the employee stock compensation expense recorded in the year ended December 31, 2007 relates to continued vesting of stock options that were granted prior to January 1, 2006. 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.



---

**Table of Contents**

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 option expense that reflected this estimated forfeiture rate for each of the quarterly periods in 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.

***Long-lived Assets***

Long-lived assets consist of property and equipment, equity securities held in privately-held companies and goodwill. In the ordinary course of our business, we incur substantial costs 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 contract. Under the terms of the screening agreement, Centocor maintained an option to exclusively negotiate a broader BMP-7 screening agreement. However, during the second quarter of 2007, Centocor notified us that it would not opt to negotiate a further BMP-7 small molecule 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. In addition, The net proceeds of \$332,000 from the sale of these impaired equipment was applied to our outstanding debt obligations with the Boston Private Bank & Trust Company. We will continue to review our estimates of remaining useful lives related to assets currently being used on our remaining programs. Any future changes to the estimated useful lives of our assets could have a material impact on our financial statements.

As of December 31, 2007, we hold equity investments in two privately-held former collaborators, Aegera Therapeutics and ES Cell International, or ESI. Equity investments in privately-held companies are reflected in the accompanying consolidated financial statements at cost, as adjusted for impairment. On a quarterly basis, we re-evaluate our investments in privately-held companies to determine if the carrying values have been impaired. During the year ended December 31, 2007, we determined that the carrying value of ESI's stock recorded at our consolidated balance sheet was in excess of the fair value of the asset. Accordingly, we recorded an impairment charge of \$145,000 by writing down the carrying value of our investment in ESI equity securities to from \$150,000 to \$5,000.

In September 2006, we were notified that Aegera was trying to secure additional financing at a value that was significantly less than the current carrying value of Aegera stock we had recorded. We believed that the terms of Aegera's planned financing adversely affected the carrying value of our equity investment in Aegera. As a result, during the third quarter of the year ended December 31, 2006, we wrote down the carrying value of our investment in Aegera equity securities by \$164,000 from \$167,000 to \$3,000.

**Table of Contents**

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 2007, 2006 and 2005, 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 2007, 2006 and 2005.

The above list is not intended to be a comprehensive list 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.

**Results of Operations***Years Ended December 31, 2007 and 2006**Revenues*

Total revenues are summarized as follows:

|  | For the Year Ended<br>December 31, |               | Percentage<br>Increase/<br>(Decrease) |
|--|------------------------------------|---------------|---------------------------------------|
|  | 2007                               | 2006          |                                       |
| Revenues:  |                                    |               |                                       |
| <b>Research and development contracts</b>          |                                    |               |                                       |
| 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%)                                 |
| <b>License fees</b>                                |                                    |               |                                       |
| 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 is 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 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



**Table of Contents**

\$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. All Wyeth-related research funding concluded in February 2008. As a result of the foregoing, we expect that revenues under our research and development contracts will continue to decline for 2008.

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 antagonist 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 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 collaboration with Genentech and our September 2005 collaboration with Procter & Gamble were partially offset by decreases in license fee revenues for two of our 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, |               | Percentage Increase/ (Decrease) |
|--|---|------------------|---------------------------------|---------------|---------------------------------|
|  |   |                  | 2007                            | 2006          |                                 |
| Hh systemic small molecule antagonist  | 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/<br>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



**Table of Contents**

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 antagonist 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, and we expect that we will not incur any material costs subsequent to February 2008 as Wyeth notified us that it was terminating our collaboration effective May 6, 2008.

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. We expect that these cancer programs will consist of a majority of our ongoing future research and development expenses for the foreseeable future.

General and administrative expenses are summarized as follows:

|   | For the Year Ended<br>December 31, |               | Percentage<br>Increase/<br>(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.

**Table of Contents**

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 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.

**Table of Contents***Years Ended December 31, 2006 and 2005**Revenues*

Total revenues are summarized as follows:

|  | For the Year Ended<br>December 31, |                     | Percentage<br>Increase/<br>(Decrease) |
|--|------------------------------------|---------------------|---------------------------------------|
|  | 2006                               | 2005                |                                       |
| Revenues:  |                                    |                     |                                       |
| <b>Research and development contracts</b>          |                                    |                     |                                       |
| Genentech  | \$ 4,758,000                       | \$ 5,856,000        | (19%)                                 |
| Wyeth  | 2,299,000                          | 2,327,000           | (1%)                                  |
| Procter & Gamble                                   | 663,000                            | 265,000             | 150%                                  |
| Centocor   | 400,000                            | 27,000              | 1,381%                                |
| Spinal Muscular Atrophy Foundation                 | 1,191,000                          | 1,955,000           | (39%)                                 |
| Other  | 28,000                             | 63,000              | (56%)                                 |
| Subtotal   | 9,339,000                          | 10,493,000          | (11%)                                 |
| <b>License fees</b>                                |                                    |                     |                                       |
| Genentech  | 1,500,000                          | 562,000             | 167%                                  |
| Wyeth  | 306,000                            | 272,000             | 13%                                   |
| Procter & Gamble                                   | 234,000                            | 24,000              | 875%                                  |
| Micromet   | 2,284,000                          | 1,400,000           | 63%                                   |
| Subtotal   | 4,324,000                          | 2,258,000           | 91%                                   |
| Substantive milestones                             | 3,000,000                          | 250,000             | 1,100%                                |
| <b>Gross Revenues</b>                              | <b>16,663,000</b>                  | <b>13,001,000</b>   | <b>28%</b>                            |
| Contra-revenues from co-development with Genentech | (1,728,000)                        | (6,999,000)         | (75%)                                 |
| <b>Net Revenue</b>                                 | <b>\$ 14,935,000</b>               | <b>\$ 6,002,000</b> | <b>149%</b>                           |

Gross revenues increased by \$3,662,000, or 28%, to \$16,663,000 for the year ended December 31, 2006 from \$13,001,000 for 2005. This increase was primarily as the result of \$3,000,000 in substantive milestone revenue that we recorded in 2006 under our Hedgehog antagonist collaboration with Genentech. In 2005, we recorded a total of \$250,000 in substantive milestone revenue relating to our Wyeth collaboration. In addition, our license revenues increased by \$2,066,000 to \$4,324,000 in 2006 from \$2,258,000 in 2005. This increase was principally due to changes in revenues under two of our collaborations. First, we entered into a settlement agreement with Micromet during the third quarter of 2006, under which we recorded revenues of \$2,284,000. In 2005, we recorded \$1,400,000 in license fee revenues from Micromet, resulting in a year-over-year increase in license fee revenues attributable to Micromet of \$884,000. In addition, we decreased our estimated performance period under our April 2005 collaboration with Genentech, resulting in an acceleration of license fee revenue of \$750,000 in 2006. The remaining increase of \$188,000 in Genentech license fee revenue is due to a full year of amortization of the April 2005 license fee during 2006 compared to only eight months during 2005. Offsetting these increases, research and development contract revenues for the year ended December 31, 2006 decreased \$1,154,000 to \$9,339,000 for 2006 as compared to \$10,493,000 for the year ended December 31, 2005. Two of our research funding arrangements concluded during the fourth quarter of 2006, including the research funding for our Hedgehog antagonist program under collaboration with Genentech and our research funding with the Spinal Muscular Atrophy Foundation. In addition, the number of our scientists for whom we received research funding from Genentech under our Hedgehog antagonist program decreased during 2006.

**Table of Contents**

Our net revenues increased \$8,933,000, or 149%, to \$14,935,000 for 2006 as compared to \$6,002,000 for 2005. This increase was primarily due to a decrease in contra-revenues of \$5,271,000 for the year ended December 31, 2006, as well as an increase in our gross revenues as discussed above, as compared to 2005. Contra-revenues represent amounts owed for the reimbursement of our equal share of costs incurred by Genentech under our collaboration related to the co-development of a basal cell carcinoma drug candidate through August 31, 2006. Contra-revenues for the year ended December 31, 2005 were significantly higher than the same period in 2006 because our participation in co-development ended on August 31, 2006. We do not expect to incur any additional costs related to this program and Genentech will be solely responsible for all future costs and development decisions regarding the basal cell carcinoma program.

*Operating Expenses*

Research and development expenses are summarized as follows:

| Research and Development Program              | Primary Indication                              | Collaborator     | For the Year Ended<br>December 31, |                      | Percentage<br>Increase/<br>(Decrease) |
|---|---|------------------|------------------------------------|----------------------|---------------------------------------|
|   |   |                  | 2006                               | 2005                 |                                       |
| Hh small molecule antagonist                  | Cancer  | Genentech        | \$ 1,695,000                       | \$ 3,625,000         | (53%)                                 |
| Single and multi-target inhibitors            | Cancer  | Internal         | 2,124,000                          |                      | 100%                                  |
| Hh small molecule agonist or protein          | Nervous system disorders/cardiovascular disease | Wyeth            | 2,409,000                          | 2,912,000            | (17%)                                 |
| Wnt signaling pathway                         | Cancer  | Genentech        | 2,763,000                          | 1,885,000            | 47%                                   |
| Hh small molecule agonist                     | Hair loss                                       | Procter & Gamble | 835,000                            | 1,061,000            | (21%)                                 |
| Discovery research                            | Spinal muscular atrophy                         | SMA Foundation   | 1,734,000                          | 2,600,000            | (33%)                                 |
| BMP-7 small molecule agonists                 | Kidney disease and other                        | Centocor         | 963,000                            |                      | 100%                                  |
| Discovery research                            | Various   | Internal         | 814,000                            | 1,408,000            | (42%)                                 |
| Impairment of equipment                       | N/A   |                  | 148,000                            |                      | 100%                                  |
| Stock-based compensation                      | N/A   |                  | 1,105,000                          | 214,000              | 417%                                  |
| <b>Total research and development expense</b> |   |                  | <b>\$ 14,590,000</b>               | <b>\$ 13,705,000</b> | <b>6%</b>                             |

Our research and development expenses increased by \$885,000, or 6%, to \$14,590,000 for 2006 from \$13,705,000 in 2005. This increase was primarily due to an increase in stock-based compensation expense of \$891,000. Our overall spending on research programs remained consistent from period to period due to the reallocation of resources to various programs. In 2006, we increased spending on our targeted cancer drug development platform programs as well as on our collaborator-funded discovery research programs with Genentech and Centocor. Also, in 2006, we decreased spending on our Hedgehog antagonist cancer program, our Hedgehog agonist for neurological disorders, and many of our discovery programs.

General and administrative expenses are summarized as follows:

|  | For the Year Ended<br>December 31, |                     | Percentage<br>Increase/<br>(Decrease) |
|--|------------------------------------|---------------------|---------------------------------------|
|  | 2006                               | 2005                |                                       |
| Personnel  | \$ 2,758,000                       | \$ 3,251,000        | (15%)                                 |
| Occupancy and depreciation                       | 678,000                            | 1,111,000           | (39%)                                 |
| Legal services                                   | 1,558,000                          | 1,510,000           | 3%                                    |
| Consulting and professional services             | 1,450,000                          | 1,081,000           | 34%                                   |
| Insurance costs                                  | 451,000                            | 424,000             | 6%                                    |
| Other general and administrative expenses        | 822,000                            | 706,000             | 16%                                   |
| Stock-based compensation                         | 2,657,000                          | 7,000               | 37,857%                               |
| <b>Total general and administrative expenses</b> | <b>\$ 10,374,000</b>               | <b>\$ 8,090,000</b> | <b>28%</b>                            |



---

**Table of Contents**

General and administrative expenses increased by \$2,284,000, or 28%, to \$10,374,000 for 2006 as compared from \$8,090,000 for 2005. The increase was primarily due to an increase in stock-based compensation expense of \$2,650,000. In addition, professional and consulting services increased \$369,000 related to the legal and accounting fees related to our restatement of our financial statements in the first quarter of 2006 and costs associated with the formation of our Chinese subsidiary. These increases were offset by decreases in personnel and occupancy costs of \$493,000 and \$433,000, respectively. The decrease in personnel costs primarily relates to executive bonuses incurred in 2005. We also recognized a \$500,000 loss in 2005 on an operating lease resulting from the loss of subtenant income.

*Other Income (Expense)*

For the year ended December 31, 2006, interest income was \$1,577,000 as compared to \$1,196,000 for the year ended December 31, 2005, an increase of \$381,000, or 32%. The increase in interest income resulted from higher interest rates for the year ended December 31, 2006 as compared to the year ended December 31, 2005.

For the year ended December 31, 2006, other expense was \$155,000 as compared to other income \$125,000 for the year ended December 31, 2005, a decrease of \$280,000, or 224%. During the year ended December 31, 2006, we wrote down the carrying value of our investment in Aegera equity securities, recognizing a charge of \$164,000.

For the year ended December 31, 2006, interest expense was \$196,000, as compared to \$308,000 for the year ended December 31, 2005, a decrease of \$112,000, or 36%. The decrease resulted from lower outstanding debt obligations during the year primarily due to the conversion of a note payable to Becton Dickinson in January 2006.

*Net Loss Applicable to Common Stockholders*

As a result of the foregoing, we incurred a net loss applicable to common stockholders of \$8,829,000 for the year ended December 31, 2006, as compared to \$14,855,000 for the year ended December 31, 2005.

**Liquidity and Capital Resources**

We have financed our operations primarily through license fees 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, 2007, our principal sources of liquidity consisted of cash, cash equivalents, and marketable securities of \$41,459,000, 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 and short-term commercial paper. We also maintain cash balances with financial institutions in excess of insured limits. We do not anticipate any losses with respect to such cash balances because the balances are invested in highly rated securities. Our 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.

The use of our cash flows for operations primarily consists 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.

To date, the primary source of our cash flows from operations has been payments received from our collaborators and licensors. Recently, however, a majority of our research and development effort and expense has shifted from our programs that are funded under collaborations relating to the Hedgehog pathway and various discovery programs to the development of programs under our targeted cancer drug development platform. While we are seeking a corporate collaborator for one or more of the programs in this platform, we are currently

---

**Table of Contents**

progressing the research and development of these programs on our own. We believe that our research and development expenses will increase in 2008 as we expect to initiate phase I clinical testing for CUDC-101, the first development candidate from our proprietary platform, as well as to select at least one additional development candidate from our proprietary platform during 2008. Should we begin clinical evaluations of CUDC-101 or another of these drug candidates, we expect that our research and development costs would increase significantly in 2008.

In general, our only source of cash flows from operations for the foreseeable future will be up-front license payments from new collaborations, if any, contingent cash payments for the achievement of development objectives, if any are met, and funded research and development that we may receive under collaboration agreements. Except for five researchers who were funded by Wyeth through February 9, 2008, substantially all of our research staff is working on developing drug candidates from our targeted cancer drug development platform. The timing of or entrance into any new collaboration agreements and any contingent cash payments under existing collaboration agreements are not assured, cannot be easily predicted and may vary significantly from quarter to quarter. Potential future cash payments, if any, are contingent upon the successful completion principally of contractually defined development and regulatory approval objectives under existing collaboration agreements, and royalty payments are contingent upon the successful commercialization of any products based upon the collaboration.

Net cash used in operating activities was \$8,594,000 for the year ended December 31, 2007, compared to \$5,980,000 for the year ended December 31, 2006. Cash used in operating activities during the year 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 affected operating cash during the year ended December 31, 2007, including a decrease in deferred revenue of \$9,034,000 as a result of accelerated license fee amortization under our Genentech and Procter & Gamble collaborations. Offsetting this decrease, and increasing our cash position, 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.

Cash used in operating activities during the years ended December 31, 2006 was primarily the result of our net loss for the period of \$8,829,000, partially offset by non-cash charges including stock-based compensation of \$3,762,000 and depreciation of \$1,408,000. In addition, changes in certain operating assets and liabilities offset these increases in operating cash during year ended December 31, 2006. Specifically, our accounts payable and accrued liabilities decreased \$1,603,000 primarily as a result of the cessation on August 31, 2006 of our co-development arrangement with Genentech and our deferred revenue decreased \$1,107,000 as a result of license fee amortization under our various collaborations.

We expect to continue to use cash in operations as we continue to research and develop our existing product candidates and advance our targeted cancer drug development platform programs through preclinical development and, we expect, 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 specified other objectives.

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 2007. Investing activities generated cash of \$3,420,000 for the year ended December 31, 2006, resulting from \$4,120,000 in net investment sales offset by \$694,000 in fixed asset purchases.

---

**Table of Contents**

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. Financing activities used \$921,000 of cash for the year ended December 31, 2006, resulting from debt repayments of \$1,233,000 on our notes offset by proceeds of \$312,000 received upon stock option exercises and purchases under our employee stock purchase plan.

On August 8, 2007, we completed a private placement of units, each with a purchase price of \$1.06375 per share and comprising one share of common stock and a warrant to purchase 0.35 shares of common stock. As a result, we issued an aggregate of 13,631,022 shares of common stock and warrants to purchase an additional 4,770,859 shares of common stock. We intend to use the \$14,422,000 in net proceeds from the private placement primarily to support our clinical and research and development efforts, working capital and other general corporate purposes. The warrants have an exercise price of \$1.02 per share and expire on August 8, 2012. We can require the mandatory exercise of the warrants in the event that our stock closing price on NASDAQ exceeds \$2.50 per share for a period of 30 days. We filed a resale registration statement in Form S-3, which was declared effective by the SEC on September 10, 2007, to register for resale the shares of common stock, and the shares of common stock underlying the warrants, held by the investors.

On March 23, 2005, we converted \$2,250,000 financed under an amended loan agreement with the Boston Private Bank & Trust Company into a 36-month term note that bears interest at a fixed rate of 7.36% for the repayment period. Under the terms of the note payable, we are required to make equal monthly payments of \$62,500 plus any accrued interest beginning on May 1, 2005 extending through April 2008, unless the outstanding principal is paid in full earlier.

On December 9, 2005, we converted \$1,450,000 financed under a separate loan agreement with the Boston Private Bank & Trust Company into a 36-month term note that bears interest at a fixed rate of 7.95% for the repayment period. During the year ended December 31, 2007, we sold certain of our assets and lab supplies for which we received \$321,000 in gross proceeds for the assets and \$11,000 for lab supplies that were not collateralized by this note. The total proceeds of \$332,000 were remitted to Boston Private Bank & Trust and were applied to the principal obligation outstanding under this loan agreement. None of the terms of the loan were changed as a result of the sale of assets collateralized under this agreement. Under the terms of the note payable, we are required to make equal monthly payments of \$40,278 plus any accrued interest beginning on January 1, 2006 extending through the repayment period, which is April 2008 after giving effect to the \$332,000 in additional principal payments, which resulted from our sale of certain of our pledged assets during 2007.

These loans are collateralized by all of our property and equipment assets, except for fixtures. The loan collateral also excludes and property or equipment that are purchased after March 23, 2005 under purchase money arrangements with equipment lenders, however, we have not completed any such purchases. As of December 31, 2007, we were in compliance with the sole covenant under each of these financing agreements. The covenant requires us to maintain a minimum working capital ratio. Should we fail to pay amounts when due or fail to maintain compliance with the covenant under the agreements, the entire obligation becomes immediately due at the option of the Boston Private Bank & Trust Company.



**Table of Contents****Contractual Obligations**

In addition to our loan agreement with Boston Private Bank & Trust Company, we also have contractual obligations including an operating lease related to our facility, research services agreements, consulting agreements, and license agreements. The following table summarizes our contractual obligations due by the period indicated at December 31, 2007:

|   | (amounts in 000 s) |                       |                       |                        |                         |
|---|--------------------|-----------------------|-----------------------|------------------------|-------------------------|
|   | Total              | Less than<br>One Year | One to<br>Three Years | Three to<br>Five Years | More than<br>Five Years |
| Debt obligations under note payable, including interest | \$ 408             | \$ 408                | \$                    | \$                     | \$                      |
| Operating lease obligations                             | 2,844              | 948                   | 1,896                 |                        |                         |
| Outside service obligations(1)                          | 1,122              | 1,122                 |                       |                        |                         |
| Licensing obligations(2)                                | 165                | 165                   |                       |                        |                         |
| <b>Total future obligations</b>                         | <b>\$ 4,539</b>    | <b>\$ 2,643</b>       | <b>\$ 1,896</b>       | <b>\$</b>              | <b>\$</b>               |

(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, 2007, excluding any cash payments that are contingent upon the achievement of defined development objectives under our ongoing collaborations with Genentech and our assignment agreement with Stryker Corporation, should enable us to maintain current and planned operations into second half of 2009. 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 second half of 2009 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. Additional financing may not be available or, if available, it may not be available on favorable terms. In addition, the sale of additional debt or equity securities could result in dilution to our stockholders. If substantial additional funding is not available, our ability to fund research and development and other operations will be significantly affected and, accordingly, our business will be materially and adversely affected. 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, 2007.

**Inflation**

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

---

**Table of Contents**

**New Accounting Pronouncements**

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159 (SFAS No. 159), *The Fair Value Option for Financial Assets and Financial Liabilities including an amendment of FASB Statement No. 115*. SFAS No. 159, which amends SFAS No. 115, allows certain financial assets and liabilities to be recognized, at our election, at fair market value, with any gains or losses for the period recorded in the statement of income. SFAS No. 159 includes available-for-sales securities in the assets eligible for this treatment. Currently, we record the gains or losses for the period in the statement of comprehensive income and in the equity section of the balance sheet. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007, and interim periods in those fiscal years. While we are currently evaluating the provisions of SFAS No. 159, the adoption is not expected to have a material impact on our consolidated financial statements.

In June 2007, the FASB issued EITF Issue No. 07-3 (EITF 07-3), *Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*. EITF 07-3 is limited to non-refundable advance payments for goods and services to be used or rendered in future research and development activities pursuant to an executory contractual arrangement. The EITF affirms that these payments should be capitalized and deferred until the goods have been delivered or the related services have been performed. EITF 07-3 is effective for fiscal years beginning after December 15, 2007, and interim periods in those fiscal years. We do not expect the adoption of EITF 07-3 to have a material impact on our consolidated financial statements.

**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, generally money market funds and corporate debt securities 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. Our marketable securities are subject to interest rate risk and will fall in value if market interest rates increase. However, because of the short-term nature of the marketable securities, we do not believe that interest rate fluctuations would materially impair the principal amount of our investments. 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 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.

As of December 31, 2007, we held Chinese Yuan Renminbi-denominated assets on our balance sheet of \$131,000. The underlying assets are expected to have a holding period of one year or less. The value of these assets could fluctuate based on changes in the exchange rate between the dollar and Chinese Yuan Renminbi. We have not entered into any hedging agreements relating to this risk. We do not believe that a 10% change in foreign currency exchange rates would have a material impact on the fair value of these assets or our net income/loss.

**Table of Contents**

**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, 2007. 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, 2007, 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, 2007 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

---

**Table of Contents**

**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, 2007 and 2006, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2007 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, 2007, 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.

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for share-based compensation in 2006.

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

March 14, 2008

**Table of Contents****CURIS, INC. AND SUBSIDIARIES****Consolidated Balance Sheets**

|   | December 31,         |                      |
|---|----------------------|----------------------|
|   | 2007                 | 2006                 |
| <b>ASSETS</b>   |                      |                      |
| Current Assets:   |                      |                      |
| Cash and cash equivalents   | \$ 17,396,599        | \$ 18,829,332        |
| Marketable securities   | 24,062,577           | 17,826,675           |
| Accounts receivable   | 230,467              | 1,315,412            |
| Prepaid expenses and other current assets   | 349,453              | 541,182              |
| <b>Total current assets</b>   | <b>42,039,096</b>    | <b>38,512,601</b>    |
| Property and equipment, net   | 2,577,602            | 4,393,604            |
| Long-term investment restricted   | 210,007              | 201,844              |
| Goodwill  | 8,982,000            | 8,982,000            |
| Other assets, net   | 7,980                | 178,204              |
|   | <b>\$ 53,816,685</b> | <b>\$ 52,268,253</b> |
| <b>LIABILITIES AND STOCKHOLDERS EQUITY</b>  |                      |                      |
| Current Liabilities:  |                      |                      |
| Debt, current portion   | \$ 403,832           | \$ 1,246,289         |
| Accounts payable  | 3,222,091            | 1,461,195            |
| Accrued liabilities   | 1,150,931            | 1,529,337            |
| Deferred revenue, current portion   | 1,852,518            | 1,755,160            |
| <b>Total current liabilities</b>  | <b>6,629,372</b>     | <b>5,991,981</b>     |
| Debt obligations, net of current portion  |                      | 733,333              |
| Deferred revenue, net of current portion  |                      | 9,131,673            |
| Other long-term liabilities   | 342,750              | 514,127              |
| <b>Total liabilities</b>  | <b>6,972,122</b>     | <b>16,371,114</b>    |
| Commitments (Notes 8 and 9)   |                      |                      |
| Stockholders Equity:  |                      |                      |
| Common stock, \$0.01 par value 125,000,000 shares authorized; 64,288,793 and 63,241,086 shares issued and outstanding, respectively, at December 31, 2007 and 50,381,561 and 49,333,854 shares issued and outstanding, respectively, at December 31, 2006 | 642,888              | 503,816              |
| Additional paid-in capital  | 742,903,399          | 725,271,688          |
| Treasury stock (at cost, 1,047,707 shares)  | (891,274)            | (891,274)            |
| Deferred compensation   | (46,286)             | (111,390)            |
| Accumulated deficit   | (695,847,738)        | (688,883,495)        |
| Accumulated other comprehensive income  | 83,574               | 7,794                |
| <b>Total stockholders equity</b>  | <b>46,844,563</b>    | <b>35,897,139</b>    |
|   | <b>\$ 53,816,685</b> | <b>\$ 52,268,253</b> |

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



**Table of Contents****CURIS, INC. AND SUBSIDIARIES****Consolidated Statements of Operations and Comprehensive Loss**

|   | Years Ended December 31, |                       |                        |
|---|--------------------------|-----------------------|------------------------|
|   | 2007                     | 2006                  | 2005                   |
| <b>Revenues:</b>  |                          |                       |                        |
| Research and development contracts                        | \$ 3,261,643             | \$ 9,339,191          | \$ 10,493,077          |
| License fees  | 13,126,911               | 4,324,173             | 2,258,677              |
| Substantive milestones                                    |                          | 3,000,000             | 250,000                |
| <b>Gross revenues</b>                                     | <b>16,388,554</b>        | <b>16,663,364</b>     | <b>13,001,754</b>      |
| Contra-revenues from co-development with Genentech        |                          | (1,727,727)           | (6,999,308)            |
| <b>Net revenues</b>                                       | <b>16,388,554</b>        | <b>14,935,637</b>     | <b>6,002,446</b>       |
| <b>Costs and Expenses:</b>                                |                          |                       |                        |
| Research and development                                  | 14,779,184               | 14,589,647            | 13,705,074             |
| General and administrative                                | 9,983,931                | 10,373,883            | 8,089,738              |
| Amortization related to intangible assets                 |                          | 27,050                | 75,072                 |
| <b>Total costs and expenses</b>                           | <b>24,763,115</b>        | <b>24,990,580</b>     | <b>21,869,884</b>      |
| <b>Loss from operations</b>                               | <b>(8,374,561)</b>       | <b>(10,054,943)</b>   | <b>(15,867,438)</b>    |
| <b>Other Income (Expense):</b>                            |                          |                       |                        |
| Interest income   | 1,608,805                | 1,576,949             | 1,195,727              |
| Other income (expense)                                    | (113,644)                | (155,124)             | 124,958                |
| Interest expense  | (84,843)                 | (196,204)             | (308,419)              |
| <b>Total other income</b>                                 | <b>1,410,318</b>         | <b>1,225,621</b>      | <b>1,012,266</b>       |
| <b>Net loss applicable to common stockholders</b>         | <b>\$ (6,964,243)</b>    | <b>\$ (8,829,322)</b> | <b>\$ (14,855,172)</b> |
| <b>Net Loss per Common Share (Basic and Diluted)</b>      | <b>\$ (0.13)</b>         | <b>\$ (0.18)</b>      | <b>\$ (0.31)</b>       |
| <b>Weighted Average Common Shares (Basic and Diluted)</b> | <b>54,914,666</b>        | <b>49,066,680</b>     | <b>48,074,181</b>      |
| <b>Net Loss</b>   | <b>\$ (6,964,243)</b>    | <b>\$ (8,829,322)</b> | <b>\$ (14,855,172)</b> |
| Unrealized Gain (Loss) on Marketable Securities           | 75,780                   | 47,196                | 41,242                 |
| <b>Comprehensive loss</b>                                 | <b>\$ (6,888,463)</b>    | <b>\$ (8,782,126)</b> | <b>\$ (14,813,930)</b> |

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

**Table of Contents****CURIS, INC. AND SUBSIDIARIES****Consolidated Statements of Stockholders' Equity**

|  | Common Stock |            |                            | Treasury Stock | Deferred Compensation | Accumulated Deficit | Accumulated Other Comprehensive Income (Loss) | Total Stockholders' Equity |
|--|--------------|------------|----------------------------|----------------|-----------------------|---------------------|---|----------------------------|
|  | Shares       | Amount     | Additional Paid-in Capital |                |                       |                     |   |                            |
| Balance, December 31, 2004   | 48,565,120   | 485,652    | 714,831,427                | (891,274)      | (834,157)             | (665,199,001)       | (80,644)                                      | 48,312,003                 |
| Issuance of common stock in connection with conversion of note payable to Elan Pharma International, Limited (Note 4(d)) | 330,552      | 3,305      | 3,302,218                  |                |                       |                     |   | 3,305,523                  |
| Other issuances of common stock  | 478,673      | 4,786      | 969,995                    |                |                       |                     |   | 974,781                    |
| Mark-to-market on stock options to non-employees   |              |            | (370,658)                  |                | 370,658               |                     |   |                            |
| Amortization of deferred compensation  |              |            |                            |                | 221,202               |                     |   | 221,202                    |
| Unrealized gain on marketable securities   |              |            |                            |                |                       |                     | 41,242  | 41,242                     |
| Net loss   |              |            |                            |                |                       | (14,855,172)        |   | (14,855,172)               |
| 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 FAS 123R  |              |            | 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 FAS 123R  |              |            | 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              |

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



**Table of Contents****CURIS, INC. AND SUBSIDIARIES****Consolidated Statements of Cash Flows**

|  | Years Ended December 31, |                |                 |
|--|--------------------------|----------------|-----------------|
|  | 2007                     | 2006           | 2005            |
| <b>Cash Flows from Operating Activities:</b>                               |                          |                |                 |
| Net loss   | \$ (6,964,243)           | \$ (8,829,322) | \$ (14,855,172) |
| Adjustments to reconcile net loss to net cash used in operating activities |                          |                |                 |
| Depreciation and amortization  | 1,302,102                | 1,407,620      | 939,619         |
| Stock-based compensation expense   | 3,190,295                | 3,762,015      | 221,202         |
| Reserve on loss of subtenant income  |                          | 98,000         | 500,000         |
| Amortization of intangible assets  |                          | 27,050         | 75,072          |
| Noncash interest expense on notes payable                                  |                          |                | 200,796         |
| Impairment on property and equipment                                       | 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  | 1,111,880                | (272,621)      | 223,949         |
| Prepaid expenses and other assets  | 216,953                  | 266,327        | 141,298         |
| Accounts payable and accrued and other liabilities                         | 1,200,778                | (1,603,100)    | 1,596,034       |
| Deferred contract revenue  | (9,034,315)              | (1,106,851)    | 2,817,910       |
| Total adjustments  | (1,629,994)              | 2,849,711      | 6,715,880       |
| Net cash used in operating activities                                      | (8,594,237)              | (5,979,611)    | (8,139,292)     |
| <b>Cash Flows from Investing Activities:</b>                               |                          |                |                 |
| Purchase of marketable securities  | (37,558,691)             | (47,076,284)   | (36,184,927)    |
| Sale of marketable securities  | 31,398,569               | 51,195,829     | 41,161,182      |
| Increase in restricted cash/restricted long-term investments               | (8,163)                  | (5,846)        | (2,832)         |
| Sale of long-term investments  |                          |                | 2,606,681       |
| Expenditures for property and equipment                                    | (66,469)                 | (694,111)      | (2,870,637)     |
| Net proceeds from sale of assets   | 316,121                  |                |                 |
| Net cash provided by (used in) investing activities                        | (5,918,633)              | 3,419,588      | 4,709,467       |
| <b>Cash Flows from Financing Activities:</b>                               |                          |                |                 |
| Proceeds from issuance of common stock, net of issuance costs              | 14,421,782               |                |                 |
| Proceeds from other issuances of common stock                              | 223,810                  | 312,391        | 974,781         |
| Proceeds from issuance of debt   |                          |                | 2,585,418       |
| Repayments of notes payable and capital leases                             | (1,565,455)              | (1,233,334)    | (500,000)       |
| Net cash provided by (used in) financing activities                        | 13,080,137               | (920,943)      | 3,060,199       |
| Net Decrease in Cash and Cash Equivalents                                  | (1,432,733)              | (3,480,966)    | (369,626)       |
| Cash and Cash Equivalents, beginning of period                             | 18,829,332               | 22,310,298     | 22,679,924      |
| Cash and Cash Equivalents, end of period                                   | \$ 17,396,599            | \$ 18,829,332  | \$ 22,310,298   |
| <b>Supplemental cash flow data</b>   |                          |                |                 |
| Cash paid during the year for:   |                          |                |                 |
| Interest   | \$ 95,080                | \$ 209,086     | \$ 144,083      |

## Edgar Filing: CURIS INC - Form 10-K

### Supplemental Disclosure of Noncash Investing and Financing Activities:

|  |    |              |              |
|--|----|--------------|--------------|
| Issuance of common stock in connection with conversion of note payable to Elan Pharma International, Limited (Note 4(d)) | \$ | \$           | \$ 3,305,523 |
| 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.

---

**Table of Contents**

**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 create new medicines, primarily for cancer. In expanding the Company's drug development efforts in the field of cancer through its targeted cancer drug development platform, Curis is building upon its past experiences in targeting signaling pathways in the areas of cancer, neurological disease and cardiovascular disease.

The Company operates in a single reportable segment: developmental biology products. 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 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, 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 grow its business and obtain adequate financing to fund this growth.

**(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.

**(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)*.



---

**Table of Contents**

**CURIS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements Continued**

**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 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.

---

**Table of Contents**

**CURIS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements Continued**

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 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, 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

## Edgar Filing: CURIS INC - Form 10-K

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.

**Table of Contents****CURIS, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements Continued**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 are recorded as deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized during the year ending December 31, 2008 are classified as long-term deferred revenue. As of December 31, 2007, the Company has short-term deferred revenue of \$1,853,000 related to its collaborations (see Note 3). As of December 31, 2007, the Company had no remaining long-term deferred revenue.

Grant Revenue.

The Company received a grant award during 2004 from the Spinal Muscular Atrophy Foundation, which terminated November 2006. Revenue under this grant was recognized as the services were provided and when payment was reasonably assured under the terms of the grant. Grant revenues are included in the Research and development contracts line item in the Revenues section of the Company's consolidated statement of operations.

Summary.

During the years ended December 31, 2007, 2006 and 2005, total gross revenues from major customers as a percent of total gross revenues of the Company were as follows:

|                                    | Year Ended December 31, |      |      |
|------------------------------------|-------------------------|------|------|
|                                    | 2007                    | 2006 | 2005 |
| Genentech                          | 76%                     | 56%  | 49%  |
| Wyeth Pharmaceuticals              | 12%                     | 16%  | 22%  |
| Spinal Muscular Atrophy Foundation | %                       | 7%   | 15%  |
| Procter & Gamble                   | 11%                     | 5%   | 2%   |
| Micromet AG                        | %                       | 14%  | 11%  |
| 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 medicinal chemistry, consulting agreements, allocations of facility costs and fringe benefits, and other costs.



**Table of Contents****CURIS, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements Continued****(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, 2007, with maturity dates ranging between one and 12 months and with a weighted average maturity of 3.8 months are as follows:

|                             | Amortized<br>Cost | Unrealized<br>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 |

The amortized cost, unrealized gains and fair value of marketable securities available-for-sale as of December 31, 2006, with maturity dates ranging between one and 12 months and with a weighted average maturity of 2.9 months are as follows:

|                             | Amortized<br>Cost | Unrealized<br>Gain | Fair Value    |
|-----------------------------|-------------------|--------------------|---------------|
| Corporate bonds and notes   | \$ 17,819,000     | \$ 8,000           | \$ 17,827,000 |
| Total marketable securities | \$ 17,819,000     | \$ 8,000           | \$ 17,827,000 |

The Company has a restricted long-term investment in the amount of \$210,000 and \$202,000 at December 31, 2007 and 2006, respectively. 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, 2007 or 2006.

**(f) FAIR VALUE OF FINANCIAL INSTRUMENTS**

The Company's financial instruments consist mainly of cash and cash equivalents, marketable securities, short-term accounts receivable, common stock in privately-held companies, accounts payable and debt obligations. The estimated fair values of the Company's financial instruments have been determined by the Company using available market information and appropriate valuation methodologies. The Company maintains cash balances with financial institutions in excess of insured limits. The Company does not anticipate any losses with respect to such cash balances because the balances are invested in highly rated securities.

Cash and cash equivalents, short-term accounts receivable and accounts payable are reflected in the accompanying consolidated financial statements at cost, which approximates fair value due to the short-term nature of these instruments.

The fair values of marketable securities and short-term investments are based on current quoted market values. Equity investments in privately-held companies are reflected in the accompanying consolidated



**Table of Contents****CURIS, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements Continued**

financial statements at cost, as adjusted for impairment. As of December 31, 2007, the Company holds equity investments in two privately-held former collaborators of the Company, Aegera Therapeutics ( Aegera ) and ES Cell International ( ESI ). On a quarterly basis, the Company reevaluates the book valuation of its investments in privately-held companies to determine if its carrying value should be changed.

During the year ended December 31, 2007, the Company determined that the carrying value of ESI s stock recorded at the Company s consolidated balance sheet was in excess of the fair value of the asset. Accordingly, the Company recorded a charge to Other expense of \$145,000 by writing down the carrying value of its investment in ESI equity securities to \$5,000 during the year ended December 31, 2007.

During the year ended December 31, 2006, the Company was notified of Aegera s need to secure additional financing at a value that was significantly less than the current carrying value of Aegera stock recorded at the Company s consolidated balance sheet. The Company believed that the terms of Aegera s financing adversely affected the Company s carrying value of its equity investment in Aegera. As a result, during the year ended December 31, 2006, the Company recorded a charge to Other expense of \$164,000 by writing down the carrying value of its investment in Aegera equity securities to \$3,000.

As of December 31, 2007 and 2006, the value of the Company s investments in privately-held companies was \$8,000 and \$153,000, respectively. These amounts are included in Deposits and other assets in the accompanying Consolidated Balance Sheets.

**(g) PROPERTY AND EQUIPMENT**

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:

| <b>Asset Classification</b>                  | <b>Estimated Useful Life</b>                         |
|--|--|
| 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) LONG-LIVED ASSETS OTHER THAN GOODWILL**

Long-lived assets other than goodwill consist of property and equipment, equity investments in certain of the Company s former privately-held collaborators, and long-term deposits. The aggregate balances for these long-lived assets were \$2,796,000 and \$4,774,000 as of December 31, 2007 and 2006, 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 Notes 2(f) and 6). During the years ended December 31, 2007 and 2006, the Company recognized an impairment charge of \$352,000 and \$148,000, respectively, related to certain equipment with no current or planned future use. This equipment was previously used in certain of the Company s discovery programs.

**Table of Contents****CURIS, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements Continued****(i) GOODWILL**

As of December 31, 2007 and 2006, 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 2007, 2006 and 2005, 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, 2007, 2006 and 2005.

**(j) 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.

**(k) 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 convertible debt outstanding throughout 2005, stock options, which are weighted based on the number of days outstanding during the respective reporting period, and warrants and shares issuable under the Company's 2000 Employee Stock Purchase Plan. Antidilutive securities were 15,371,793, 9,561,899 and 11,743,926 as of December 31, 2007, 2006 and 2005, respectively, consisting of the following:

|  | <b>For the years ended December 31,</b> |                  |                   |
|--|---|------------------|-------------------|
|  | <b>2007</b>                             | <b>2006</b>      | <b>2005</b>       |
| Weighted average stock options outstanding | 8,969,102                               | 7,913,407        | 9,340,769         |
| Warrants outstanding                       | 6,399,271                               | 1,630,976        | 1,680,976         |
| Shares issuable under ESPP                 | 3,420                                   | 17,516           | 6,070             |
| Convertible debt                           |   |                  | 716,111           |
| <b>Total antidilutive securities</b>       | <b>15,371,793</b>                       | <b>9,561,899</b> | <b>11,743,926</b> |

**(l) 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



**Table of Contents****CURIS, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements Continued**

instruments be recognized as an expense in the financial statements as services are performed. Prior to January 1, 2006, the Company accounted for employee share-based payments under the recognition and measurement provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and related Interpretations, as permitted by SFAS Statement No. 123, *Accounting for Stock-Based Compensation* (SFAS 123). In accordance with APB 25, no compensation cost was required to be recognized for options granted to employees that had an exercise price equal to the market value of the underlying common stock on the date of grant and only certain pro forma disclosures were required.

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, 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). The results for the prior periods have not been restated.

Effective January 1, 2006, the Company adopted the straight-line attribution method for recognizing compensation expense. Previously, under the pro forma disclosure-only provisions of SFAS 123, the Company used the straight-line attribution method for expense recognition. For all unvested options outstanding as of January 1, 2006, the previously measured but unrecognized pro forma compensation expense, based on the fair value at the original grant date, will be recognized on a straight-line basis over the remaining vesting period. For share-based payments granted subsequent to January 1, 2006, compensation expense, based on the fair value on the date of grant, will be recognized on a straight-line basis over the vesting period.

**(m) OPERATING LEASES**

As of December 31, 2007, 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)).

The following table summarizes changes in the reserve for the loss of subtenant income for the Company's 61 Moulton Street sublet space, for which the subtenant defaulted in August 2006, included under Accrued liabilities within Current liabilities in the Company's consolidated balance sheet for the respective periods:

|   |              |
|---|--------------|
| Reserve balance at December 31, 2005                  | \$ (500,000) |
| <i>Changes for the year ending December 31, 2006:</i> |              |
| Amounts charged against the reserve                   | 353,000      |
| Increases to the reserve                              | (98,000)     |
| Reserve balance at December 31, 2006                  | (245,000)    |
| <i>Changes for the year ending December 31, 2007:</i> |              |
| Amounts charged against the reserve                   | 271,000      |
| Increases to the reserve                              | (50,000)     |
| Reversal of excess reserve                            | 24,000       |
| Reserve balance at December 31, 2007                  | \$           |



---

**Table of Contents**

**CURIS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements Continued**

(n) DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES

SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, as amended by SFAS No. 137, SFAS No. 138 and SFAS No. 149, establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities. As of December 31, 2007, 2006 and 2005, the Company did not have any derivative instruments.

(o) NEW ACCOUNTING PRONOUNCEMENTS

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159 ( SFAS No. 159 ), *The Fair Value Option for Financial Assets and Financial Liabilities*. SFAS No 159, which amends SFAS No. 115, allows certain financial assets and liabilities to be recognized, at the Company's election, at fair market value, with any gains or losses for the period recorded in the statement of income. SFAS No. 159 includes available-for-sales securities in the assets eligible for this treatment. Currently, the Company records the gains or losses for the period in the statement of comprehensive income and in the equity section of the balance sheet. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007, and interim periods in those fiscal years. While the Company is currently evaluating the provisions of SFAS No. 159, the adoption is not expected to have a material impact on its consolidated financial statements.

In June 2007, the FASB issued EITF Issue No. 07-3 ( EITF 07-3 ), *Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*. EITF 07-3 is limited to non-refundable advance payments for goods and services to be used or rendered in future research and development activities pursuant to an executory contractual arrangement. The EITF affirms that these payments should be capitalized and deferred until the goods have been delivered or the related services have been performed. EITF 07-3 is effective for fiscal years beginning after December 15, 2007, and interim periods in those fiscal years. The Company does not expect the adoption of EITF 07-3 to have a material impact on its consolidated financial statements.

**(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, or antagonize, the Hedgehog pathway for the treatment of various cancers. The collaboration consists of two programs: the development of a small molecule Hedgehog antagonist formulated for the topical treatment for basal cell carcinoma; and the development of systemically administered small molecule and antibody Hedgehog antagonists for the treatment of certain other solid tumor cancers. Under this second program, Genentech is currently conducting a Phase I clinical trial of a compound under the collaboration and has indicated that it expects to commence Phase II clinical testing of such compound in one or more solid tumor indications in 2008.

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 \$6,000,000 in such contingent cash payments for the achievement of



---

**Table of Contents**

**CURIS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements Continued**

development objectives under the agreement. 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. Such licensors were paid an aggregate of \$300,000 in connection with the Company's receipt of contingent cash payments from Genentech.

The collaboration agreement provides the Company with the option to co-develop topically administered Hedgehog antagonist 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 the program. Since the termination of its co-development participation, the Company has not incurred any additional co-development costs or internal costs for a topically administered basal cell carcinoma product candidate. Should Genentech determine to develop a topically administered Hedgehog antagonist 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 antagonist product in the field of basal cell carcinoma, the collaboration provides for the development of systemically administered small molecule and antibody Hedgehog antagonists 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 antagonist 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

**Table of Contents**

**CURIS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements Continued**

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.

- (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 antagonist 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 antagonist research and development efforts, all of which are being conducted exclusively by Genentech. Further, the Company terminated all internal research activities involving Hedgehog antagonists immediately upon the conclusion of the research funding in December 2006.

---

**Table of Contents**

**CURIS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements Continued**

Genentech manages all aspects of research and development of Hedgehog antagonists covered by this collaboration. Genentech designed, enrolled and continues to manage all aspects of the ongoing Phase I clinical trial of a small molecule Hedgehog antagonist. 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. During the fourth quarter of 2007, Genentech informed the Company that it had initiated enrollment in an expansion cohort in an ongoing Phase I clinical trial and that it plans to progress the Phase I Hedgehog antagonist into Phase II clinical testing in 2008. The Company's input was not sought on these development decisions and the Company does not expect that Genentech would seek the Company's input in the future on any program covered under this collaboration. Going forward, the Company estimates that its involvement in the joint steering committee will be limited to participation in up to two joint steering committee meetings per year, and the Company does not expect that it will provide substantive input at these meetings. Rather, the Company expects that it will use the periodic joint steering committee meetings as a means of receiving updates on the development of Hedgehog antagonists that is underway at Genentech. Since submission of the IND application in October 2006, there have been two steering committee meetings, each convened at the request of the Company.

Accordingly, 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 antagonist 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 a systemically administered small molecule Hedgehog antagonist 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 meets each of the criteria set forth in the Company's revenue recognition policy related to substantive milestones.

In October 2007, the Company received a payment of \$3,000,000 from Genentech upon the achievement of a Phase II clinical development objective under the agreement. This payment did not meet the criteria to be classified as a substantive milestone, and the Company has recorded this amount as revenue within "License Fees" in the Revenues section of its Consolidated Statement of Operations for the year ended December 31, 2007.

During the years ended December 31, 2007, 2006 and 2005, the Company also recorded revenue within "Research and development contracts" of \$322,000, \$202,000 and \$120,000, 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, 2007, the Company had recorded \$105,000 as amounts receivable from Genentech under this collaboration in "Accounts receivable" in the Company's Current Assets section of its Consolidated Balance Sheets.

**Table of Contents****CURIS, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements Continued**

The Company's right to co-develop the Hedgehog antagonist 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 will be solely responsible for all future costs and development decisions regarding the basal cell carcinoma program. The Company has recorded \$1,728,000 and \$6,999,000 in co-development payments to Genentech for the years ended December 31, 2006 and 2005, respectively, as contra-revenues at 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. DECEMBER 2004 AGREEMENT***(i) Agreement Summary*

On December 10, 2004, the Company entered into an amendment to its June 2003 agreement with Genentech.

The December 2004 amendment, effective from June 12, 2004 to June 11, 2005, increased the Company's commitment of full-time equivalents providing research and development services for the systemic Hedgehog antagonist program from eight to sixteen and increased Genentech's funding commitment from \$2,000,000 to \$4,000,000 for this period. The agreement also provided for the Company to provide xenograft tumor samples to Genentech during the period from June 12, 2004 to June 11, 2005, for which Genentech paid the Company \$100,000 in December 2004. In addition, the second \$2,000,000 maintenance payment due under the June 2003 arrangement was removed with no economic effect since it was replaced by a \$2,000,000 payment for research services made to the Company in December 2004. The remaining \$2,000,000 for research services provided from December 12, 2004 through June 11, 2005 was paid in June 2005.

*(ii) Accounting Summary*

The Company considered the provisions of EITF 00-21 and determined that this agreement should be accounted for as a separate agreement and not part of its June 2003 agreement 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 equivalents providing research and development services, included a separate performance obligation for the Company 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 2005. The Company applied the provisions of SAB No. 104 and recognized the incremental funding as revenues under this collaboration as the incremental research services were performed from December 2004 through June 2005. 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 2005. During the year ended December 31, 2005, the Company recorded \$1,674,000 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 2006. As of December 31, 2007, 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.

---

**Table of Contents**

**CURIS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements Continued**

(c) 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 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 years ended December 31, 2006 and 2005, the Company recorded \$898,000 and \$2,212,000 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 2004. As of December 31, 2007, 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.

(d) 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.

---

**Table of Contents**

**CURIS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements Continued**

*(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 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 2005 or 2004. As of December 31, 2007, the Company had no amounts receivable from Genentech under this collaboration.

**(e) 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 March 7, 2008, Wyeth provided the Company with written notice that it will terminate this license agreement effective May 6, 2008. On the termination date, the licenses granted by the Company to Wyeth shall terminate and all terminated license rights will revert to the Company. The Company intends to seek to license this technology to a third party collaborator.

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, 2007.

*(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

---

**Table of Contents**

**CURIS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements Continued**

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 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 is being recognized as the research services are 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, 2007, 2006 and 2005, the Company recorded revenue of \$1,968,000, \$2,604,000 and \$2,849,000, respectively, related to the Company's research efforts under the Wyeth arrangement, of which \$439,000, \$306,000 and \$272,000, respectively, were recorded in License Fees and \$1,332,000, \$2,298,000 and \$2,327,000, respectively, were recorded in Research and development contracts in the Company's Revenues section of its Consolidated Statement of Operations. Additionally, for the year ended December 31, 2005, the Company recorded \$250,000 in the Substantive milestones section of its Consolidated Statement of Operations. Included within Research and development contracts, the Company recorded \$197,000, \$298,000 and \$327,000 for the years ended December 31, 2007, 2006 and 2005, respectively, as revenue related to expenses incurred on behalf of Wyeth that were paid by the Company and for which Wyeth is obligated to

---

**Table of Contents**

**CURIS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements Continued**

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, 2007, the Company had recorded \$77,000 as amounts receivable from Wyeth in Accounts receivable in the Company's Current Assets section of its Consolidated Balance Sheets.

As of December 31, 2007, the Company has not provided any consideration to Wyeth.

(f) 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 has primary responsibility for research and development activities 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 us \$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 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



---

**Table of Contents****CURIS, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements Continued**

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, \$4,316,000 and \$2,412,000 during the years ended December 31, 2007, 2006 and 2005, respectively. Of this amount, approximately \$938,000, \$1,500,000 and \$563,000 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, 2006 and 2005, respectively. In addition, the Company recorded \$639,000, \$2,811,000 and \$1,849,000 related to research services performed by the Company's full-time equivalent researchers for the years ended December 31, 2007, 2006 and 2005, 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.

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 Company's revenue recognition policy related to substantive milestones. Accordingly, the Company would recognize such contingent payments as revenue ratably over the remaining performance period at the time such contingent payment is received. 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

---

**Table of Contents**

**CURIS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements Continued**

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, 2007, 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.

**(g) 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 will assume all future costs subsequent to the December 27, 2007 effective date related to maintenance and prosecution of the patent portfolio. The Company recorded the \$1,750,000 received as short-term deferred revenue in the Company's Current Liabilities section of its Consolidated Balance Sheet as of December 31, 2007 because the Company has not delivered all of the assets to Stryker as required by the agreement. The Company completed the transfer of all assets in the first quarter of 2008, at which time no material ongoing performance obligations remain under the agreement.

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 have 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.

**(4) FORMER COLLABORATIONS**

**(a) PROCTER & GAMBLE**

*(i) Agreement Summary*

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



**Table of Contents****CURIS, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements Continued**

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.

*(ii) Accounting Summary*

The Company considered its arrangement with Procter & Gamble to be a revenue arrangement with multiple deliverables. The Company's deliverables under this collaboration included an exclusive license to evaluate and develop potential treatments for hair growth regulation and skin disorders and certain performance obligations, including research and development services and participation on at least one steering committee. The Company applied the provisions of EITF No. 00-21 and determined that its deliverables represented a single unit of accounting. The Company determined that these performance obligations represented a single unit of accounting, since the Company believed that the license did not have stand-alone value to Procter & Gamble without the Company's research services and steering committee participation during certain phases of the development process and because objective and reliable evidence of the fair value of the Company's research and steering committee participation could not be determined. Because the Company could not reasonably estimate the total level of effort required over the performance period, it was recognizing revenue on a straight-line basis over the performance period, which it had originally estimated to be six years through September 2011. The original performance period was based on the Company's expectation that it would exercise a co-development option under the agreement, which provided that the Company would jointly fund development costs and participate on a clinical development steering committee through Phase IIb clinical trials. The steering committee effort was also expected to be consistent over the performance period. The Company has attributed an aggregate of \$2,183,000 to the undelivered research and steering committee services. This amount is comprised of (i) a \$500,000 up-front fee, (ii) \$683,000 in research funding, and (iii) a \$1,000,000 contingent cash payment that the Company received in March 2006 upon the achievement of a preclinical development objective.

As a result of Procter & Gamble's May 9, 2007 decision to terminate the license agreement, the Company's estimated performance period was changed during the year ended December 31, 2007 to coincide with the November 9, 2007 termination 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.

The Company recorded revenue under this collaboration of \$1,878,000, \$898,000 and \$289,000 during the years ended December 31, 2007, 2006 and 2005, respectively. Of these amounts, \$1,242,000, \$235,000 and \$24,000 was 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, 2006 and 2005. Of the remaining amounts, \$548,000, \$107,000 and \$28,000 were related to research services performed by the Company's two full-time equivalents for the years ended December 31, 2007, 2006 and 2005, respectively, and \$88,000, \$556,000 and \$237,000

---

**Table of Contents**

**CURIS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements Continued**

for the years ended December 31, 2007, 2006 and 2005, 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. As of December 31, 2007, the Company had recorded \$34,000 as amounts receivable from Procter & Gamble in Accounts receivable in the Company's Current Assets section of its Consolidated Balance Sheets.

As of December 31, 2007, the Company has not provided any consideration, such as payments under co-development arrangements, to Procter & Gamble.

(b) ORTHO BIOTECH PRODUCTS, L.P.

(i) *Agreement Summary*

In November 2002, the Company licensed certain of its broad bone morphogenetic protein, or BMP, technology portfolio to Ortho Biotech Products, L.P.. The transaction related to all of the Company's proprietary BMP compounds including BMP-7, which has been studied in animal models as a treatment for chronic kidney disease and systemic complications, such as renal osteodystrophy, a form of bone disease, and blood vessel complications that have been associated with chronic kidney disease. The agreement provided for Ortho Biotech to provide the Company with an up-front payment of \$3,500,000, which was paid in December 2002, and contingent cash payments assuming various objectives are met.

On May 18, 2007, Ortho Biotech Products provided the Company with written notice that it intended to terminate the license agreement. Pursuant to the license agreement, the agreement terminated on August 16, 2007 and the licenses granted by the Company to Ortho Biotech Products terminated. The Company entered into a transaction with Stryker to continue development of this technology (see Note 3(g)).

(ii) *Accounting Summary*

The Company had no deliverables under the license agreement and applied the provisions of SAB No. 104 for recognizing revenue under this collaboration. The Company recognized the up-front payment of \$3,500,000 as revenue in 2002 because the Company had no continuing performance obligations under the contract.

The Company has not recognized any revenues under its arrangement with Ortho Biotech for the years ended December 31, 2007, 2006, or 2005.

As of December 31, 2007, the Company has not provided any consideration to Ortho Biotech Products.

(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.



**Table of Contents****CURIS, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements Continued***(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 years ended December 31, 2006 and 2005, the Company recognized \$1,191,000 and \$1,955,000, respectively, 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 year ended December 31, 2007.

*(d) ELAN INTERNATIONAL SERVICES*

On May 16, 2003, the Company and affiliates of Elan Corporation, plc entered into a termination agreement to conclude the joint venture that the Company and Elan had originally formed in July 2001. The purpose of the joint venture, called Curis Newco, was to research and develop molecules that stimulate the Hedgehog signaling pathway in the field of neurology. Prior to the termination, the Company and Elan owned 80.1% and 19.9%, respectively, of the outstanding shares of Curis Newco. As a result of the termination, Elan transferred its 19.9% share of Curis Newco to the Company, such that Curis Newco became a wholly-owned subsidiary of the Company and Curis Newco was consolidated into the Company's consolidated financial statements. Curis Newco was dissolved on November 5, 2004 and is therefore no longer a subsidiary of the Company as of the November 4, 2004 dissolution date.

In July 2001, the Company entered into a convertible note payable with Elan Pharma International Limited, or EPIL, of which \$4,900,000 was outstanding at the May 16, 2003 termination date. As part of the termination, of the \$4,900,000 outstanding, the Company repaid \$1,500,000 in cash and EPIL forgave \$400,000. The Company then entered into an amended and restated convertible note payable with EPIL for the remaining principal amount of \$3,000,000. The terms of the amended and restated convertible note payable were substantially the same as those under the original note payable except that the interest rate was reduced from 8% to 6% and the conversion rate was increased to \$10.00 from \$8.63. On January 7, 2005, EPIL elected to convert the entire balance of its outstanding convertible note, including interest, totaling \$3,305,523, into shares of the Company's common stock. In accordance with the terms of the amended and restated convertible note payable with EPIL, 330,552 shares of the Company's common stock were issued to EPIL based on a conversion rate of \$10.00 per share. The Company has no further obligations to EPIL.

Lastly, as a result of the termination, all rights granted by both the Company and Elan at the formation of Curis Newco under separate license agreements with Curis Newco terminated. In addition, intellectual property created by Curis Newco is owned by the Company. According to provisions in the termination agreement the Company will pay Elan future compensation, in the form of future royalty payments, in the event of any direct sales or third party commercialization agreements related to certain compounds.

*(e) 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, \$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

**Table of Contents****CURIS, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements Continued**

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 EUR 4,500,000, subject to certain conditions. As a result of Micromet's financing in October 2004, the Company received a EUR 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 EUR 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. 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



---

**Table of Contents**

**CURIS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements Continued**

1,000,000 shares or 4% of outstanding stock on January 1 of each year. As of December 31, 2007, the number of shares of common stock reserved for issuance under the 2000 Plan is 17,000,000 and 4,724,837 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, 2007, the Company's Board of Directors granted stock options to purchase 2,219,000 shares of common stock to the Company's employees, executive officers and non-employee directors under the 2000 Plan. Stock options to purchase 930,000 shares of common stock will vest over a four-year period, stock options to purchase 390,000 shares of common stock will vest over a two-year period and stock options to purchase 151,500 shares of common stock will vest one year from their grant date. Stock options to purchase 612,500 shares of common stock were issued to the executive officers of the Company with a performance condition and will vest on December 6, 2012 or upon the consummation of a collaboration, licensing or other similar agreement regarding programs under the Company's targeted cancer drug development platform 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 officer's continued employment. The remaining stock options to purchase 135,000 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.

In addition, the Company's non-employee directors were granted a total of 60,000 shares of common stock under the 2000 Plan at par value, or \$0.01 per share. The closing market price of the Company's common stock on the NASDAQ Global Market on June 6, 2007, the date of the grant, was \$1.39 per share. There were no restrictions or vesting requirements related to these awards. Accordingly, the Company recognized \$83,000 in compensation expense related to the issuance of the 60,000 shares of common stock for the year ended December 31, 2007.

During the year ended December 31, 2007, the Company's Board of Directors granted stock options to purchase 75,000 shares of common stock under the 2000 Plan to non-employees.

**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.

**Table of Contents****CURIS, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements Continued**

During the year ended December 31, 2007, the Company's Board of Directors granted options to its Board of Directors to purchase 30,000 shares of common stock under the 2000 Director Plan, which fully vested on the grant date of June 6, 2007. On December 17, 2007, the Company appointed a new director to its Board, and, upon joining the Board, the director received an initial grant of options to purchase 25,000 shares of the Company's common stock, which will vest in four equal installments beginning on June 2, 2008 with full vesting on June 2, 2011. 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, 2007, the number of shares of common stock subject to issuance under the 2000 Director Plan is 500,000 and there are 50,000 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, 2007, 159,547 shares were issued under the ESPP and there are 417,101 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<br>Shares | Weighted<br>Average<br>Exercise<br>Price per<br>Share |
|--|---------------------|---|
| Outstanding, December 31, 2006 (5,949,585 exercisable at weighted average price of \$4.11 per share) | 9,098,968           | \$ 3.53   |
| Granted employees  | 2,274,000           | 1.38  |
| Granted non-employees  | 75,000              | 1.24  |
| Exercised  | (50,663)            | 1.24  |
| Cancelled  | (2,156,339)         | 3.79  |
| Outstanding, December 31, 2007 (6,207,111 exercisable at weighted average price of \$3.51 per share) | 9,240,966           | \$ 2.93   |

The table below summarizes options outstanding and exercisable at December 31, 2007:

| Exercise Price Range | Options Outstanding    |  |  | Options Exercisable    |  |
|----------------------|------------------------|--|--|------------------------|--|
|                      | Number<br>of<br>Shares | Weighted<br>Average<br>Remaining<br>Contractual<br>Life (in years) | Weighted<br>Average<br>Exercise Price<br>per Share | Number<br>of<br>Shares | Weighted<br>Average<br>Exercise Price<br>per Share |
| \$ 0.56 - \$ 1.34    | 809,594                | 6.47   | \$ 1.15  | 479,906                | \$ 1.06  |
| 1.39 - 2.10          | 4,013,907              | 8.21   | 1.48   | 1,670,530              | 1.54   |
| 2.11 - 3.96          | 2,212,209              | 4.71   | 3.00   | 2,192,771              | 3.01   |
| 3.97 - 5.89          | 1,750,435              | 6.44   | 4.42   | 1,409,083              | 4.50   |
| 6.91 - 17.94         | 442,257                | 2.68   | 12.53  | 442,257                | 12.53  |
| 20.00 - 29.26        | 12,564                 | 2.59   | 21.89  | 12,564                 | 21.89  |

|           |      |    |      |           |    |      |
|-----------|------|----|------|-----------|----|------|
| 9,240,966 | 6.61 | \$ | 2.93 | 6,207,111 | \$ | 3.51 |
|-----------|------|----|------|-----------|----|------|

**Table of Contents****CURIS, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements Continued**

The aggregate intrinsic value of options outstanding at December 31, 2007 was \$112,000, of which \$99,000 related to exercisable options, and the weighted average remaining contractual life of vested stock options at December 31, 2007 was 5.46 years. The weighted average grant-date fair values of stock options granted during the years ended December 31, 2007, 2006 and 2005 were \$1.10, \$1.62 and \$2.89, respectively. As of December 31, 2007, there was approximately \$3,765,000, 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 4.08 years. The intrinsic value of employee stock options exercised during the years ended December 31, 2007, 2006 and 2005 were \$13,000, \$45,000 and \$949,000, respectively. The total fair value of vested stock options for the years ended December 31, 2007, 2006 and 2005 were \$3,300,000, \$3,423,000 and \$4,814,000, 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:

|                         |           | Year Ended December 31, |          |      |
|-------------------------|-----------|-------------------------|----------|------|
|                         |           | 2007                    | 2006     | 2005 |
| Expected term (years)   | Employees | 5.5-7.0                 | 5.5-6.25 | 5.0  |
| Expected term (years)   | Directors | 7.0                     | 5.0      | 5.0  |
| Risk-free interest rate |           | 3.6-4.9%                | 4.5-5.2% | 3.8% |
| Expected volatility     |           | 90-97%                  | 95-102%  | 95%  |
| 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. For the year ended December 31, 2005, the expected term of the options granted was calculated using an estimate of the expected term as calculated under SFAS 123. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant.

For the years ended December 31, 2007 and 2006, 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 the volatility of the stock price. For the year ended December 31, 2005, the expected volatility of the options granted was calculated using an estimate of historical volatility as calculated under SFAS 123. 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.

**Table of Contents****CURIS, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements Continued**

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 utilizes 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 will be recognized in subsequent periods.

For the years ended December 31, 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:

|  | Year Ended December 31, |                   |
|--|-------------------------|-------------------|
|  | December 31, 2007       | December 31, 2006 |
| Compensation expense recognized under ESPP | \$ 64,000               | \$ 80,000         |
| Expected term                              | 6 months                | 6 months          |
| Risk-free interest rate                    | 3.3-5.0%                | 4.6-5.3%          |
| Volatility                                 | 64-71%                  | 70-85%            |
| Dividends                                  | None                    | None              |

Stock-based compensation for employees for the years ended December 31, 2007 and 2006 of \$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 54,914,666 and 49,066,680 for the years ended December 31, 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 \$0.06 and \$0.08 per share.

The following table shows the pro forma effect on the Company's net income and net income per share for the year ended December 31, 2005, had compensation expense been determined based upon the fair value at the grant date for awards consistent with the methodology prescribed by SFAS 123. The pro forma effect may not be representative of expense in future periods since the estimated fair value of stock options on the date of grant is amortized to expense over the vesting period, and additional options may be granted or options may be cancelled in future years:

|  | Year Ended<br>December 31,<br>2005 |
|--|------------------------------------|
| Net loss applicable to common stockholders as reported   | \$ (14,855,000)                    |
| Add back: employee stock-based compensation included in net loss, as reported                            | 7,000                              |
| Less: employee stock-based compensation expense determined under fair value based methods for all awards | (4,814,000)                        |
| Pro forma net loss   | \$ (19,662,000)                    |
| Net loss per common share (basic and diluted)  |                                    |
| As reported  | \$ (0.31)                          |
| Pro forma  | (0.41)                             |

**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



**Table of Contents****CURIS, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements Continued**

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 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 \$85,000 and \$214,000 related to non-employee stock options and stock awards for the years ended December 31, 2007 and 2005, 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, 2007, the Company had recorded \$46,000 in deferred compensation related to unvested non-employee options.

For the years ended December 31, 2007, 2006 and 2005, 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:

|   | <b>For the Year ended December 31,</b> |                     |                   |
|---|--|---------------------|-------------------|
|   | <b>2007</b>                            | <b>2006</b>         | <b>2005</b>       |
| Research and development expenses             | \$ 803,000                             | \$ 1,105,000        | \$ 214,000        |
| General and administrative expenses           | 2,387,000                              | 2,657,000           | 7,000             |
| <b>Total stock-based compensation expense</b> | <b>\$ 3,190,000</b>                    | <b>\$ 3,762,000</b> | <b>\$ 221,000</b> |

**(6) PROPERTY AND EQUIPMENT**

Property and equipment consist of the following:

|  | <b>December 31,</b> |                     |
|--|---------------------|---------------------|
|  | <b>2007</b>         | <b>2006</b>         |
| Laboratory equipment, computers and software           | \$ 3,647,000        | \$ 7,911,000        |
| Laboratory equipment and computers under notes payable | 777,000             | 1,759,000           |
| Leasehold improvements                                 | 4,619,000           | 4,635,000           |
| Leasehold improvements under notes payable             | 1,623,000           | 1,623,000           |
| Office furniture and equipment                         | 368,000             | 938,000             |
|  | 11,034,000          | 16,866,000          |
| Less Accumulated depreciation and amortization         | (8,456,000)         | (12,472,000)        |
| <b>Total</b>   | <b>\$ 2,578,000</b> | <b>\$ 4,394,000</b> |

The Company recorded depreciation and amortization expense of \$1,302,000, \$1,408,000 and \$940,000 for the years ended December 31, 2007, 2006 and 2005, 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

## Edgar Filing: CURIS INC - Form 10-K

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.



**Table of Contents****CURIS, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements Continued**

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 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.

In September 2004, the Company extended its lease for the 45 Moulton Street facility until December 2010. The lease previously ended in April 2007. As a result, the Company extended the depreciable lives of its leasehold improvements at the 45 Moulton Street facility to the lesser of their useful lives or the remaining lease term.

**(7) ACCRUED LIABILITIES**

Accrued liabilities consist of the following:

|                        | December 31,        |                     |
|------------------------|---------------------|---------------------|
|                        | 2007                | 2006                |
| Accrued compensation   | \$ 708,000          | \$ 578,000          |
| Professional fees      | 73,000              | 200,000             |
| Facility-related costs | 192,000             | 484,000             |
| Other                  | 178,000             | 267,000             |
| <b>Total</b>           | <b>\$ 1,151,000</b> | <b>\$ 1,529,000</b> |

**(8) DEBT OBLIGATIONS**

Short- and long-term debt, including accrued interest, consists of the following at December 31, 2007 and 2006:

|   | December 31, |                   |
|---|--------------|-------------------|
|   | 2007         | 2006              |
| Notes payable to financing agencies for capital purchases | \$ 404,000   | \$ 1,980,000      |
| Less current portion                                      | (404,000)    | (1,246,000)       |
| <b>Total long-term debt obligations</b>                   | <b>\$</b>    | <b>\$ 734,000</b> |

*Boston Private Bank & Trust Company.* On March 23, 2005, the Company converted \$2,250,000 borrowed under an amended loan agreement with the Boston Private Bank & Trust Company into a 36-month term note that bears interest at a fixed rate of 7.36% for the repayment period. Under the terms of the note payable, the Company is required to make equal monthly payments of \$62,500 plus any accrued interest beginning on May 1, 2005, and extending through the 36-month term.

## Edgar Filing: CURIS INC - Form 10-K

On December 9, 2005, the Company converted \$1,450,000 borrowed under a separate loan agreement with the Boston Private Bank & Trust Company into a 36-month term note that bears interest at a fixed rate of 7.95% for the repayment period. Under the terms of the note payable, the Company is required to make equal monthly payments of \$40,278 plus any accrued interest beginning on January 1, 2006,

**Table of Contents****CURIS, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements Continued**

and extending through the 36-month term. However, the Company sold certain of its assets during 2007 and prepaid \$332,000 of the principal obligation under this note. Because of these prepayments, the Company expects to fully pay this term note in April 2008.

As of December 31, 2007, the net book value of assets collateralized under this note was \$421,000, and the Company owed \$151,000, including \$1,000 in interest, under this note.

During the year ended December 31, 2007, the Company sold certain of its assets with a net book value of \$229,000 after effect of impairment. Gross proceeds from the sale of these assets, as well as various lab supplies that had no book value, were \$332,000 and were directly remitted to Boston Private Bank & Trust and applied to the principal obligation outstanding under this loan agreement. None of the terms of the loan were changed as a result of the sale of assets collateralized under this agreement. The Company also recorded expenses of \$5,000 related to these sales resulting in a net gain on sale of assets of \$88,000, which was reflected as a reduction of Research and development expenses in the Company's Consolidated Statement of Operations for the year ended December 31, 2007. Any future proceeds from the sale of collateralized assets will be applied to the Company's outstanding principal obligations under its loan agreements with the Boston Private Bank & Trust Company.

As of December 31, 2007, the Company is in compliance with the sole covenant under each of the agreements with the Boston Private Bank & Trust Company. The covenant requires the Company to maintain a minimum working capital ratio. Should the Company fail to pay amounts when due or fail to maintain compliance with the covenant under the agreements, the entire obligation becomes immediately due at the option of the Boston Private Bank & Trust Company.

*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.

Maturities of short-term debt are as follows:

|  |                   |
|--|-------------------|
| <b>Year Ending December 31,</b>  |                   |
| 2008   | \$ 408,000        |
| Thereafter   |                   |
| <b>Total minimum payments</b>  | <b>408,000</b>    |
| Less Amount representing interest  | (4,000)           |
| <b>Principal obligation, including accrued interest, as of December 31, 2007</b> | <b>\$ 404,000</b> |

**Table of Contents****CURIS, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements Continued****(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:

| <b>Year Ending December 31,</b> |                     |
|---------------------------------|---------------------|
| 2008                            | \$ 948,000          |
| 2009                            | 948,000             |
| 2010                            | 948,000             |
| Thereafter                      |                     |
| <b>Total minimum payments</b>   | <b>\$ 2,844,000</b> |

Rent expense for all operating leases was \$541,000, \$863,000 and \$871,000 for the years ended December 31, 2007, 2006 and 2005, respectively, net of settlement proceeds received during 2007 and facility sublease income of \$262,000, \$185,000 and \$412,000 in 2007, 2006 and 2005, 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 \$199,000, \$295,000 and \$190,000 for the years ended December 31, 2007, 2006 and 2005, respectively.

**(10) WARRANTS**

The Company has warrants to purchase an aggregate of 6,399,271 shares of its common stock outstanding as of December 31, 2007. 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*.

Pursuant to the Registration Rights Agreement, as amended, the Company agreed to file a registration statement with the SEC within 30 days after the closing of the private placement to register the resale of the shares and the shares issuable upon exercise of the warrants. The Company

## Edgar Filing: CURIS INC - Form 10-K

also agreed to use its best efforts to have the registration statement declared effective within 120 days after the filing date of the registration statement, or within 150 days of the filing

**Table of Contents****CURIS, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements Continued**

date if the SEC determines to review the registration statement. In the event the registration statement is in default of these timelines, the Company agreed to pay each investor as liquidated damages an amount equal to 1% of the purchase price paid by each such investor in the private placement per 30-day period or portion thereof during which the registration default remains uncured thereafter, subject to an aggregate limit of 10% of the aggregate purchase price paid by each such investor in the private placement as liquidated damages. The Company filed a resale registration statement on Form S-3 on August 24, 2007 to register for resale the shares of common stock, and the shares of common stock underlying the warrants, held by the investors, which was declared effective on September 10, 2007 by the SEC. Accordingly, the Company will not pay any liquidated damages under the registration default provisions of the registration rights agreement.

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, 2007, none of these warrants have been exercised.

- (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, 2007, none of these warrants have been exercised.
- (c) In connection with the private placement of 3,589,700 shares of its common stock on August 14, 2003, the Company issued warrants to purchase 1,076,910 shares of its common stock at an exercise price of \$4.45 per share. The warrants expire on August 14, 2008. As of December 31, 2007, none of these warrants have been exercised.
- (d) At December 31, 2007, 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, 2007, Curis Shanghai was not operational. There were only nominal transactions related to administrative expenses at Curis Shanghai for the years ended December 31, 2007 and 2006. There were no intercompany transactions during the years ended December 31, 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.

**Table of Contents****CURIS, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements Continued****(12) INCOME TAXES**

For the years ended December 31, 2007, 2006 and 2005, 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:

|  | <b>For the Year Ended</b> |             |             |
|--|---------------------------|-------------|-------------|
|  | <b>December 31,</b>       |             |             |
|  | <b>2007</b>               | <b>2006</b> | <b>2005</b> |
| Statutory federal income tax rate          | 34.0%                     | 34.0%       | 34.0%       |
| State income taxes, net of federal benefit | 5.2%                      | 5.0%        | 4.5%        |
| Research and development tax credits       | 7.4%                      | 9.0%        | 4.1%        |
| Deferred compensation                      | (6.9%)                    | (6.5%)      | (0.5%)      |
| NOL expirations                            | (70.3%)                   | (19.5%)     | (11.5%)     |
| Other                                      | (0.2%)                    | (0.6%)      | 4.9%        |
| Net increase in valuation allowance        | 30.8%                     | (21.4%)     | (35.5%)     |
| Effective income tax rate                  | %                         | %           | %           |

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, 2007 and 2006, respectively are as follows:

|   | <b>December 31,</b> |               |
|---|---------------------|---------------|
|   | <b>2007</b>         | <b>2006</b>   |
| <b>Deferred Tax Assets:</b>                       |                     |               |
| Net operating loss carryforwards                  | \$ 71,296,000       | \$ 70,580,000 |
| Research and development tax credit carryforwards | 9,586,000           | 9,661,000     |
| Depreciation and amortization                     | 2,663,000           | 2,596,000     |
| Capitalized research and development expenditures | 23,725,000          | 23,894,000    |
| Deferred revenue                                  | 746,000             | 4,384,000     |
| Impairment of investments                         | 124,000             | (77,000)      |
| Stock options                                     | 1,482,000           | 775,000       |
| Accrued expenses and other                        | 257,000             | 210,000       |
| Total Gross Deferred Tax Asset                    | 109,879,000         | 112,023,000   |
| Valuation Allowance                               | (109,879,000)       | (112,023,000) |
| Net Deferred Tax Asset                            | \$                  | \$            |

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

Edgar Filing: CURIS INC - Form 10-K

|                                 | December 31,  |               |
|---------------------------------|---------------|---------------|
|                                 | 2007          | 2006          |
| Deferred Tax Assets:            |               |               |
| Current deferred tax assets     | \$ 996,000    | \$ 218,000    |
| Non-current deferred tax assets | 108,883,000   | 111,805,000   |
| Valuation Allowance             | (109,879,000) | (112,023,000) |
| Net Deferred Tax Asset          | \$            | \$            |



---

**Table of Contents**

**CURIS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements Continued**

As of December 31, 2007, the Company had federal and state net operating losses ( NOLs ) of \$200,838,000 and \$48,033,000, respectively, and federal and state research and experimentation credit carryforwards of approximately \$8,029,000 and \$2,349,000, respectively, which will expire at various dates starting in 2008 through 2027. The Company had \$13,414,000 of federal net operating losses generated in 1992 and \$5,022,000 of Massachusetts net operating losses generated in 2002 that expired in 2007. 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 \$109,879,000 has been established at December 31, 2007. 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 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, 2007, 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 1993 through 2006 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.

---

**Table of Contents**

**CURIS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements Continued**

**(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, 2006 and 2005, the Board of Directors authorized matching contributions of \$129,000, \$139,000 and \$114,000, respectively.

**(14) RELATED PARTY TRANSACTIONS**

The Company and Stephen K. Carter, a member of the Company's Board of Directors, entered into a consulting agreement effective May 11, 2007. This agreement will expire one year from the effective date. Either party may terminate the agreement upon 30 days' written notice to the other party. In consideration for the services rendered by Dr. Carter to the Company, the Company agreed to pay Dr. Carter compensation in the amount of \$2,000 per day for each day of consulting work, or \$250 per hour for portions thereof, not to exceed \$20,000 during the one-year term. The Company made payments to Dr. Carter under this consulting agreement prior to his appointment to the Board in December 2007. These payments totaled \$3,000 for the year ended December 31, 2007. The consulting agreement was still effective as of December 31, 2007.

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 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 year ended December 31, 2007, the Company incurred \$13,000 in Scientific Advisory Board services provided by Dr. Davie. Of this amount, \$6,000 was included in Accounts payable in the Company's Consolidated Balance Sheet as of December 31, 2007. 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.

During the years ended December 31, 2006 and 2005, the Company made consulting payments to Douglas A. Melton, Ph.D., who was then a member of the Company's Board of Directors, for service

**Table of Contents****CURIS, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements Continued**

as chairman on its Scientific Advisory Board. This agreement expired on July 31, 2006 and Dr. Melton is no longer serving on the Company's Scientific Advisory Board. These payments were in addition to compensation earned in his capacity as a director. On June 7, 2007, Dr. Melton's directorship with the Company expired. These consulting payments totaled \$44,000 and \$75,000, respectively, for the years ended December 31, 2006 and 2005.

**(15) SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)**

The following are selected quarterly financial data for the years ended December 31, 2007 and 2006:

|  | Quarter Ended             |                          |                               |                              |
|--|---------------------------|--------------------------|-------------------------------|------------------------------|
|  | March 31,<br>2007         | June 30,<br>2007         | September 30,<br>2007         | December 31,<br>2007         |
| Net 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                   |
|  | <b>March 31,<br/>2006</b> | <b>June 30,<br/>2006</b> | <b>September 30,<br/>2006</b> | <b>December 31,<br/>2006</b> |
| Net revenues   | \$ 2,038,430              | \$ 2,558,885             | \$ 4,270,439                  | \$ 6,067,883                 |
| Income (loss) from operations                                | (4,350,719)               | (4,251,875)              | (1,701,398)                   | 249,049                      |
| Net income (loss) applicable to common stockholders          | (4,048,994)               | (3,924,195)              | (1,536,627)                   | 680,494                      |
| Basic net income (loss) per share                            | \$ (0.08)                 | \$ (0.08)                | \$ (0.03)                     | \$ 0.01                      |
| Diluted net income (loss) per share                          | \$ (0.08)                 | \$ (0.08)                | \$ (0.03)                     | \$ 0.01                      |
| Shares used in computing basic net income (loss) per share   | 48,854,964                | 49,032,837               | 49,146,609                    | 49,240,712                   |
| Shares used in computing diluted net income (loss) per share | 48,854,964                | 49,032,837               | 49,146,609                    | 49,422,874                   |

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)).

The net loss amounts presented above for the quarter ending December 31, 2006 include \$3,000,000 of substantive milestone revenue recognized under the Genentech June 2003 collaboration.

---

**Table of Contents**

**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, 2007. 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, 2007, 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 fiscal quarter ended December 31, 2007 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

None.

**Table of Contents**

**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 2008 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 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 2008 annual meeting of stockholders under the headings Compensation of Executive Officers, Director Compensation, Report of the Compensation Committee on Executive Compensation and Comparative Stock Performance 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 2008 annual meeting of stockholders under the headings Compensation of Executive Officers 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 2008 annual meeting of stockholders under the headings Director Compensation and Compensation of Executive Officers, 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 2008 annual meeting of stockholders under the heading Independent Auditor's Fees, which information is incorporated herein by reference.

**Table of Contents**

**PART IV**

**ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

(a)(1) *Financial Statements.*

|  | <b>Page<br/>number<br/>in this<br/>report</b> |
|--|---|
| <b><u>Curis, Inc. and Subsidiaries</u></b>   |   |
| <u>Report of Independent Registered Public Accounting Firm</u>   | 60  |
| <u>Consolidated Balance Sheets as of December 31, 2007 and 2006</u>  | 61  |
| <u>Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2007, 2006 and 2005</u> | 62  |
| <u>Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2007, 2006 and 2005</u>              | 63  |
| <u>Consolidated Statements of Cash Flows for the Years Ended December 31, 2007, 2006 and 2005</u>                        | 64  |
| <u>Notes to Consolidated Financial Statements</u>  | 65  |
| (a)(2) <i>Financial Statement Schedules.</i>   |   |

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.

**Table of Contents****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: March 14, 2008

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.

| <b>Signature</b>   | <b>Title</b>  | <b>Date</b>    |
|--|---|----------------|
| <i>/s/ DANIEL R. PASSERI</i><br><b>Daniel R. Passeri</b>     | President, Chief Executive Officer and Director<br>(Principal Executive Officer)                    | March 14, 2008 |
| <i>/s/ MICHAEL P. GRAY</i><br><b>Michael P. Gray</b>         | Chief Operating Officer and Chief Financial Officer<br>(Principal Financial and Accounting Officer) | March 14, 2008 |
| <i>/s/ JAMES R. MCNAB, JR.</i><br><b>James R. McNab, Jr.</b> | Chairman of the Board of Directors  | March 14, 2008 |
| <i>/s/ SUSAN B. BAYH</i><br><b>Susan B. Bayh</b>             | Director  | March 14, 2008 |
| <i>/s/ STEPHEN K. CARTER</i><br><b>Stephen K. Carter</b>     | Director  | March 14, 2008 |
| <i>/s/ JOSEPH M. DAVIE</i><br><b>Joseph M. Davie</b>         | Director  | March 14, 2008 |
| <i>/s/ MARTYN D. GREENACRE</i><br><b>Martyn D. Greenacre</b> | Director  | March 14, 2008 |
| <i>/s/ KENNETH I. KAITIN</i><br><b>Kenneth I. Kaitin</b>     | Director  | March 14, 2008 |
| <i>/s/ JAMES R. TOBIN</i>                                    | Director  | March 14, 2008 |

**James R. Tobin**



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

| Exhibit No.  | Description  | Form              | Incorporated by Reference |                | Filed with this 10-K |
|--|--|-------------------|---------------------------|----------------|----------------------|
|  |  |                   | SEC Filing Date           | Exhibit Number |                      |
| <i>Articles of Incorporation and By-laws</i>                                     |  |                   |                           |                |                      |
| 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            |                      |
| <i>Instruments defining the rights of security holders, including indentures</i> |  |                   |                           |                |                      |
| 4.1  | Form of Curis Common Stock Certificate   | 10-K              | 03/01/04                  | 4.1            |                      |
| <i>Material contracts Management Contracts and Compensatory Plans</i>            |  |                   |                           |                |                      |
| #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  | Offer Letter, dated as December 10, 2003, between Curis and Michael P. Gray  | 10-K              | 03/01/04                  | 10.4           |                      |
| #10.4  | 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           |                      |
| #10.5  | Offer Letter, dated May 2, 2001, by and between Curis and Changgeng Qian.  |                   |                           |                | X                    |
| #10.6  | 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                                  |                   |                           |                | X                    |
| #10.7  | 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 |                   |                           |                | X                    |
| #10.8  | Offer Letter, dated January 11, 2001, by and between Curis and Mark W. Noel  | 10-K              | 03/02/07                  | 10.6           |                      |
| #10.9  | 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           |                      |

**Table of Contents**

| Exhibit No. | Description  | Form              | Incorporated by Reference |                | Filed with this 10-K |
|-------------|--|-------------------|---------------------------|----------------|----------------------|
|             |  |                   | SEC Filing Date           | Exhibit Number |                      |
| #10.10      | Offer Letter, dated as of July 25, 2002, between Curis and Mary Elizabeth Potthoff   | 10-K              | 03/01/04                  | 10.5           |                      |
| #10.11      | 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           |                      |
| #10.12      | 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           |                      |
| #10.13      | 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           |                      |
| #10.14      | 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           |                      |
| #10.15      | 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           |                      |
| #10.16      | 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           |                      |
| #10.17      | 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           |                      |
| #10.18      | Indemnification Agreement between Curis, Inc. and Dr. Stephen Carter, dated January 29, 2008   | 8-K               | 1/31/08                   | 10.1           |                      |
| #10.19      | Consulting Agreement dated May 11, 2007 by and between Curis and Dr. Stephen Carter.   |                   |                           |                | X                    |
| #10.20      | Curis 2000 Stock Incentive Plan  | S-4/A (333-32446) | 05/31/00                  | 10.71          |                      |
| #10.21      | Curis 2000 Director Stock Option Plan  | S-4/A (333-32446) | 05/31/00                  | 10.72          |                      |
| #10.22      | Curis 2000 Employee Stock Purchase Plan  | S-4/A (333-32446) | 05/31/00                  | 10.73          |                      |
| #10.23      | 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           |                      |
| #10.24      | 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           |                      |
| #10.25      | 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           |                      |

**Table of Contents**

| Exhibit<br>No.                                 | Description  | Form            | Incorporated by Reference |                   | Filed with<br>this 10-K |
|--|--|-----------------|---------------------------|-------------------|-------------------------|
|  |  |                 | SEC Filing<br>Date        | Exhibit<br>Number |                         |
| <i>Material contracts Leases</i>               |  |                 |                           |                   |                         |
| 10.26  | 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             |                         |
| 10.27  | 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              |                         |
| 10.28  | 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              |                         |
| 10.29  | 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              |                         |
| <i>Material contracts Financing Agreements</i> |  |                 |                           |                   |                         |
| 10.30  | 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             |                         |
| 10.31  | Security Agreement, dated restated on September 23, 2004, between Curis and Boston Private Bank & Trust Company  | 10-K            | 03/15/05                  | 10.19             |                         |
| 10.32  | Secured Non-Revolver 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             |                         |
| 10.33  | 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              |                         |
| 10.34  | Secured Non-Revolver Time Note, issued by Curis, Inc. to Boston Private Bank & Trust Company, dated June 9, 2005   | 8-K             | 06/15/05                  | 10.2              |                         |
| 10.35  | Security Agreement (Equipment), between Curis, Inc. and Boston Private Bank & Trust Company, dated June 9, 2005  | 8-K             | 06/15/05                  | 10.3              |                         |

**Table of Contents**

| Exhibit No.  | Description  | Form              | Incorporated by Reference |                | Filed with this 10-K |
|--|--|-------------------|---------------------------|----------------|----------------------|
|  |  |                   | SEC Filing Date           | Exhibit Number |                      |
| <i>Material contracts License and Collaboration Agreements</i> |  |                   |                           |                |                      |
| 10.36  | Master Restructuring Agreement, dated as of October 15, 1998, between Creative and Stryker Corporation   | 10-K              | 03/30/99                  | 10.10          |                      |
| 10.37  | Second Amendment to Master Restructuring Agreement, dated October 1, 2002, between Curis and Stryker Corporation   | 10-Q              | 11/12/02                  | 10.5           |                      |
| 10.38  | Irrevocable License Agreement, dated November 20, 1998, between Creative and Stryker Corporation   | 10-K              | 03/13/00                  | 10.7           |                      |
| 10.39  | Stryker Irrevocable License Agreement, dated November 20, 1998, between Creative and Stryker Corporation   | 10-K              | 03/13/00                  | 10.8           |                      |
| 10.40  | Cross-License Agreement, dated as of July 15, 1996, by and among Creative, Genetics Institute, Inc. and Stryker Corporation  | 10-Q              | 11/06/96                  | 10.1           |                      |
| 10.41  | 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          |                      |
| 10.42  | 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          |                      |
| 10.43  | 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          |                      |
| 10.44  | 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          |                      |
| 10.45  | 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          |                      |
| 10.46  | Agreement, dated as of November 27, 2002, by and between Curis and Ortho Biotech Products, L.P.  | 8-K               | 12/09/02                  | 10.1           |                      |
| 10.47  | Collaborative Research, Development and License Agreement, dated June 11, 2003, between Curis and Genentech, Inc.  | 8-K               | 07/10/03                  | 10.1           |                      |

**Table of Contents**

| Exhibit No.                             | Description   | Form | Incorporated by Reference |                |                      |
|---|---|------|---------------------------|----------------|----------------------|
|   |   |      | SEC Filing Date           | Exhibit Number | Filed with this 10-K |
| 10.48                                   | 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          |                      |
| 10.49                                   | 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           |                      |
| 10.50                                   | Drug Discovery and Collaboration Agreement dated April 1, 2005 by and between Curis, Inc. and Genentech, Inc.   | 10-Q | 4/29/05                   | 10.1           |                      |
| 10.51                                   | Collaboration, Research and License Agreement, dated January 12, 2004, between Curis and Wyeth  | 10-K | 03/01/04                  | 10.29          |                      |
| 10.52                                   | 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           |                      |
| <i>Material contracts Miscellaneous</i> |   |      |                           |                |                      |
| 10.53                                   | 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           |                      |
| 10.54                                   | Registration Rights Agreement, dated June 13, 2003, between Curis and Genentech, Inc.   | 8-K  | 07/10/03                  | 10.3           |                      |
| 10.55                                   | Common Stock Purchase Agreement, dated June 11, 2003, between Curis and Genentech, Inc.   | 8-K  | 07/10/03                  | 10.2           |                      |
| 10.56                                   | Common Stock Purchase and Registration Rights Agreement, dated January 9, 2004, between Curis and Wyeth   | 10-K | 03/01/04                  | 10.34          |                      |
| 10.57                                   | 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           |                      |
| 10.58                                   | 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           |                      |
| 10.59                                   | 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           |                      |
| 10.60                                   | 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           |                      |
| 10.61                                   | 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           |                      |

**Table of Contents**

| Exhibit No.                | Description   | Form | Incorporated by Reference |                | Filed with this 10-K |
|----------------------------|---|------|---------------------------|----------------|----------------------|
|                            |   |      | SEC Filing Date           | Exhibit Number |                      |
| 10.62                      | 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           |                      |
| 10.63                      | 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           |                      |
| <i>Code of Conduct</i>     |   |      |                           |                |                      |
| 14                         | Code of Business Conduct and Ethics   | 10-K | 03/01/04                  | 14             |                      |
| <i>Additional Exhibits</i> |   |      |                           |                |                      |
| 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. |      |                           |                |                      |