

05

CURIS

ANNUAL REPORT



Dear Shareholders,

2005 was an important year for us. Through our collaboration with Genentech, we brought our first Hedgehog antagonist into the clinic, for the topical treatment of basal cell carcinoma. Although the trial has not progressed as we had hoped, we are encouraged that the compound demonstrated some levels of activity and that no significant safety or toxicity issues arose.

In 2005, we signed new agreements with Procter & Gamble and Genentech. Our second collaboration agreement with Genentech is for the discovery and development of small molecule compounds that modulate a signaling pathway that plays an important role in cell proliferation. This pathway is a regulator of tissue formation and repair and its abnormal activation is associated with certain cancers. We believe that our agreement with Procter & Gamble marks the beginning of a promising collaboration to identify compounds to treat hair growth disorders. In addition to our new collaborations, we expanded our relationships with existing partners, including Centocor, Wyeth and Genentech. The diversity of our product pipeline should help to decrease our risk and allow us an increased opportunity for multiple successes across a wide range of diseases.

Our Collaborations with Genentech

BASAL CELL CARCINOMA

Topically-Applied Small Molecule Hedgehog Antagonist

On January 23, 2006, we provided an update on the Phase I clinical trial for the treatment of basal cell carcinoma via topical administration of a small molecule Hedgehog antagonist. The preliminary data from a dose-escalation segment of the Phase I clinical trial for this basal cell carcinoma candidate suggest that the drug candidate revealed no significant safety or toxicity issues, and has shown signs of activity; however, there has been less clinical activity observed than anticipated. Based on these data, and in conjunction with Genentech, we temporarily suspended further enrollment in the second segment of the trial, in which additional patients were to be treated at the highest dose level from the dose escalation segment. The companies will determine whether to re-open enrollment in this segment based on a secondary administrative analysis that will occur at a later date. The internal data review board also recommended that a third segment of the trial that is evaluating biological activity using a pharmacodynamic endpoint be enrolled as planned. This third segment, among other things, may shed light on the extent to

which the active compound in the drug candidate as formulated is penetrating the patients' skin.

We expect to have final results from the Phase I clinical trial in mid 2006. When the final Phase I results are obtained, Genentech and we will determine whether this drug candidate should proceed to Phase II clinical trials. Should this drug candidate not progress into Phase II clinical trials, Genentech and we will evaluate various criteria, including the data from the biological activity segment of the trial, and determine the alternatives for the basal cell carcinoma program. Possible scenarios include, but are not limited to, the following: extending the duration of the treatment regimen of the existing drug candidate, developing a new topical formulation of the existing drug candidate, selection of a new drug candidate, negotiation of the return of the compounds to us for our further development, or termination of the basal cell carcinoma drug program.

SOLID TUMORS

Systemically Administered Small Molecule Hedgehog Antagonist

In April 2005, we announced an amendment of our first agreement with Genentech to extend Genentech's funding of the Hedgehog antagonist cancer collaboration that is ongoing between the two companies. Under this amendment, Genentech has paid us an additional \$2 million and has agreed to pay us up to \$1.25 million to support our personnel and other third party resources dedicated to developing our Hedgehog antagonist technologies for the systemic treatment of solid tumor cancers through June 11, 2006. In October 2005, we announced that Genentech had selected a lead clinical candidate under our solid tumor program. We expect Genentech to file an IND for a systemically administered small molecule Hedgehog antagonist for the treatment of various solid tumor cancers by the end of 2006.

UNDISCLOSED PATHWAY

Small Molecule Discovery Research

In April 2005, we announced that we had established a second major collaboration with Genentech, Inc. This new collaboration involves the discovery and development of small molecule modulators of an undisclosed pathway that plays an important role in cell proliferation. This pathway is a key regulator of tissue formation and repair, and its abnormal activation is associated with certain cancers.

Our Collaboration with Procter & Gamble

HAIR GROWTH REGULATION

Topically Applied Hedgehog Small Molecule Agonist

We entered into a collaboration with Procter & Gamble in September 2005 to evaluate and develop potential treatments for hair growth regulation utilizing our Hedgehog agonist technology. Future efforts may be expanded to address other skin disorders. To date, our scientists have demonstrated that small molecule Hedgehog agonists can induce hair growth in preclinical models. Under the terms of the agreement, we have granted Procter & Gamble an exclusive, worldwide royalty-bearing license for the non-systemic, dermatological use of our Hedgehog agonist technology, via topical administration. We have an option to co-develop a development candidate through Phase II clinical trials. We have seen good early progress in this program, reaching our first preclinical milestone in March 2006, resulting in a \$1 million payment.

Our Collaboration with Wyeth

NEUROLOGICAL DISORDERS

Systemically Administered Small Molecule Agonist

In November 2005, Wyeth exercised its option under its 2004 agreement to extend funding to continue development of therapeutic applications of the Hedgehog agonist with a primary focus on neurological disorders, particularly stroke. By exercising this option, Wyeth has agreed to extend the research term by one year through February 9, 2007. We expect Wyeth to select a development candidate in the next twelve to eighteen months, and to file an IND approximately twelve months thereafter. We continue to be pleased with our relationship with Wyeth and the insight into the program that we get during our quarterly joint steering committee meetings.

Our Collaboration with Centocor

VARIOUS APPLICATIONS

Small Molecule Discovery Research—BMP Agonists

In December 2005, Centocor expanded its relationship with us by entering into a new agreement, under which we will screen for small molecule agonists that mimic the bioactivity of BMP-7 and activate the BMP pathway. The screening effort is expected to last fifteen months. We will own any small molecule BMP agonist compounds that are discovered as part of this screening; however, Centocor will have a first right of negotiation

to enter into a new collaboration and license agreement for the further development of such compounds. We believe that expanding existing relationships with our collaborators is a testament to the exceptional work of our scientists and look forward to future progress in this BMP discovery program.

Our Other Programs

We continue to make progress in our sponsored research program with the Spinal Muscular Atrophy Foundation. We also possess robust small molecule drug screening technologies and preclinical scientific expertise that we believe we can use to identify future drug candidates.

We believe that 2006 will be a pivotal year for our company. We expect to complete the Phase I clinical trial for basal cell carcinoma and expect to get valuable data on the activity of the topical Hedgehog antagonist. We continue to expect that Genentech will file an IND for the solid tumor program before the end of the year and we anticipate potentially achieving the second preclinical milestone in our collaboration with Procter & Gamble for the hair growth program, where we have retained a co-development option.

As always, we look forward to reporting to you on the progress of our programs throughout the coming year. I would like to thank our shareholders for their continued support, our Board of Directors for their counsel and our employees for their commitment and their successes over the past year.

Sincerely,



Daniel R. Passeri
President and Chief Executive Officer
Curis, Inc.

05

CURIS

FORM 10-K

**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, 2005

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)

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

61 Moulton Street
Cambridge, Massachusetts 02138
(Address of principal executive offices) (Zip Code)

617-503-6500
(Registrant's telephone number, including area code)

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

None

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, \$0.01 par value per share

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, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer

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

As of June 30, 2005, the aggregate market value of the common stock held by non-affiliates of the registrant was approximately \$161,929,000 based on the closing sale price of the registrant's common stock on The Nasdaq National Market on such date.

As of March 22, 2006, there were 48,996,294 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 1, 2006, 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, 2005 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.

CURIS, INC.
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PART I

This annual report on Form 10-K contains forward-looking statements that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause the results of Curis 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 projections 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

Our Company

We are a therapeutic drug development company principally focused on the discovery, development and future commercialization of products that modulate key regulatory signaling pathways controlling the repair and regeneration of human tissues and organs. Our product development approach involves using small molecules, proteins or antibodies to modulate these regulatory signaling pathways, for example, to increase the pathway signals when they are insufficient or to decrease them when they are excessive.

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 61 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.

Our lead product candidate is a topical therapy for the treatment of basal cell carcinoma and, as part of our June 2003 Hedgehog antagonist collaboration, is currently under development with Genentech. On January 28, 2005, under the terms of the Hedgehog antagonist collaboration agreement with Genentech, we exercised our co-development option in the basal cell carcinoma program in the U.S. market pursuant to which we are now sharing equally in the U.S. development costs and will share equally in any future U.S. net profits and/or losses in this program. As a result of participating in co-development, we will forego U.S. development milestone and royalty payments on potential future U.S. sales of the basal cell carcinoma product candidate. On June 8, 2005, we announced that the dosing of the first patient in the Phase I clinical trial for basal cell carcinoma was completed. This Phase I clinical trial is being conducted by Genentech and Curis, and is expected to be completed in the first half of 2006. The Phase I clinical trial is a double-blind, randomized, placebo-controlled study that is expected to enroll approximately 60 patients with a single or multiple basal cell carcinoma. The primary objective of the Phase I clinical trial is to obtain data about the safety and tolerability of a four-week regimen of the drug candidate. In addition, Genentech and we are evaluating the clinical activity of the drug candidate, where activity is defined as the complete eradication of the treated basal cell carcinoma lesion and is determined by clinical and microscopic examinations of the lesions. At the conclusion of this Phase I clinical

trial, we and Genentech plan to make a decision about whether to advance the drug candidate, a topical antagonist of the Hedgehog signaling pathway, into a Phase II clinical trial.

On January 23, 2006, we provided an update on this Phase I clinical trial. At that time, 29 of the Phase I clinical trial patients had participated in a dose-escalation segment, in which seven patients were randomized to receive treatment in each of four dose levels. The dose-escalation segment of the Phase I clinical trial had recently been completed, and the preliminary data had been reviewed by an internal Genentech data review board. The preliminary data from the dose-escalation segment suggested that the drug candidate appeared likely to be safe, well tolerated, and had shown signs of activity. However, there had been less clinical activity observed to date than anticipated. Based on these data, the internal data review board recommended that Genentech and we temporarily suspend further enrollment in the second segment of the trial, in which additional patients were to be treated at the highest dose level from the dose escalation segment. Genentech and we will determine whether to re-open enrollment in this segment based on a secondary interim analysis that will occur at a later date. The internal data review board also recommended that a third segment of the trial that evaluates biological activity using a pharmacodynamic endpoint be enrolled as planned. This third segment, among other things, may shed light on the extent to which the active compound in the drug candidate as formulated is penetrating the patients' skin.

We expect the Phase I clinical trial to be completed during the first half of 2006. When the final results of the clinical trial are obtained, we will determine in conjunction with Genentech whether this drug candidate should proceed to Phase II clinical trials. Should this drug candidate not progress into Phase II clinical trials, we will evaluate in conjunction with Genentech various criteria, including the data from the biological activity segment of the trial, and determine the alternatives for the basal cell carcinoma program. Possible scenarios include, but are not limited to the following: extending the duration of the treatment regimen of the existing drug candidate, developing a new topical formulation of the existing drug candidate, selection of a new drug candidate, negotiation of the return of the compounds to us for our further development, or termination of the basal cell carcinoma drug program.

In addition to our lead basal cell carcinoma product candidate, we have successfully used our product development approach to produce multiple compounds with the potential for use in several different disease indications including preclinical product candidates in the fields of cancer, neurological disorders, and hair growth regulation. We also possess robust small molecule drug screening technologies and preclinical scientific expertise that we believe may enable us to create a sustainable drug candidate pipeline, including, for example, our efforts in the development of drug candidates to treat spinal muscular atrophy, or SMA.

Regulatory signaling pathways, also referred to as signaling pathways, are prominent regulators of specific tissue and organ formation during prenatal development and are used by the body throughout life to repair and regulate human tissue. We, together with collaborators and licensors, are developing our product candidate programs around several major signaling pathways including the Hedgehog and Bone Morphogenetic Protein, or BMP, pathways. We have substantial intellectual property rights and know-how in these signaling pathways, which we believe will enable us to have a technological and competitive advantage in developing therapeutic products based upon these pathways. We have also used our knowledge about the Hedgehog and BMP pathways to begin researching additional signaling pathways. In addition to expanding our internal research capacities, we may seek to expand our technology offerings and associated intellectual property portfolio through in-licensing arrangements and the acquisition of complimentary technologies.

Our research programs are conducted both internally and through strategic collaborations. We currently have strategic collaborations with Genentech, The Procter & Gamble Company, or Procter & Gamble, and Wyeth Pharmaceuticals, or Wyeth, to develop therapeutics, which modulate the signaling of the Hedgehog pathway. We have a second collaboration with Genentech focusing on the discovery and development of small molecule modulators of another signaling pathway. We have licensed our BMP pathway patent portfolio to Ortho Biotech Products L.P., a subsidiary of Johnson & Johnson, for systemic administration in all non-orthopedic and

non-dental therapeutic applications. This program is under development at Centocor, another subsidiary of Johnson & Johnson. In 2005, Centocor entered into an agreement with us pursuant to which Centocor will fund a portion of a new Curis BMP small molecule agonist screening program. Lastly, a majority of our SMA research is funded through a sponsored research agreement with the SMA Foundation.

Our strategic collaborations and license agreements generally provide for our research, development and commercialization programs to be wholly or the majority funded by our collaborators and licensors and provide us with the opportunity to receive additional payments if specified milestones are achieved, as well as royalty payments upon the successful commercialization of any products under the collaboration. In some cases, we have retained rights under such programs, including co-development rights and development and commercialization rights in specific therapeutic areas where we believe we can attain additional value through the application of our own internal resources. Examples of retained rights within our programs under collaboration include co-development rights for the development of a basal cell carcinoma product candidate under our Hedgehog antagonist collaboration with Genentech, as well as retained rights to our Hedgehog agonist for topical applications, ex vivo use and for local delivery in cardiovascular applications under our Hedgehog agonist collaboration with Wyeth. In September 2005, we licensed the topical applications of the Hedgehog agonist, including for use in hair growth, to Procter & Gamble. Under the terms of the agreement, we granted Procter & Gamble an exclusive, worldwide, royalty-bearing license for the non-systemic, dermatological use of our Hedgehog agonist technology, via topical administration. We will have an option to co-develop a development candidate from investigational new drug filing through Phase II clinical trials.

We believe that our various collaborative structures provide additional opportunities for our licensed assets. We believe that our approach allows us to augment our development capabilities and capacities through collaborations with leading pharmaceutical and biotechnology companies. For example, under our co-development arrangement with Genentech, we are able to retain a significant percentage of ownership of our basal cell carcinoma product candidate, while working with Genentech, a company with established clinical development, regulatory, and commercialization skills. Also, through our retained rights to specific fields under our broad Hedgehog agonist collaboration with Wyeth, we were able to secure an additional collaboration relating to the Hedgehog agonist through our September 2005 collaboration with Procter & Gamble. We believe that developing our assets in collaboration with companies possessing clinical development expertise increases the likelihood of development success. For products under collaborative development in a milestone and royalty structure, we are provided with the opportunity to discover and develop products while reducing our internal product development costs and related financial risks.

Our sponsored research agreement with the SMA Foundation provides for support of a majority of our SMA research program costs. We will own any compounds that we generate under this collaboration and will also have the ability to bring such compounds into the clinic, either using our own resources or with a collaborating third party. If any drug candidates developed under the agreement are successfully commercialized, we will be required to make limited payments to the SMA Foundation if cumulative revenues from the sales of such products exceed \$100,000,000.

In the future, we plan to continue to seek corporate collaborators and licensors for the further development and commercialization of some of our technologies. We also may continue to seek sponsored research funding from foundations or other non-profit entities, similar to our existing sponsored research agreement with the SMA Foundation.

Recent Development – Restatement of Financial Statements

As described in Note 2 of the Notes to our consolidated financial statement included elsewhere in this annual report on Form 10-K, we have restated our financial results for 2004 and 2003. The restatement adjusts our consolidated balance sheets contained herein:

- to correct amounts in prepaid expenses and other current assets, deposits and other assets, short- and long-term deferred revenues, additional paid-in capital, and accumulated deficit, and

- to restate our consolidated 2004 and 2003 statements of operations to correct amounts reported in gross revenues and research and development expenses.

As a result of these restatements, amounts in the consolidated statements of cash flows for the years periods ended December 31, 2004 and 2003 have also been corrected.

Our annual reports on Form 10-K and our quarterly reports on Form 10-Q from the second quarter of 2003 through fiscal 2004 have not been revised to reflect the restatement and the consolidated financial statements contained in those reports should not be relied upon. Instead, the consolidated financial statements for fiscal 2004 and 2003 included in this annual report on Form 10-K should be relied upon. For additional information regarding the restatement, refer to Note 2 “Restatement of Financial Statements” in the notes to the consolidated financial statements in this annual report on Form 10-K.

Regulatory Signaling Pathways Background

Regulatory signaling pathways are the means by which cells exchange instructional messages that regulate specific biological functions. Early in prenatal development, the instructional messages that direct the formation of tissues and organs are controlled by master pathways, including the Hedgehog, BMP, and other pathways, which act by initiating cascades of gene signaling required for tissue formation and regulation. The body also uses these master pathways to repair damage and regenerate tissues. For example, in damaged nerve tissue, our preclinical models demonstrate that activation of the Hedgehog pathway promotes repair and regeneration of nerve function, in part, by inducing the activation of a cascade of secondary signaling that promotes the growth of new cells and blood vessels.

The ability to modulate certain signaling pathways is of great interest to biotechnology and pharmaceutical companies as many diseases and disorders are now known to be associated with components of these signaling pathways. For example, there is significant pharmaceutical interest in the inhibition of abnormally or inappropriately activated signaling pathways that have been implicated in certain cancers.

Abnormal activation of the Hedgehog signaling pathway has been shown to be associated with certain cancers, including basal cell carcinoma, small cell lung cancer, pancreatic cancer and others. We have developed small molecule Hedgehog pathway antagonists and Hedgehog blocking antibodies. Our small molecule Hedgehog pathway antagonists and antibodies, which we are developing are under collaboration with Genentech, have been demonstrated to slow or halt the growth of several cancers in preclinical models of tumor growth. Because the Hedgehog signaling pathway appears to control the expression of tissue growth factors and blood vessel growth factors, we believe that our Hedgehog pathway inhibitors may be applicable to a broad array of cancers.

Our Strategy

Our goal is to become a leading therapeutic drug development company focusing on regulatory signaling pathways. Our strategy to accomplish this goal includes the following:

- ***Focus on markets where our regulatory signaling pathway product candidates address significant unmet medical needs.*** We believe that we are one of the leading companies in the regulatory signaling pathway field and that our skills and knowledge allow us to develop product candidates that address disease indications that have attractive markets with unmet medical needs. We are principally focused on developing proprietary regulatory signaling pathway-based drugs for large markets including, for example, cancer, neurological disorders, and hair growth regulation where we believe our product candidates can provide compelling clinical advantages over existing products. We have recently also begun research work in disease areas with smaller market sizes, but for which there are significant unmet medical needs. We believe that our work in these areas, such as our SMA research program, could provide us with a potential product candidate that we could progress into clinical development on our own.

- ***Pursue collaborations with companies that will complement our skill sets.*** We have entered into and plan to seek additional collaborations with companies that will advance selected product candidates through the clinic. Since our regulatory signaling pathway-based product candidates have broad applications to a variety of human diseases, some of the indications will require complex and expensive clinical trials, which exceed our current ability and capacity to develop and fund. Since pharmaceutical and large biotechnology companies have more resources and experience and are better capitalized to develop and run clinical trials, we believe that these collaborations will better allow our product candidates to be successfully commercialized. By leveraging our expertise in preclinical development, we believe that we will be in an attractive position when negotiating the terms of these collaborations. Also by entering into collaborations and co-development agreements, we believe we will be able to strengthen our capabilities and capacities for developing and managing clinical trials in the future.
- ***Develop additional intellectual property around other key regulatory signaling pathways.*** We currently own or have rights to a broad patent estate. Most of our intellectual property portfolio relates specifically to our Hedgehog and BMP technologies. We have made a substantial investment in protecting our proprietary technologies and product candidates. We believe that the quality and scope of our intellectual property provides us and our collaborators and licensees with a strong patent position. In order to enhance our current intellectual property position, we intend to invest in regulatory signaling pathway-related research and development efforts, including attracting and retaining highly talented and experienced personnel. We also intend to expand our intellectual property position around other key regulatory signaling pathways and technologies for modulating these pathways by investing in selected internal research and development efforts and potentially acquiring complementary intellectual property.
- ***Discover, develop and commercialize our own products.*** We will retain the development, sales and marketing rights to selected proprietary product candidates in specialty markets that we may be able to more readily address. Program selection will be based on an assessment of the time, expense and complexity of clinical trials that we estimate will be required for approval.

Product Development Programs and Strategic Collaborations and License Agreements

We are developing product candidates in several important medical fields where there are substantial unmet therapeutic needs. These product development initiatives, described in the chart below, are being pursued using our internal resources or through collaborations and licensing arrangements with pharmaceutical or biotechnology companies that are able to dedicate additional resources and clinical development expertise, and, in return, provide us with potential revenue from development milestones and royalties on future product sales. These product development initiatives are derived primarily from our substantial intellectual property portfolio in key regulatory signaling pathways.

Most of our programs are in various stages of preclinical drug development. In the table below, the term discovery means that we are searching for compounds that may be relevant for treating a particular disease area, early preclinical means we are seeking to obtain initial demonstrations of therapeutic efficacy in preclinical models of human disease, mid-preclinical means we are seeking to obtain multiple demonstrations of efficacy in preclinical models of human disease, late preclinical means we are seeking to obtain both multiple demonstrations of efficacy in preclinical models of human disease and relevant toxicology and safety data required for an investigational new drug, or IND, application filing with the FDA seeking to commence a Phase I clinical trial to assess safety and tolerability in humans, and Phase I means that we are currently treating human patients in a Phase I clinical trial, the principal purpose of which is to evaluate safety of the compound being tested.

All of our estimates below regarding the status of our product development programs are solely our judgments. These estimates may not reflect the beliefs or expectations of our corporate collaborators or licensors, if applicable. Moreover, because of the early stages of development of these programs, our ability and that of our collaborators and licensors to successfully complete preclinical or clinical studies of these product candidates, and the timing of completion of such programs, is highly uncertain.

Product Candidate	Primary Indication	Collaborator/Licensee	Status
Hedgehog topical small molecule antagonist	Basal cell carcinoma	Genentech	Phase I
Hedgehog systemic small molecule or antibody antagonist	Cancer (1)	Genentech	Late preclinical
Discovery research	Undisclosed pathway	Genentech	Discovery
Hedgehog small molecule agonist	Nervous system disorders	Wyeth	Mid-preclinical/Discovery (2)
Hedgehog small molecule agonist	Hair growth	Procter & Gamble	Late preclinical
BMP-7 protein	Kidney disease and other disorders	Ortho Biotech Products/Centocor	Mid-preclinical
Discovery research	Spinal muscular atrophy	Spinal Muscular Atrophy Foundation	Discovery
Hedgehog agonist/gene	Cardiovascular disease	Internal development (3)	Mid-preclinical
Discovery research	Various signaling pathways	Internal development	Discovery

- (1) Genentech has selected a lead clinical candidate for this program, a small molecule antagonist of the Hedgehog pathway. We currently expect that Genentech will file an IND for this program in the second half of 2006.
- (2) Curis and Wyeth are currently evaluating drug candidates in a particular class of agonist small molecule compounds. This class of compounds is currently in a mid-preclinical development status. Should the companies determine that this class of compounds will not generate a lead clinical development candidate, we expect that we will continue to seek a backup class of compounds. Our efforts to seek a backup class of compounds would initially be in discovery development.
- (3) We have incurred nominal expenses related to our cardiovascular disease program. Our preclinical data relating to this program have been primarily derived from studies conducted at Caritas St. Elizabeth's Medical Center in Boston, Massachusetts. Wyeth has a right of first negotiation to obtain an exclusive license to the cardiovascular applications. If Wyeth declines to exercise its option, or if we are unable to reach an agreement with Wyeth on terms within the contractually specified period, we are free to seek another collaborator for this program. In the event that Wyeth declines to exercise its option, we will actively explore other licensing opportunities for this program. Should we be successful in our efforts to license this program, either to Wyeth or to another collaborator, any investigational new drug filing will likely be the responsibility of the collaborator.

There is a risk that any drug discovery and development program may not produce products or revenues. Due to uncertainties inherent in drug discovery and development, including those factors described below under Item 1A "Risk Factors," we and our collaborators may not be able to successfully develop and commercialize any of the product candidates included in the table above.

Our strategy for development and commercialization of products depends in part upon successful strategic collaborations with third parties. We use strategic collaborations and license agreements as a means to provide us with the requisite capital, as well as the necessary preclinical and clinical development and manufacturing and marketing capabilities to commercialize product candidates produced by our discovery and preclinical programs. In evaluating possible strategic collaborations, we consider the following criteria:

- technical and commercial resources committed to our programs;
- up-front payments in the form of license fees and equity investments;
- royalties and milestone payments;
- our ability to retain certain rights, including, for example, co-development rights and retained rights in certain fields, that we feel increase the overall potential value of the collaboration;
- technology and patent rights; and
- scientific and development resources.

Since inception in 2000, substantially all of our revenues have been derived from our collaborations and other agreements with third parties. We anticipate that for the next several years substantially all of our revenues

will continue to be generated from these sources. For the year ended December 31, 2005, Genentech accounted for \$6,419,000, or 49%, of our gross revenues, Wyeth accounted for \$2,849,000, or 22%, of our gross revenues, Procter & Gamble accounted for \$289,000, or 2%, of our gross revenues, and the SMA Foundation grant accounted for \$1,955,000, or 15%, of our gross revenues. In addition, Micromet, a former collaborator, accounted for \$1,400,000, or 11%, of our revenues for 2005. Co-development costs incurred under our Genentech collaboration accounted for \$6,999,000 in contra-revenue that offset our gross revenues and, as a result, net revenues from Genentech were negative for 2005.

The following provides brief summaries of each of our product development programs and, when applicable, a description of the corporate collaboration, license agreement or sponsored research agreement under which product candidates under the program are being developed.

Hedgehog Topical Small Molecule Antagonist Program

Under Collaboration with Genentech

Program Summary

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 factors. The growth factors stimulate new tissue formation, and the angiogenic factors stimulate new blood vessel growth to nourish the newly formed tissue.

Several years ago, our scientists and scientists at independent academic and medical research laboratories discovered that the Hedgehog signaling pathway is activated at very high levels in the vast majority of basal cell carcinomas. Basal cell carcinoma, a skin cancer, is the most common form of all human cancers with approximately 800,000 to 1,000,000 new cases every year in the U.S. In many of these cases, excessive unregulated Hedgehog signaling activity is due to the presence of inactivating mutations in “patched,” or Ptch, a negative regulator of the pathway, or to constitutively activating mutations in “smoothed,” or Smo, an activator of the pathway. Unregulated activation of Hedgehog signaling in the outer layer of skin cells leads to increased rates of cell division resulting in tumor formation. Thus, we believe that our small molecule Hedgehog signaling antagonists directly target the known mechanism of action underlying the formation of basal cell carcinomas.

Our preclinical evidence indicates that inhibition of the Hedgehog pathway with our topically applied Hedgehog antagonists in various models of basal cell carcinoma results in the selective death of tumor cells while sparing adjacent normal cells and maintaining the typical architecture of the skin at the treatment site. In contrast, most basal cell carcinoma patients are currently treated with surgery, which often results in significant scarring at the treatment site. We believe that the selective action of our Hedgehog antagonists in cancer cells may result in a better cosmetic outcome than that of other basal cell carcinoma treatments, particularly in the case of surgery, and therefore may represent a significant competitive advantage for our basal cell carcinoma product candidate.

Collaboration Summary

In June 2003, we established a broad collaboration with Genentech around our Hedgehog antagonist technologies, including the continued development of our basal cell carcinoma product candidate. Under the terms of the collaboration, we retained a co-development option in the basal cell carcinoma program in the U.S. market that enables us to share in U.S. development costs and future U.S. net profits or losses in this program. On January 28, 2005, we elected to exercise this co-development option and are now sharing equally in the U.S. development costs and will share equally in any future U.S. net profits or losses of the basal cell carcinoma program. On June 8, 2005, we announced that the dosing of the first patient in the Phase I clinical trial for basal cell carcinoma was completed. This Phase I trial is being conducted by Genentech and Curis and we currently

expect that the trial will be completed during the first half of 2006. Upon the completion of the Phase I clinical trial, Genentech and we will determine whether to advance the product candidate into Phase II clinical trials. Assuming the successful advancement of the basal cell carcinoma product candidate through Phase I and Phase II clinical trials, we expect that we will incur approximately \$20,000,000 in development costs and that the Phase II clinical trial will be completed in mid-2007.

In addition to our U.S. co-development rights, in certain international markets, we will receive milestone payments if specific clinical development objectives are achieved and a royalty on any international sales of the topical Hedgehog antagonist.

Hedgehog Systemic Small Molecule Antagonist and Antibody Antagonist Cancer Programs

Under Collaboration with Genentech

Program Summary

Scientists have discovered that abnormal Hedgehog signaling may be contributing to the growth of certain cancers, including, for example, small cell lung cancer, pancreatic cancer, prostate cancer, colon cancer and medulloblastoma, an aggressive form of childhood brain cancer.

Our preclinical evidence suggests that Hedgehog protein produced by tumor cells may signal certain adjacent cells within the tumor environment to produce various growth and angiogenic, or blood vessel forming, factors that can positively influence 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 are selectively targeting fundamental mechanisms involved in the maintenance and progression of tumor growth, and as such, may represent a new generation of cancer therapeutics.

Collaboration Summary

In June 2003, we established a collaboration with Genentech for the continued development of Hedgehog systemic antagonist drug candidates, in addition to the development of a topical treatment for basal cell carcinoma. The current focus of the collaboration, excluding the basal cell carcinoma clinical development, is to develop systemically administered Hedgehog antagonists for cancer indications. Pursuant to the collaboration agreement, Genentech agreed to make specified cash payments, including up-front payments of \$8,500,000, which consisted of a \$3,509,000 non-refundable license fee payment and \$4,991,000 in exchange for 1,323,835 shares of our common stock. Genentech also agreed to make license maintenance fee payments totaling \$4,000,000 over the first two years of the collaboration and cash payments at various intervals during the clinical development and regulatory approval process of small molecule and antibody Hedgehog antagonist product candidates, assuming specified clinical development and regulatory approval objectives are met. In addition, Genentech will pay a royalty to us on potential future net product sales, which will increase with increasing sales volume.

We have entered into two amendments to the June 2003 collaboration agreement related to the Hedgehog antagonist. Pursuant to the amendments, Genentech increased the number of researchers that it would fund and extended its funding obligation through June 2006. As part of these amendments, Genentech committed to provide us with up to \$5,250,000 in incremental research funding over the period of December 2004 to June 2006.

Discovery Research on an Undisclosed Signaling Pathway

Under Collaboration with Genentech

Program Summary

We established a drug discovery program for the discovery and subsequent development of small molecule compounds that modulate a signaling pathway that plays an important role in cell proliferation. This pathway is a regulator of tissue growth, formation and repair, the abnormal activation of which is associated with certain cancers.

Collaboration Summary

On April 1, 2005, we entered into a drug discovery collaboration agreement with Genentech to further our discovery research and development of drug candidates that modulate this signaling pathway. Under the terms of the agreement, we granted Genentech an exclusive, royalty-bearing license to make, use and sell small molecule compounds that are modulators of the pathway. We have retained the rights for ex vivo cell therapy uses, except in the areas of oncology and hematopoiesis. We have primary responsibility for drug discovery and research activities and Genentech will be responsible for clinical development, manufacturing, and commercialization of products that may result from the collaboration.

Genentech paid us an up-front license fee of \$3,000,000 and has agreed to fund up to \$6,000,000 for research activities during the initial two-year research term, subject to certain termination rights. Genentech has also agreed to make cash payments to us that are contingent upon the successful achievement of certain preclinical and clinical development and drug approval objectives. Excluding royalties on potential net product sales, the total potential cash payments from this collaboration could exceed \$140,000,000, assuming that two products are commercialized in two indications each. Genentech has an option to extend the initial two-year research term for up to two additional years in one-year increments. Genentech will also pay us royalties on net product sales if product candidates derived from the collaboration are successfully developed.

Hedgehog Small Molecule Agonist Neurological Disorders Programs

Under Collaboration with Wyeth

Program Summary

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 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.

Our scientists have developed a series of small molecule Hedgehog agonists that, in preclinical models, have been shown to be capable of activating the Hedgehog pathway. Many of these small molecule Hedgehog agonists are orally available and can cross the blood brain barrier, a protective barrier formed by blood vessels and brain tissue that prevents most substances in the blood from entering the central nervous system. Small molecules that cross this blood brain barrier can potentially reach and treat the central nervous system, therefore making them attractive product development candidates for certain brain disorders.

We believe that the positive effects of the Hedgehog agonists in neuronal disease models are due to neuroprotection that is induced by activation of the Hedgehog signaling pathway. Neuroprotection is the prevention of the progressive death of cells in the brain caused by disease or injury. In addition, we believe that activation of the Hedgehog pathway results in an increased proliferation of stem cells in the brain. We are currently exploring the possibility that this may enable us to develop drugs that can promote the replacement of cells lost as a result of injury or disease.

Collaboration Summary

In January 2004, we licensed our Hedgehog proteins and small molecule Hedgehog pathway agonists to Wyeth for therapeutic applications in the treatment of neurological diseases and other disorders. Wyeth is one of the world's largest research-driven pharmaceutical companies with broad expertise in the development of drugs to treat neurological disorders and other diseases. 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 our common stock.

Wyeth has agreed to assume all future responsibility for clinical development of the Hedgehog small molecule and protein agonists as systemic treatments for neurological and other disorders. Wyeth is also obligated to make cash payments if the licensed programs successfully achieve clinical development and drug approval objectives and to pay us a royalty on net product sales, if any should occur, that escalates with increasing sales volume. Our agreement with Wyeth would result in more than \$170,000,000 in contingent cash payments, assuming at least two products are successfully developed and commercialized.

In addition to these initial and potential future contingent cash payments, Wyeth is obligated to provide financial support of our research under the collaboration, at \$250,000 per full-time equivalent researcher, for an initial period of up to two years based on the number of full-time equivalent researchers performing services under the collaboration. We are obligated to dedicate between five and ten full-time equivalents to this program, as determined by the steering committee in six-month intervals, for two years. After the initial two-year period, Wyeth can, at its option, elect to extend our research obligation, and Wyeth's funding thereof, for an initial one-year extension on the same terms and conditions as the initial two-year term. In November 2005, Wyeth exercised this option to extend the initial term. By exercising this option, Wyeth agreed to extend the research term by one year through February 9, 2007. After the initial one-year extension, the agreement may be extended for additional one-year periods upon recommendation of the steering committee with such full-time equivalent researchers and related Wyeth funding obligations as may be consistent with fulfilling the objectives of the research plan.

As part of the agreement, we have retained development and licensing options for certain therapeutic applications of the Hedgehog agonist technologies, including topical treatment for skin diseases and disorders including hair growth regulation, ex vivo cell therapy, local delivery applications for treatment of cardiovascular disease, and those applications that qualify as orphan drug indications. Wyeth has a right of first negotiation to obtain an exclusive license to the orphan drug indications and the cardiovascular applications. If Wyeth declines to exercise its right, or if we are unable to reach an agreement with Wyeth on terms within the contractually specified period, we are free to seek another collaborator for these programs.

Hedgehog Agonist Hair Growth Program

Under collaboration with Procter and Gamble

Program Summary

Our scientists have demonstrated that small molecule Hedgehog agonists can induce hair growth in preclinical models. Some of our recent results were presented in February 2005 at the annual meeting of the American Academy of Dermatology in New Orleans, Louisiana. In October 2005, we published data in the *Journal of Investigational Dermatology*, reporting on the therapeutic efficacy of one of our proprietary Hedgehog pathway activators in a preclinical model of hair growth. The results of the study show that a topically applied small molecule agonist of the Hedgehog signaling pathway can stimulate the transition of hair follicles from the resting to the growth stage of the hair cycle.

Collaboration Summary

The Hedgehog agonist program was exclusively licensed to Wyeth in February 2004. Under the terms of the license agreement, we retained the right to develop Hedgehog agonists for topical treatment of hair growth and other dermatological disorders. The terms of the agreement include Wyeth's right to authorize the reversion of any compounds that we will develop in this area. In December 2004 and in August 2005, Wyeth approved the reversion of a group of Hedgehog agonist compounds for use in our hair program thereby inducing hair growth. On September 18, 2005, we entered into a collaboration, research and license agreement with Procter & Gamble, to evaluate and develop potential treatments for hair growth regulation and skin disorders utilizing these reverted Hedgehog agonist compounds.

Under the terms of the agreement, we granted to Procter & Gamble an exclusive, worldwide, royalty-bearing license for the development and commercialization of topical dermatological and hair growth products that incorporate our Hedgehog agonist technology. In accordance with the terms of the agreement, the parties shall jointly undertake a research program with the goal of identifying one or more compounds to be developed and commercialized by Procter & Gamble. Procter & Gamble is solely responsible for the cost of worldwide development and commercialization of any product candidates developed pursuant to the research program, provided however, that at the time that Procter & Gamble determines to file the first IND application with the FDA for a product candidate, we shall have the option, at our sole discretion, to co-develop a product candidate through Phases I and II of clinical development. We would receive a higher royalty in the event that we exercise our co-development option and subsequently share in development expense through Phase II clinical trials. Should we elect to exercise this co-development option, we will forego contingent cash payments that would otherwise be payable for the achievement of certain development objectives during the period from IND application filing through the completion of a Phase II clinical trial. Procter & Gamble has paid us an up-front license fee of \$500,000 and has agreed to fund up to \$600,000 for two of our full-time equivalent employees to provide research and development activities during the initial one-year research term, subject to its termination rights. Procter & Gamble has an option to extend the initial one-year research term for up to three additional years in one-year increments.

Procter & Gamble has also agreed to make cash payments to us that are contingent upon the successful achievement of certain research, development, clinical and drug approval milestones. Procter & Gamble will also pay us royalties on net product sales if product candidates derived from the collaboration are successfully developed. We will receive a higher royalty in the event that we exercise our co-development option and subsequently share in development expenses through Phase II clinical trials.

In March of 2006, we reached the first preclinical development objective in our hair growth program with Procter & Gamble Pharmaceuticals, a division of The Procter & Gamble Company. The program is focused upon the potential development of a topical Hedgehog agonist for hair growth disorders, such as male pattern baldness and female pattern hair loss. As part of the initial agreement signed in September of 2005, P&G agreed to pay Curis up to \$2,800,000 in cash payments that are contingent upon the certain achievement of certain preclinical development objectives. The first of two preclinical development objectives was successfully completed and resulted in a payment to Curis of \$1,000,000.

BMP-7 Program

Licensed to Ortho Biotech Products, a Subsidiary of Johnson & Johnson and under development at Centocor, also a subsidiary of Johnson & Johnson

Program Summary

BMP-7 is a signaling protein that is expressed in the kidney and in other tissues and organs and has been implicated in the maintenance of the normal health of the kidney, the skeleton, and the vascular system. In recent years, several academic researchers have demonstrated the potential of using BMP-7 as a treatment for chronic kidney disease and systemic complications, such as renal osteodystrophy, a form of bone disease, and blood vessel complications that are associated with chronic kidney disease.

License Agreement Summary

In November 2002, we entered into an agreement with Ortho Biotech Products, a subsidiary of Johnson & Johnson, pursuant to which Ortho Biotech obtained the license rights to our BMP-7 technology and assumed control of the continued development of this product candidate. Ortho Biotech Products is a pharmaceutical company with broad expertise in protein-based therapeutic drug development and has an established presence in the kidney disease marketplace. In 2005, Johnson & Johnson moved responsibility for the further development of BMP-7 to Centocor, another subsidiary of Johnson & Johnson, and Centocor has assumed all future costs and responsibility for BMP-based product development. We are entitled to receive a series of contingent cash payments that are tied to the achievement of clinical development and regulatory objectives, and royalties on product sales if any BMP-based products are successfully commercialized. Centocor has sole responsibility for deciding if and when human clinical trials of BMP-7 will begin.

Other Programs

Spinal Muscular Atrophy Program (Retained by Curis). On September 7, 2004, we entered into a sponsored research agreement with the SMA Foundation. Under the agreement, the SMA Foundation will grant us up to \$5,364,000 over a three-year period for the identification of therapeutic compounds to treat spinal muscular atrophy, a neurological disease that is the leading genetic cause of infant and toddler death.

The research will utilize our proprietary technologies and expertise to develop and refine assays in motor neurons and then use those assays to screen for potential drug candidates. We will own any compounds that we generate under this collaboration and will also have the ability to bring any such compounds into the clinic, either using our own resources or with a collaborating third party. If any drug candidates developed under the agreement are successfully commercialized, we will be required to make cash payments to the SMA Foundation if cumulative revenues from the sales of such products exceed \$100,000,000. Unless terminated earlier, the agreement will continue until the expiration of the research activities.

BMP Agonist Small Molecule Screening Program (Retained by Curis/Centocor Right of First Negotiation). In December 2005, we expanded our relationship with Centocor. Under the new agreement, we will screen for small molecule agonists that mimic the bioactivity of BMP-7 and activate the bone morphogenetic pathway. The term of the agreement is expected to last fifteen months. We will own any small molecule BMP agonist compounds that are discovered as part of this screening and Centocor will have an exclusive option to first negotiate a new collaboration and exclusive license agreement for the development of such small molecules.

Hedgehog Agonist Cardiovascular Disease Program (Retained by Curis/Wyeth Right of First Negotiation). As part of our collaboration with Wyeth, we have retained the right to locally deliver Hedgehog agonists for the treatment of cardiovascular diseases including peripheral vascular disease and acute myocardial infarction, or heart attack. Wyeth has a right of first negotiation to obtain an exclusive license to the cardiovascular applications. If Wyeth declines to exercise its option, or if we are unable to reach an agreement with Wyeth on terms within the contractually specified period, we will actively explore other licensing opportunities for this program.

We have incurred nominal expenses related to our cardiovascular disease program for the year ended December 31, 2005. Our preclinical data relating to this program has been derived from studies conducted at Caritas St. Elizabeth's Medical Center in Boston, Massachusetts. We are exploring collaborative opportunities where a potential collaborator would utilize this biological property of the Hedgehog pathway to develop locally administered drug candidates to treat cardiovascular disorders such as heart attacks and peripheral vascular disease.

Discovery Research (Retained by Curis). In addition to the research and development programs listed above, we also plan to bolster our pipeline by expanding into other signaling pathways by utilizing our proprietary screening technologies and know-how to find potential new therapeutic product candidates.

Website Access to Reports

We maintain a website with the address www.curis.com. We are not including the information contained in our website as part of, or incorporating it by reference into, this annual report on Form 10-K. Our website address is included in this annual report on Form 10-K as an inactive textual reference only. We make available free of charge through our website our annual reports on Form 10-K, our quarterly reports on Form 10-Q, current reports on Form 8-K and any such amendments to those reports as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the Securities and Exchange Commission. The Securities and Exchange Commission maintains a website, www.sec.gov, that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. The public may read and copy any materials we file with the Securities and Exchange Commission at the SEC's Public Reference Room at 450 Fifth Street, N.W., 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 United States 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 United States expiring on various dates between 2006 and 2022 with pending United States 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.

Hedgehog Pathway. We have issued U.S. patents and allowed U.S. applications expiring on various dates between 2014 and 2021, which relate to the Hedgehog pathway. These 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 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.

Bone Morphogenetic Pathway. We have issued U.S. patents expiring on various dates between 2006 and 2022, which relate to the BMP pathway. These patents and patent applications cover certain BMP proteins, nucleic acids, antibodies, drug screening and discovery methods, methods of protein manufacturing, as well as methods of using these BMP proteins, nucleic acids or antibodies 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 BMP-related products.

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 and to use technologies in our research and development processes. The consideration payable in exchange for these licenses includes up-front fees, issuances of shares of common stock, annual royalties, milestone payments and running 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 with 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. Our research group, working closely with our business development group, also strives to identify external technologies that might provide in-licensing or acquisition opportunities, consistent with our broad interest in regulatory signaling pathways. As of December 31, 2005, our research group consists of 47 employees, consisting of molecular biologists, cell biologists, pharmacologists and other scientific disciplines.

During the years ended December 31, 2005, 2004 and 2003, our total company-sponsored research and development expenses were approximately \$705,000, \$9,000,000 and \$4,000,000, respectively, and our collaborator-sponsored research and development expenses were approximately \$13,000,000, \$3,700,000 and \$10,400,000, respectively. In addition, we incurred costs of \$6,999,000 for our portion of co-development costs of the basal cell carcinoma product candidate that are reported as contra-revenues.

Regulatory Matters

FDA Requirements for New Drug Compounds

Numerous governmental authorities in the United States and other countries extensively regulate the research, testing, manufacture, import and export and marketing of drug products. In the United States, drugs 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 United States include preclinical laboratory tests, animal tests and formulation studies, under the FDA's good laboratory practice regulations, the submission to the FDA of a notice of claimed investigational exemption or an investigational new drug 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, 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 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 good laboratory practice regulations. Preclinical testing may not be completed successfully within any specified time period, if at all, and may not assure success in clinical trials. The results of preclinical testing are submitted to the FDA as part of an investigational new drug application, together with manufacturing information and analytical and stability data. The investigational new drug application must become effective before clinical trials can begin in the United States. An investigational new drug 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 investigational new drug application. In that case, the investigational new drug 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 investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal regulations and requirements, under protocols detailing 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 investigational new drug 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. 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. Phase II usually involves trials in a limited patient population, to determine dosage tolerance and optimum dosage, identify possible adverse effects and safety risks, and provide preliminary support for the efficacy of the drug in the indication being studied. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase II evaluations, Phase III trials are undertaken to further evaluate clinical efficacy and to further test for safety within an expanded patient population, typically at geographically dispersed clinical trial sites. 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 United States and 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 patient. 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 is prepared and submitted to the FDA. FDA approval of the new drug application 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, the new drug application must be accompanied by a substantial user fee.

If the FDA's evaluation of the new drug application and inspection of the manufacturing facilities are favorable, the FDA may issue an approval letter, or, in some cases, an approvable letter followed by an approval letter. An approvable letter generally contains a statement of specific conditions that must be met in order to secure final approval of the new drug application. 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 new drug application approval, the FDA may require post approval testing 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 and submission of periodic reports and drug sampling and distribution requirements. Additionally, the FDA also strictly regulates the promotional claims that may be made about prescription drug products. In particular, 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. 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 new drug application submission or manufacturing facilities is not favorable, the FDA may refuse to approve the new drug application or issue a not approvable letter. The not approvable letter outlines the deficiencies in the 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 new drug application regardless of prior advice it may have provided or commitments it may have made to the sponsor.

Foreign Regulation of New Drug Compounds

Approval of a 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. The approval procedure varies among countries and can involve requirements for additional testing. The time required may differ from that required for 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 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 all medicinal products which 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. We do not expect the cost of complying with these laws and regulations to be material.

Competition

Our product candidates 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 and medical device firms. For example, we have identified biotechnology companies that claim to have intellectual property rights 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 significant competitive advantages over us. Others have extensive experience in undertaking clinical trials, in obtaining regulatory approval to market products and in manufacturing products on a large scale, which may enhance their competitive position relative to ours. 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 change. 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 our collaborators or we 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 United States and abroad. Other companies may succeed in developing similar products that are introduced earlier, are more effective, or are produced and marketed more effectively. For example, our competitors may discover, characterize and develop important inducing 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.

We rely on or will rely on our 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. Some of our strategic collaborators are conducting 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.

Our lead product candidate, a topical therapy for the treatment of basal cell carcinoma under co-development with Genentech, will face competition from both surgical and medical alternatives. Surgery is

currently the standard of care, is typically performed by dermatologists and has an efficacy rate of approximately 90%. The American Cancer Society describes the four main surgical treatment alternatives and their drawbacks as follows:

- Simple excision/excisional biopsy: The tumor is cut out, along with some normal skin around it. The remaining skin is carefully stitched back together. This surgery will leave a scar.
- Curettage and electrodesiccation: In this treatment the cancer is removed by scraping it with a long, thin instrument. The area is treated with an electric needle to destroy any remaining cancer cells. The process is repeated 1 to 3 times. This treatment will also leave a scar.
- Cryosurgery: In this treatment liquid nitrogen is used to freeze and kill cancer cells. After the dead tissue thaws, blistering and crusting may occur. The wound may take several weeks to heal and will leave a scar. The treated area may have less color after treatment.
- Mohs surgery: In this surgery, the doctor removes a layer of skin that the tumor may have invaded and then carefully maps its location. The doctor checks the sample under a microscope right away. If it is cancer, more pieces of the tumor will be removed and examined until the skin samples are found to be free of cancer cells. This process is slow, but it means that normal skin next to the tumor can be saved. This assures a better appearance after surgery. Only doctors who have had special training perform this type of surgery.

In addition to surgery, certain types of basal cell carcinomas can be treated using other FDA-approved topical treatments, including 3M's Aldara® (Imiquimod) and ICN's Efudex® (Fluorouracil). These FDA-approved topical treatments are limited to a subset of basal cell carcinomas, called superficial basal cell carcinoma, which is the least severe form of basal cell carcinoma and is not as prevalent as the more serious form of the disease, nodular basal cell carcinoma. A market assessment that we completed during 2004 estimates that approximately 35% of basal cell carcinomas are superficial basal cell carcinomas, 55% are nodular basal cell carcinomas, and 10% are associated with other types of basal cell carcinomas. Aldara is an immune response modulator that was approved in July 2004 for the treatment of a subset of superficial basal cell carcinoma lesions. Its mechanism of curing superficial basal cell carcinoma will generally result in skin irritation including possible scabbing, flaking, burning or itching of the skin. Efudex's active ingredient, Fluorouracil, or 5FU, is chemotherapy that is given as a treatment for some types of cancer including bowel, breast and stomach cancer. Because Efudex is a chemotherapeutic agent, we believe that there may be side effects which are greater than our basal cell carcinoma product candidate.

We believe that our basal cell carcinoma product candidate directly targets the known mechanism of action underlying the formation of basal cell carcinomas and that our product may be superior because we believe that it induces selective death of tumor cells while sparing adjacent normal cells and maintaining the typical architecture of the skin at the treatment site. Because of this, we believe that our product may produce minimal scarring when compared to the treatments described above and may be more effective than any of the topical treatments listed above. However, we acknowledge that our basal cell carcinoma product candidate, if approved by FDA, will face the challenge of displacing entrenched competition from at least the surgical and topical treatments listed above.

Manufacturing

We have no experience or capabilities in manufacturing. We have no current plans to develop manufacturing capability and instead plan to rely on our corporate collaborators or subcontractors to manufacture products.

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 our corporate collaborators for product sales, marketing and distribution.

Scientific Advisory Board

We have established a scientific advisory board made up of leading scientists and physicians in the field of signaling pathways. Members of our scientific advisory board consult with us on matters relating to our research and development programs, 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:

<u>Name</u>	<u>Position/Institutional Affiliation</u>
Douglas A. Melton, Ph.D. (Chairman)	Investigator, Howard Hughes Medical Institute Thomas Dudley Cabot Professor of the Natural Sciences, Department of Molecular and Cellular Biology Harvard University
Brigid Hogan, Ph.D.	Professor and Chair, Department of Cell Biology Duke University Medical School
Thomas Jessell, Ph.D.	Investigator, Howard Hughes Medical Institute Professor, Biochemistry and Molecular Biophysics Columbia University, College of Physicians and Surgeons
Andrew P. McMahon, Ph.D.	Frank B. Baird, Jr. Professor of Science, Department of Molecular and Cellular Biology Harvard University
Roeland Nusse, Ph.D.	Investigator, Howard Hughes Medical Institute Professor, Department of Developmental Biology Stanford University Medical School
Martin C. Raff, M.D.	Emeritus Professor, Biology Department and MRC Laboratory for Molecular Cell Biology and Cell Biology Unit University College London
Matthew Scott, Ph.D.	Investigator, Howard Hughes Medical Institute Professor, Departments of Developmental Biology and Genetics Chairman, Bio-X Scientific Leadership Council Stanford University School of Medicine
Clifford J. Tabin, Ph.D.	Professor, Department of Genetics Harvard Medical School

Employees

As of December 31, 2005, we had 68 full-time employees, of whom 36 hold Ph.D. or other advanced degrees. Of these employees, 47 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.

ITEM 1A. RISK FACTORS

Factors That May Affect Results

RISKS RELATING TO OUR FINANCIAL RESULTS AND NEED FOR FINANCING

We have recently 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 have 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 cause our stock price to decline and could subject us to securities litigation.

As discussed in Note 2 of the notes to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we have recently concluded that we made accounting errors in prior periods primarily relating 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 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 2005, 2004 or 2003. Instead, we will defer the \$7,509,000 in payments and recognize this amount as revenue only when we can reasonably estimate when our contractual steering committee obligations will cease or after we no longer have contractual steering committee obligations under this agreement with Genentech. The contractual term of our steering committee obligations extends for as long as Hedgehog antagonist products subject to this collaboration are being developed or commercialized by either of the parties. Accordingly, the contractual term of our steering committee obligations is indefinite and we expect that we will not record any revenue related to these payments for at least several years.

We are also restating previously reported research and development expenses associated with \$410,000 in license fee payments that were payable to university licensors in connection with the June 2003 Hedgehog antagonist collaboration with Genentech. We had previously capitalized this amount as "Prepaid expenses and other current assets" and "Deposits and other assets" in our consolidated balance sheets and amortized this amount to research and development expense as the related license fee was recognized. We have determined that we should have instead recognized the entire \$410,000 immediately as research and development expense in June 2003.

In connection with the restatement, we have also corrected other previously identified immaterial errors which had previously been corrected through a cumulative adjustment to the consolidated financial statements in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2005. The restatement allocates the adjustment among the correct periods.

The restatement could result in a decline in our stock price and securities class action litigation. In the past, 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 will be expensive and will 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.

We have incurred substantial losses, we expect to continue to incur substantial losses and we may never achieve profitability.

We expect to incur substantial operating losses for the foreseeable future, and we have no current sources of material ongoing revenue. As of December 31, 2005, we had an accumulated deficit of approximately \$680,054,000. If we are not able to commercialize any products, whether alone or with a collaborator, we will not achieve profitability. Other than OP-1, which we and Stryker discovered under a former collaboration and Stryker has subsequently commercialized, we have not commercialized any products to date, either alone or with a third-party collaborator. 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 on our research and development programs in order to produce products which we can commercialize. Even if our collaboration agreements provide funding for a portion of our research and development expenses, we will need to generate significant revenues in order to fund our operation 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 "Factors That May Affect Results". 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 product offerings or continue our operations.

We will require additional financing, which may be difficult to obtain and may dilute our existing shareholder ownership interest in us.

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 primarily include the need for working capital to:

- fund our portion of the U.S. development costs for a basal cell carcinoma drug candidate pursuant to our equal cost-sharing co-development arrangement with Genentech;
- support our research and development activities for our internal programs, including our program in cardiovascular disease and any unfunded portion of our small molecule discovery screening programs;
- expand our infrastructure; and
- fund our general and administrative costs and expenses.

We believe that our existing cash and working capital should be sufficient to fund our operations until mid-2007; however, our future capital requirements may vary from what we expect. There are factors that may 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:

- continued progress in our research and development programs, as well as the magnitude of these programs;
- the time and cost, including unplanned cost, involved in advancing clinical trials for the basal cell carcinoma drug candidate being co-developed with Genentech;
- the cost of additional facilities requirements;
- our ability to establish and maintain collaborative arrangements;
- the timing, receipt and amount of research funding and milestone, license, royalty, profit-sharing and other payments, if any, from collaborators;
- the timing, payment and amount of research funding and milestone, license, royalty and other payments due to licensors of patent rights and technology used to make, use and sell our product candidates;
- the timing, receipt and amount of sales revenues and associated royalties, if any, that we receive from our product candidates in the market; 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 and may seek additional funding from additional strategic collaborators or additional foundations, such as the funding that we were awarded under our Spinal Muscular Atrophy Foundation research grant. However, the market for biotechnology stock in general, and the market for our common stock in particular, is highly volatile. Due to various factors, including market conditions and the 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.

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 in Note 2 of the notes to consolidated financial statements included elsewhere in this annual report on Form 10-K, we have recently determined to restate our consolidated financial statements for 2004 and 2003 and for the quarters ended March 31, 2005, June 30, 2005 and September 30, 2005 to correct errors in prior periods including the following:

- we prematurely recorded accounts receivable within the assets section of our consolidated Balance Sheets as well as an offsetting amount to our deferred revenues within the liabilities section of our consolidated Balance Sheets in connection with a collaboration agreement executed in 2003;
- we used the contractually negotiated price rather than the closing market price to calculate the value of common shares sold in connection with two of our collaboration agreements; and
- we treated certain annual maintenance payments under a collaboration as accounts receivable in our consolidated balance sheets prior to the date such cash payments were received.

For a further discussion of the estimates and judgments that we make and the critical accounting policies that affect these estimates and judgments, see “Critical Accounting Policies and Estimates” below.

RISKS RELATING TO OUR COLLABORATIONS

We are dependent on collaborators for the development and commercialization of many of our product candidates and for a significant portion of our revenue. If we lose any of these collaborators, or if they 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 product candidates depends upon our ability to form and maintain productive strategic collaborations. We currently have strategic collaborations with Genentech, Wyeth, Procter & Gamble, Centocor, and Ortho Biotech Products. During the years ended December 31, 2005 and 2004, \$9.6 million and \$3.1 million, or 85% and 74%, respectively, of our gross revenue was derived from licensing and research and development payments received from these collaborators. We hope

to enter into additional collaborations in the future. Our existing and any future collaborations may not be scientifically or commercially successful.

The risks that we face in connection with these collaborations include the following:

- Each of our collaborators has significant discretion in determining the efforts and resources that they will apply to the collaboration. The timing and amount of any future royalty, profit-sharing and milestone revenue that we may receive under such collaborative arrangements will depend on, among other things, such collaborator's efforts and allocation of resources.
- All of our strategic collaboration agreements are for fixed terms and are subject to termination under various circumstances, including in some cases, on short notice without cause. If any collaborator were to terminate an agreement, we may not have the funds available to independently undertake product development, manufacturing and commercialization and we may not have the funds or capability to do this, which could result in a discontinuation of such program.
- Our strategic collaboration agreements permit our collaborators wide discretion in terms of deciding which product candidates to advance 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 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 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 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. 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 additional strategic collaborations or other alternative arrangements. Our research and development pipeline may be insufficient or our programs may be deemed too early 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 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 fields of regulatory signaling pathways and functional genomics, which includes our work with Genentech in the field of cancer, with Wyeth in the field of neurology, with Procter & Gamble in the field of hair growth regulation, is highly competitive. A number of entities are seeking to identify and patent randomly sequenced genes and gene fragments, typically without specific knowledge of the function

that such genes or gene fragments perform. Our competitors may discover, characterize and develop important inducing molecules or genes before we do. We also face competition from these and other entities in gaining access to DNA samples used in our research and development projects.

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. As a result, they may be more successful in commercialization and/or may develop competing products more rapidly and at a lower cost. For those programs that are subject to a collaboration agreement, competitors may discover, develop and commercialize products which render our products non-competitive or obsolete.

We expect competition to intensify in genomics research and regulatory signaling pathways as technical advances in the field are made and become more widely known.

While many of our technologies are subject to collaborations, our remaining technologies that are available for internal programs have several potential applications. We have limited resources and are pursuing a strategy of undertaking foundation-funded research for orphan disease indications. The limited markets that are associated with such indications as well as conditions of funding arrangements may result in our failure to capitalize on other potentially profitable applications of our technologies.

We have limited financial and managerial resources to devote to new internal programs. These limitations have led us to adopt a strategy where we have undertaken funded research for certain orphan disease indications and to forego the exploration of other product opportunities. While our new technologies may permit us to work in multiple areas, resource commitments may require trade-offs resulting in delays in the development of certain programs or research areas, which may place us at a competitive disadvantage. In addition, our funded research includes screening of compounds that are not proprietary to us and may result in identification of a drug candidate that would not result in a commercially viable product and/or may divert resources away from other market opportunities, which ultimately prove to be more profitable.

If we or any of our 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.

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 and developing 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 claims would require us to spend significant time, money and other resources to defend such claims and could ultimately lead to our having to pay a significant damage award. Product liability insurance is expensive to procure for biopharmaceutical companies such as ours. Although we

maintain product liability insurance coverage for the clinical trials of our products under development, it is possible that we will not be able to obtain additional product liability insurance on acceptable terms, if at all, and that our product liability insurance coverage will 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 highly depend upon our senior management and scientific staff. 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. Key members of our senior management team include Daniel R. Passeri, our president and Chief Executive Officer and Dr. Lee L. Rubin, our Executive Vice President and Chief Scientific Officer. Our executive officers, including these individuals, can terminate their employment with us at any time. The loss of the services of any of our executive officers may significantly delay or prevent the achievement of product research and development and other business objectives. 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.

If we make any acquisitions, we will incur a variety of costs and may never successfully integrate the acquired business into ours.

We may attempt to acquire businesses, technologies, services or products that we believe are a strategic complement to our business model. We may encounter operating difficulties and expenditures relating to integrating an acquired business, technology, service or product. These acquisitions may also absorb significant management attention that would otherwise be available for ongoing development of our business. Moreover, we may never realize the anticipated benefits of any acquisition. We may also make dilutive issuances of equity securities, incur debt, experience a decrease in the cash available for our operations, or incur contingent liabilities in connection with any future acquisitions.

RISKS RELATING TO INTELLECTUAL PROPERTY

If we or any of our licensees and 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 and expect to enter into similar agreements with third parties in the future. Under these agreements, we 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 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 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 standards which the United States Patent and Trademark Office uses to grant patents, and the standards which courts use to interpret patents, are not always applied predictably or uniformly and can change, particularly as new technologies develop. Consequently, the level of protection, if any, that will be provided by our patents if we attempt to enforce them, and they are challenged, is uncertain. The long-term success of our enterprise 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 sufficiently broad 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 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 which 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 impair our ability to exploit our technology. As a result, we or our 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.

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

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 which 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 or opposition proceedings to determine the priority of invention if our competitors file patent applications that claim technology also claimed by us;
- 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 which 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 our 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 our 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. Patent litigation and other proceedings may also absorb significant management time and expense.

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 agreements with our employees, consultants and other third-party contractors as well as through other security measures. These confidentiality 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 CLINICAL AND REGULATORY MATTERS

We expect to rely heavily on third parties for the conduct of clinical trials of our product candidates as well as certain preclinical testing. If clinical trials are not successful, or if our collaborators decide to terminate development efforts for a particular compound, or if we or our collaborators are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates.

In order to obtain regulatory approval for the commercial sale of our product candidates, we and our 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. We have limited experience in conducting clinical trials and expect to rely primarily on collaborative partners and contract research organizations for their performance and management of clinical trials of our product candidates.

Clinical development, including preclinical testing, is a long, expensive and uncertain process. Accordingly, preclinical testing and clinical trials, if any, of our product candidates under development may not be successful. We and our collaborators could experience delays in preclinical or clinical trials of any of our product candidates which obtain unfavorable results in a development program, or fail to obtain regulatory approval for the commercialization of a product. Preclinical studies or clinical trials may produce negative, inconsistent or inconclusive results, and we or our 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 early clinical trials may not be statistically significant or predictive of results that will be obtained from expanded, advanced clinical trials. Furthermore, the timing and completion of clinical trials, if any, 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.

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. Also, 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 our 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. Additionally, the failure of third parties conducting or overseeing the operation of the clinical trials to perform their contractual or regulatory obligations in a timely fashion could delay the clinical trials.

Failure of clinical trials can occur at any stage of testing for a variety of reasons. Any of these events would adversely affect our ability to market a product candidate.

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

To the extent that we, or our collaborative partners, are able to successfully advance a product candidate through the clinic, we, or such partner, will be required to obtain regulatory approval prior to marketing and selling such product.

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. The process of obtaining FDA and other required regulatory approvals for many of our products under development is further complicated because some of these products use non-traditional or novel materials in non-traditional or novel ways, and the regulatory officials have little precedent to follow. 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, or our collaborative partners, also are 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.

As a result of these factors, we or our 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 our 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.

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

Even if regulatory approval of a product candidate is obtained by us or our collaborators, the approval may be subject to limitations on the indicated uses for which the product is marketed or require costly post-marketing follow-up studies. After marketing approval for any product is obtained, the manufacturer and the manufacturing facilities for that product will be subject to continual review and periodic inspections by the FDA and other

regulatory agencies. The subsequent discovery of previously unknown problems with the product, or with the manufacturer or facility, may result in restrictions on the product or manufacturer, including withdrawal of the product from the market.

If there is a failure to comply with applicable regulatory requirements, we or our collaborator may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecution.

We and our collaborators are subject to governmental regulations other than those imposed by the FDA. We and our 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 our collaborators are subject to regulation under 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 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 PRODUCT MANUFACTURING AND SALES

We will depend on our 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 products, apply for regulatory approvals, and commercialize our products, we or our collaborators must be able to manufacture products in adequate clinical and commercial quantities, in compliance with regulatory requirements, at acceptable quality and cost 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 on a timely basis or at all or are contaminated or otherwise lost, clinical trials by us and our 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 our collaborators seek to enter into manufacturing arrangements with third parties, we and such collaborators will depend upon these third parties to perform their obligations in a timely and effective manner and in accordance with government regulations. Contract manufacturers may breach their manufacturing agreements because of factors beyond our control or may terminate or fail to renew a manufacturing agreement based on their own business priorities at a time that is costly or inconvenient for us.

Any contract manufacturers that we enter into manufacturing arrangements with 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. Failure of contract manufacturers or our 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 these 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 our collaborators may not be able to initiate or continue clinical trials of products that are under development;
- we and our collaborators may be delayed in submitting applications for regulatory approvals for our product candidates; and
- we and our 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, Wyeth, Procter & Gamble and Ortho Biotech Products, we have granted our collaborators 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 which 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.

RISKS RELATED TO OUR COMMON STOCK

Our stock price will 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 \$2.46 per share for the period January 1, 2004 through December 31, 2005. 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;
- the market's reaction to our announcement regarding our determination to restate our 2004 and 2003 consolidated financial statements;
- actual or anticipated changes to our research and development plans;
- deviations in our operating results from the estimates of securities analysts;
- adverse results or delays in clinical trials being conducted by us or our collaborators;
- any intellectual property lawsuits involving us;
- sales of large blocks of our common stock;
- sales of our common stock by our executive officers, directors or significant stockholders;
- 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.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell such shares, could reduce the market price of our common stock. As of December 31, 2005, we had outstanding approximately 48.3 million shares of common stock. Substantially all of these shares may also be resold in the public market at any time. In addition, we have a significant number of shares that are subject to outstanding options and warrants. The exercise of these options and warrants and the subsequent sale of the underlying common stock could cause a further decline in our stock price. These sales also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

We 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 have three facilities which are located at 25, 45 and 61 Moulton Street in Cambridge, Massachusetts and which consist of 1,526, 35,095, and 17,800 square feet, respectively. The facilities at 25 and 61 Moulton Street are leased until April 2006 and April 2007, respectively. In August 2004, we extended the lease for the 45 Moulton Street location until December 2010. Except for 11,980 square feet at our 61 Moulton Street facility that we have sublet until April 2007, we currently use our space to conduct research and development initiatives and to manage the administrative aspects of our business. We believe that our existing facilities will be suitable and adequate to meet our needs for the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS

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

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

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

EXECUTIVE OFFICERS OF THE REGISTRANT

Our executive officers are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Daniel R. Passeri	45	President and Chief Executive Officer
Lee L. Rubin, Ph.D	55	Executive Vice President of Research and Chief Scientific Officer
Michael P. Gray	35	Vice President of Finance and Chief Financial Officer
Mark W. Noel	47	Vice President, Technology Management and Business Development
Mary Elizabeth Potthoff, Esq	52	Vice President, General Counsel

Daniel R. Passeri 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 a M.Sc. in biotechnology, and of Northeastern University, with a B.S. in Biology.

Lee L. Rubin, Ph.D Dr. Rubin has served as our Executive Vice President of Research since October 2004. He served as our Senior Vice President of Research and Chief Scientific Officer from September 2000 to October 2004 and as our Vice President of Research from March 2000 to September 2000. From October 1997 to March 2000, Dr. Rubin was employed by Ontogeny, Inc. a predecessor life sciences company, as Vice President of Research. Prior to joining Ontogeny, Dr. Rubin spent six years at Eisai London Laboratories at University College London, where he served as Director and Professor of Neurobiology. Prior to that, Dr. Rubin worked for four years with Athena NeuroSciences, Inc., a life sciences company, where he served as senior scientist and head of the blood-brain barrier program. Dr. Rubin completed his Ph.D. at Rockefeller University and his B.A. at Cornell University.

- Michael P. Gray Mr. Gray has served as our Vice President of Finance and Chief Financial Officer since December 2003 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.
- 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 completed his B.S. at the University of Maryland.
- Mary Elizabeth Potthoff, Esq Ms. Potthoff has served as our Vice President, General Counsel and Assistant Secretary since August 2002 and as Secretary since December 2003. From August 1999 to April 2002, Ms. Potthoff was Vice President, General Counsel and Corporate Secretary at Wheelhouse Corporation, an internet marketing software and consulting services company. From July 1994 to August 1999, Ms. Potthoff was Vice President, General Counsel and Corporate Secretary at Shiva Corporation, a technology company focused on remote access network products and services. From July 1989 to July 1994, Ms. Potthoff was Senior Corporate Counsel at Bytex Corporation, a technology company focused on network matrix switch products and services. Ms. Potthoff received her J.D., cum laude, from Suffolk University, an M.B.A. from Providence College, and a B.A. from the State University of New York.

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 National 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 National Market:

	Curis Common Stock	
	High	Low
<u>Year ended December 31, 2004</u>		
First Quarter	\$6.59	\$4.50
Second Quarter	\$5.17	\$3.51
Third Quarter	\$4.95	\$2.46
Fourth Quarter	\$5.94	\$3.14
<u>Year ended December 31, 2005</u>		
First Quarter	\$5.32	\$3.27
Second Quarter	\$4.35	\$3.23
Third Quarter	\$4.94	\$3.81
Fourth Quarter	\$4.69	\$3.50

(b) *Holder of Record.* On March 22, 2006, the last reported sale price of our common stock on the NASDAQ National Market was \$2.29 and there were 306 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.

(d) *Changes in Securities and Use of Proceeds.* None.

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. As described in Note 2 to our consolidated financial statements, we have restated our consolidated financial statements for the years ended December 31, 2004 and 2003.

	(in thousands, except per share data)				
	Year Ended December 31,				
	2005	2004	2003	2002	2001
		(as restated)	(as restated)		
Consolidated Statement of Operations Data:					
Revenues:					
Research and development contracts and government grants	\$ 10,493	\$ 3,407	\$ 1,629	\$ 245	\$ 968
License and maintenance fees	2,258	242	8,749	3,758	119
Substantive milestones	250	50	—	—	—
Royalties	—	—	—	14,388	—
Contra-revenues(1)	(6,999)	—	—	—	—
Net revenues	<u>6,002</u>	<u>3,699</u>	<u>10,378</u>	<u>18,391</u>	<u>1,087</u>
Costs and expenses:					
Research and development	13,705	12,662	14,388	13,281	35,228
General and administrative	8,090	7,757	6,883	11,097	14,695
Amortization of and impairment charge related to intangible assets(3)	75	75	75	474	23,339
Loss of property and equipment(2)	—	—	—	5,337	—
Impairment of goodwill(2)	—	—	—	64,098	—
Restructuring expenses(2)	—	—	—	3,490	—
Total costs and expenses	<u>21,870</u>	<u>20,494</u>	<u>21,346</u>	<u>97,777</u>	<u>73,262</u>
Loss from operations	<u>(15,868)</u>	<u>(16,795)</u>	<u>(10,968)</u>	<u>(79,386)</u>	<u>(72,175)</u>
Equity in loss from joint venture(4)	—	—	—	(4,311)	(13,453)
Other income (expense):					
Interest and other income (expense)	1,321	2,131	(1,017)	2,329	4,548
Interest expense	(308)	(411)	(694)	(947)	(784)
Total other income (expense)	<u>1,013</u>	<u>1,720</u>	<u>(1,711)</u>	<u>1,382</u>	<u>3,764</u>
Net loss	<u>(14,855)</u>	<u>(15,075)</u>	<u>(12,679)</u>	<u>(82,315)</u>	<u>(81,864)</u>
Accretion on Series A Redeemable Preferred					
Stock	—	—	(271)	(723)	(326)
Net loss applicable to common stockholders	<u>\$(14,855)</u>	<u>\$(15,075)</u>	<u>\$(12,950)</u>	<u>\$(83,038)</u>	<u>\$(82,190)</u>
Basic and diluted net loss per common share	<u>\$ (0.31)</u>	<u>\$ (0.35)</u>	<u>\$ (0.36)</u>	<u>\$ (2.57)</u>	<u>\$ (2.58)</u>
Weighted average common shares					
(basic and diluted)	<u>48,074</u>	<u>42,686</u>	<u>36,016</u>	<u>32,267</u>	<u>31,859</u>

	(in thousands)				
	As of December 31,				
	2005	2004	2003	2002	2001
		(as restated)	(as restated)		
Consolidated Balance Sheet Data:					
Cash, cash equivalents and marketable securities	\$ 44,209	\$ 49,514	\$ 35,148	\$ 36,573	\$ 52,107
Working capital	36,010	46,854	33,376	30,697	42,848
Long-term investment—restricted	196	193	191	4,403	—
Total assets	60,914	67,332	51,450	62,442	144,756
Debt and lease obligations, net of current portion	1,967	—	—	3,424	4,951
Convertible notes payable	2,605	5,710	5,334	6,885	2,507
Series A Convertible/Exchangeable Preferred Stock	—	—	—	13,064	12,341
Accumulated deficit	(680,054)	(665,199)	(650,124)	(637,174)	(554,136)
Total stockholders' equity	38,000	48,312	39,300	19,736	101,020

- (1) Contra-revenues consist of our share of co-development costs for a basal cell carcinoma product candidate under collaboration with Genentech. We exercised this option during the year ended December 31, 2005.
- (2) During the year ended December 31, 2002, we recorded an impairment charge of \$64,098,000 related to the carrying value of our goodwill. In addition, we realigned our research and development programs and recognized restructuring expenses of \$3,490,000 related to workforce reductions, closing of clinical programs and decommissioning of a facility. Also, as a result of the realignment, we recorded impairment charges of property and equipment of \$5,337,000 related to the decommissioning of a facility.
- (3) We recorded expense of approximately \$23,114,000 related to goodwill amortization for the year ended December 31, 2001. Effective January 2002, goodwill is no longer amortized in accordance with SFAS No. 142.
- (4) On May 16, 2003, Curis 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 joint venture did not generate any revenues or incur any costs beyond 2002 and, accordingly, we did not record any equity in net loss from this joint venture after 2002.

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 therapeutic drug development company principally focused on the discovery, development and future commercialization of products that modulate key regulatory signaling pathways controlling the growth, repair and regeneration of human tissues and organs. Our product development approach involves using small molecules, proteins or antibodies to modulate these regulatory signaling pathways, for example, to increase the pathway signals when they are insufficient or to decrease them when they are excessive or unregulated. We have successfully used our product development approach to produce multiple compounds with potential use for several different disease indications. For example, we have developed a product candidate for the topical treatment of basal cell carcinoma, which is currently in a Phase I clinical trial and under co-development with Genentech, a collaborator. We have also developed several promising preclinical product candidates in various fields, including cancer, neurological disorders and hair growth regulation. We operate in a single reportable segment: developmental biology products. We expect 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.

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 \$680,054,000 as of December 31, 2005. We expect to incur significant operating losses for the next several years as we devote substantially all of our resources to research and development of our product candidates. We will need to generate significant revenues to achieve profitability and do not expect to achieve profitability in the foreseeable future, if at all.

Our research programs are conducted both internally and through strategic collaborations. We currently have strategic collaborations with Genentech, Procter & Gamble, and Wyeth Pharmaceuticals, or Wyeth, to develop therapeutics, which modulate the signaling of the Hedgehog pathway. We have a second collaboration with Genentech focusing on the discovery and development of small molecule modulators of another signaling pathway. We have licensed our bone morphogenetic protein, or BMP, pathway patent portfolio to Ortho Biotech Products, a subsidiary of Johnson & Johnson, for systemic administration in all non-orthopedic and non-dental therapeutic applications. This program is under development at Centocor, another subsidiary of Johnson & Johnson. In 2005, Centocor entered into an agreement with us whereby Centocor will fund a portion of a new Curis BMP small molecule screening program. Lastly, a majority of our spinal muscular atrophy, or SMA, research is funded through a sponsored research agreement with the SMA Foundation.

Our current strategic collaborations and license agreements generally provide for our research, development and commercialization programs to be wholly or the majority funded by our collaborators and provide us with the opportunity to receive additional payments if specified milestones are achieved, as well as royalty payments upon the successful commercialization of any products based upon the collaboration. These strategic license and collaboration agreements included \$18,500,000 in up-front payments, of which we received \$6,629,000 from the sale of shares of our common stock, and also include approximately \$750,000,000 in contingent cash payments

that are tied to future clinical development and regulatory approval objectives, assuming that all of the collaborations continue for their full terms, multiple products for multiple indications are developed, and all milestone payments are received upon the successful completion of specified research and/or development objectives and regulatory approvals. In January 2005, we exercised a co-development option with Genentech pursuant to which we are now sharing equally in the U.S. development costs and will share equally in any future U.S. net profits and/or losses in this program. Through December 31, 2005, we had incurred \$6,999,000 in co-development costs under this program. In the future, we plan to continue to seek corporate collaborators for the further development and commercialization of some of our other technologies.

In some cases, we have retained rights under such programs, including co-development rights and development and commercialization rights in specific therapeutic areas where we believe we can attain additional value through the application of our own internal resources. Examples of retained rights within our programs under collaboration include co-development rights for the development of a basal cell carcinoma product candidate under our Hedgehog antagonist collaboration with Genentech, as well as retained rights to our Hedgehog agonist for topical applications, for local delivery in cardiovascular applications and for ex vivo use under our broad Hedgehog agonist collaboration with Wyeth.

Restatement of Financial Statements

As described in Note 2 of our consolidated financial statements, we have restated our financial results for 2004 and 2003.

The restatement adjusts our consolidated 2004 balance sheet contained herein to correct amounts in prepaid expenses and other current assets, deposits and other assets, short-term and long-term deferred revenues, additional paid-in capital, and accumulated deficit and to restate our consolidated 2004 and 2003 statements of operations to correct amounts reported in gross revenues and research and development expenses. As a result of these restatements, amounts in the consolidated statement of cash flows for the years ended December 31, 2004 and 2003 have also been corrected. These adjustments are more fully described below:

- *Genentech license fee payments:* We had been recognizing revenue in connection with \$7,509,000 in payments received from Genentech as part of the June 2003 Hedgehog antagonist collaboration between the parties over an eight-year period based on our belief that our participation on the steering committees 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. We have determined that we should not have recognized any of this revenue in 2005, 2004 and 2003. Instead, we will defer the \$7,509,000 in payments and recognize this amount as revenue only when we can reasonably estimate when our contractual steering committee obligations will cease or after we no longer have contractual steering committee obligations under this agreement with Genentech. The contractual term of our steering committee obligations extends for as long as Hedgehog antagonist products subject to this collaboration are being developed or commercialized by either of the parties. Accordingly, the contractual term of our steering committee obligations is indefinite and we expect that we will not record any revenue related to these payments for at least several years. The consolidated financial statements for 2004 and 2003 have been restated to reverse all revenue recognized related to the amortization of this up-front payment and to correct the related deferred revenue balances at December 31, 2004 and 2003.
- *Expenses due to university licensors:* We are restating previously reported research and development expenses associated with \$410,000 in license fee payments that were payable by us to university licensors in connection with the June 2003 Hedgehog antagonist collaboration with Genentech. We had previously capitalized this amount as "Prepaid expenses and other current assets" and "Deposits and other assets" in our consolidated balance sheets and amortized this amount to research and development expense as the related license fee revenue was recognized. We have determined that we should have instead recognized the entire \$410,000 immediately as research and development expense in June 2003.

The consolidated financial statements for 2004 and 2003 have been restated to reverse the expense recorded in 2004, to expense the entire payment of \$410,000 in 2003 and to correct “Prepaid expenses and other current assets” and “Deposits and other assets” at December 31, 2004 to reflect the expensing of these payments.

- *Correction of previously identified immaterial errors — Allocation of up-front payments received from Genentech and Wyeth:* In connection with the restatement, we will also correct other previously identified immaterial errors which had previously been corrected through a cumulative adjustment to the consolidated financial statements in our quarterly report on Form 10-Q for the quarter ended September 30, 2005. The restatement will allocate the adjustment among the correct periods.

These errors relate our sale of shares of our common stock in connection with the June 2003 Genentech and January 2004 Wyeth collaboration agreements. In each case, we calculated the value of the common stock using the negotiated price, which was less than the closing market price on the agreement date. Because of this, we understated additional paid-in capital and overstated deferred revenues by \$1,629,000. The overstatement of deferred revenues resulted in an overstatement of license fee revenues in 2004 and 2003 because, in each case, we amortized deferred revenue over the estimated performance period to revenues in our consolidated statements of operations. The consolidated financial statements for 2004 and 2003 have been restated to: (i) reverse all revenue recognized related to the amortization of the deferred revenue related to the June 2003 Genentech Hedgehog antagonist collaboration, (ii) correct revenue recognized related to the amortization of the deferred revenue related to the 2004 Wyeth collaboration, (iii) correct additional paid-in capital at December 31, 2004 and 2003, to reflect the fair value on the date of issuance of the common stock issued to Genentech and Wyeth and (iv) correct deferred revenue at December 31, 2004, to reflect the impact of these adjustments. The correction of the accounting for the January 2004 Wyeth collaboration agreement resulted in a \$138,000 increase in net cash used in operating activities and a corresponding increase in net cash provided by financing activities for the year ended December 31, 2004. The correction of the accounting for the June 2003 Genentech collaboration agreement resulted in a \$1,491,000 increase in net cash used in operating activities and a corresponding increase in net cash provided by financing activities for the year ended December 31, 2003.

As a result of this restatement, we have filed amendments No. 1 on Forms 10-Q/A to restate our March 31, 2005, June 30, 2005 and September 30, 2005 financial statements. We do not anticipate filing amended annual reports on Form 10-K or quarterly reports on Form 10-Q for any periods prior to the first quarter of 2005. Accordingly, our annual reports on Form 10-K and our quarterly reports on Form 10-Q from the second quarter of 2003 through fiscal 2004 have not been revised to reflect the restatement and the financial statements for fiscal 2004 and 2003 included in this annual report on Form 10-K should be relied upon. Management’s discussion and analysis of the financial condition and our results of operations for the years ended December 31, 2004 and 2003 have been updated to reflect these restated amounts.

Recent Developments

Phase I Basal cell carcinoma clinical trial update. A Phase I clinical trial of topically-applied small molecule antagonist of the Hedgehog signaling pathway is being conducted by Genentech and Curis. The Phase I clinical trial is a double-blind, randomized, placebo-controlled study that is expected to enroll approximately 60 patients with a single or multiple basal cell carcinoma. The primary objective of the Phase I clinical trial is to obtain data about the safety and tolerability of a four-week regimen of the drug candidate. In addition, Genentech and Curis are evaluating the clinical activity of the drug candidate, where activity is defined as the complete eradication of the treated basal cell carcinoma lesion and is determined by clinical and microscopic examinations of the lesions. At the conclusion of this Phase I clinical trial, Genentech and we plan to make a decision about whether to advance the drug candidate into a Phase II clinical trial.

On January 23, 2006, we provided an update on the Phase I clinical trial. At that time, 29 of the Phase I clinical trial patients had participated in a dose-escalation segment, in which seven patients were randomized to receive treatment in one of four dose levels. The dose-escalation segment of the Phase I clinical trial had recently been completed, and the preliminary data had been reviewed by an internal Genentech data review board. The preliminary data from the dose-escalation segment suggested that the drug candidate appeared likely to be safe, well tolerated, and had shown signs of activity. However, there had been less clinical activity observed to date than anticipated. Based on these data, the internal data review board recommended that Genentech and we temporarily suspend further enrollment in the second segment of the trial, in which additional patients were to be treated at the highest dose level from the dose escalation segment. Genentech and we will determine whether to re-open enrollment in this segment based on a secondary interim analysis that will occur at a later date. The internal data review board also recommended that a third segment of the trial that is evaluating biological activity using a pharmacodynamic endpoint be enrolled as planned. This third segment, among other things, may shed light on the extent to which the active compound in the drug candidate as formulated is penetrating the patients' skin.

Genentech and we expect to have final results from the Phase I clinical trial during the first half of 2006. When the final results are obtained, Genentech and we will determine whether this drug candidate should proceed to Phase II clinical trials. Should this drug candidate not progress into Phase II clinical trials, Genentech and we will evaluate various criteria, including the data from the biological activity segment of the trial, and determine the alternatives for the basal cell carcinoma program. Possible scenarios include, but are not limited to the following: extending the duration of the treatment regimen of the existing drug candidate, developing a new topical formulation of the existing drug candidate, selection of a new drug candidate, negotiation of the return of the compounds to us for our further development, or termination of the basal cell carcinoma drug program development.

Preclinical milestone received from Procter & Gamble. In March of 2006, Curis reached the first preclinical development objective in our hair growth program with Procter & Gamble Pharmaceuticals, a division of The Procter & Gamble Company. The program is focused upon the potential development of a topical Hedgehog agonist for hair growth disorders, such as male pattern baldness and female pattern hair loss. As part of the initial agreement signed in September of 2005, P&G agreed to pay Curis up to \$2,800,000 in cash payments that are contingent upon the achievement of certain preclinical development objectives. The first of two preclinical development objectives was successfully completed and resulted in a payment to Curis of \$1,000,000.

2005 Business Summary

2005 was an important year for Curis. During 2005, with our basal cell carcinoma program, we moved our first product candidate into clinical testing since 2001. Genentech selected a lead candidate for clinical development under the systemic Hedgehog antagonist program, and we entered into new corporate collaborations with Genentech and Procter & Gamble. We also expanded our existing relationship with Centocor and two of our collaborators, Genentech and Wyeth, extended their contractual commitments under their respective programs. We believe that these extensions of these research collaborations demonstrate the contribution of our scientists to each of these programs. The year was not without its challenges. Two of our product development programs experienced delays during 2005, including our Hedgehog agonist under collaboration with Wyeth and our BMP-7 protein product candidate under development with Centocor. The following provides additional information on key events in 2005:

- *Basal Cell Carcinoma Product Candidate to Phase I Clinical Trial:* Pursuant to the terms of our collaboration agreement with Genentech, on January 28, 2005 we elected to exercise a co-development option with Genentech pursuant to which we are now sharing in the U.S. development costs and will share equally in any future U.S. net profits and/or losses in this program. As a result of participating in co-development, we will forego U.S. development milestone and royalty payments on potential future U.S. sales of the basal cell carcinoma product candidate. On June 8, 2005, we announced that the dosing of the first patient in the Phase I clinical trial for basal cell carcinoma was completed. This Phase I trial

is being conducted by Genentech and Curis. As noted under “Recent Developments” above, on January 23, 2006, we provided an update on the progress of this Phase I clinical trial.

- *New Collaboration with Genentech:* On April 1, 2005, we entered into a drug discovery collaboration agreement with Genentech for discovery and development of small molecule compounds that modulate a signaling pathway that plays an important role in cell proliferation. This pathway is a regulator of tissue growth, formation and repair, the abnormal activation of which is associated with certain cancers. 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 pathway. We have retained the rights for ex vivo cell therapy, except in the areas of oncology and hematopoiesis. Genentech paid us an up-front license fee of \$3,000,000 and has agreed to fund up to \$6,000,000 for research activities during the initial two-year research term, subject to certain termination rights. Genentech has also agreed to make cash payments to us that are contingent upon the successful achievement of certain preclinical and clinical development milestones and drug approval milestones. Excluding royalties on potential net product sales, the total potential cash payments from this collaboration could exceed \$140,000,000, assuming that two products are commercialized in two indications each. Genentech will also pay us royalties on net product sales if product candidates derived from the collaboration are successfully developed.
- *Genentech Selects Lead Clinical Candidate for the Systemic Hedgehog Antagonist Program:* On October 13, 2005, we announced that Genentech selected a lead candidate, a small molecule antagonist of the Hedgehog pathway, for the systemic treatment of solid tumor cancers. Other than our basal cell carcinoma program, this is our most advanced program. We expect that Genentech will file an IND relating to this program during the second half of 2006.
- *Genentech Extends Research Funding for the Systemic Hedgehog Antagonist Program:* During 2005, Genentech elected twice to extend funding to support Curis personnel dedicated to developing Curis’ Hedgehog antagonist technologies for the systemic treatment of solid tumor cancers for the period of June 2005 through June 2006. As part of these extensions, Genentech committed to provide us with up to an additional \$3,250,000.
- *Hedgehog Agonist for Hair Growth Collaboration with Procter & Gamble:* In September 2005, we announced that we had entered into an exclusive worldwide research and development agreement with Procter & Gamble Pharmaceuticals, a division of The Procter & Gamble Company, to evaluate and develop potential treatments for hair growth regulation utilizing our Hedgehog agonist technology. Future efforts may be expanded to address other skin disorders. Under the terms of the agreement, we granted Procter & Gamble an exclusive, worldwide royalty-bearing license for the non-systemic, dermatological use of our Hedgehog agonist technology, via topical administration. We will have an option to co-develop a development candidate from investigational new drug application filing through Phase II clinical trials.
- *Hedgehog Agonist Lead Clinical Candidate Selection Delayed:* On March 23, 2005, we announced that Wyeth had paid us a preclinical milestone under our Hedgehog agonist program. The milestone was based on Wyeth’s and our continued progress in preclinical development of Hedgehog pathway agonists for the treatment of stroke, neurological and other disorders. We had anticipated that Wyeth would select the drug candidate as a lead clinical development candidate in 2005 and that Wyeth would file an IND in 2006 to begin human clinical testing in stroke. Under the collaboration, we have generated promising preclinical data demonstrating significant neuroprotection with a series of small molecule compounds, but to date we have not yet identified a compound to advance into clinical development. We continue to work with Wyeth towards achieving the objective of identifying and selecting a lead clinical candidate that meets both the efficacy and toxicity profiles required for clinical development. The program is presently assessing the therapeutic efficacy and potential toxicity for a systemic therapy, particularly for stroke.
- *Wyeth Extends Research Funding of Hedgehog Agonist Program:* In November 2005, Wyeth exercised its option under the 2004 agreement to extend funding to continue development of therapeutic

applications of the Hedgehog agonist with a primary focus on neurological disorders. By exercising this option, Wyeth agreed to extend the research term by one year through February 9, 2007. After the initial one-year extension, the agreement may be extended for additional one-year periods with our consent and upon recommendation of the steering committee with such full-time equivalent resources and related Wyeth funding obligations as may be consistent with fulfilling the objectives of the research plan.

- *BMP-7 Lead Clinical Candidate Selection Delayed:* In the second quarter, we adjusted our clinical timeline estimates related to our BMP-7 program with Johnson & Johnson. Earlier in 2005, Johnson & Johnson moved primary development responsibility of this program from Ortho Biotech Products to Centocor, another one of Johnson & Johnson's subsidiaries. Under this new arrangement, Curis and Centocor expect to establish a cross-company clinical team to share information on the development and progress of the BMP-7 program. We believe that the transfer of the BMP-7 program to Centocor was primarily to address specialized manufacturing requirements and complexities in relation to this protein. With this transition of the BMP-7 program, we are anticipating an IND filing no sooner than 2007.
- *Expansion of Centocor Relationship:* In December 2005, we expanded our relationship with Centocor. Under a new agreement, we will screen for small molecule agonists that mimic the bioactivity of BMP-7 and activate the bone morphogenetic pathway. The screening effort is expected to last fifteen months. We will own any small molecule BMP agonist compounds that are discovered as part of this screening and Centocor will have an exclusive option to first negotiate a new collaboration and exclusive license agreement for the development of the small molecules.

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 upon, 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 clinical trials. We believe that our existing capital resources at December 31, 2005, together with the payment of all contractually-defined payments under our collaborations and research programs with Genentech, Wyeth, Procter & Gamble and the SMA Foundation, assuming these programs continue as planned, should enable us to maintain current and planned operations into the second half of 2007, including expected spending related to our co-development of our lead product candidate for the treatment of basal cell carcinoma. Our ability to continue funding our planned operations beyond the second half of 2007 is dependent upon the success of our collaborations, 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 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, milestone payments and other amounts that we have received from our strategic collaborators and licensees, including Genentech, Wyeth, Ortho Biotech Products/Centocor, Procter & Gamble and the SMA Foundation as well as royalty revenue and payments received upon monetization of certain royalty rights from Stryker Corporation, under the terms of which Stryker paid us \$14,000,000 in cash in 2002 in exchange for the termination of Stryker's future royalty obligations. Since our equal share of the basal cell carcinoma co-development costs will be recorded as a reduction to any revenue recognized under our collaborations with Genentech in accordance with EITF 01-9, we do not expect to generate any net revenue from our two collaborations with Genentech until we obtain FDA approval to commercialize our basal cell carcinoma product candidate. In the future, we will seek to generate revenues from a combination of license fees, research and development funding and milestone payments, royalties resulting from the sale of products that incorporate our intellectual property in connection with strategic licenses and collaborations, and sales of any products we successfully develop and commercialize, either alone or in collaboration with third parties. We expect that any

revenues we generate will fluctuate from quarter to quarter as a result of the timing and amount of payments received under our strategic collaborations, and the amount and timing of payments we receive upon the sale of our products, to the extent that any are successfully commercialized.

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, supplies and reagents, outside service costs including medicinal chemistry, consulting and sponsored research collaborations, and occupancy and depreciation charges. We expense research and development costs as incurred.

Most of our programs are in various stages of preclinical drug development. The following table summarizes our primary research and development programs, including the current development status of each program. In the table, the term discovery means that we are searching for compounds that may be relevant for treating a particular disease area, early preclinical means we are seeking to obtain initial demonstrations of therapeutic efficacy in preclinical models of human disease, mid-preclinical means we are seeking to obtain multiple demonstrations of efficacy in preclinical models of human disease, late preclinical means we are seeking to obtain both multiple demonstrations of efficacy in preclinical models of human disease and relevant toxicology and safety data required for an investigational new drug, or IND, application filing with the FDA seeking to commence a Phase I clinical trial to assess safety and tolerability in humans, and Phase I means that we are currently treating human patients in a Phase I clinical trial, the principal purpose of which is to evaluate safety of the compound being tested.

All of our estimates below regarding the status of our product development programs are solely our judgments. These estimates may not reflect the beliefs or expectations of our corporate collaborators or licensors, if applicable. Moreover, because of the early stages of development of these programs, our ability and that of our collaborators and licensors to successfully complete preclinical or clinical studies of these product candidates, and the timing of completion of such programs, is highly uncertain.

Product Candidate	Primary Indication	Collaborator/Licensee	Status
Hedgehog topical small molecule antagonist	Basal cell carcinoma	Genentech	Phase I
Hedgehog systemic small molecule or antibody antagonist	Cancer (1)	Genentech	Late preclinical
Discovery research	Undisclosed pathway	Genentech	Discovery
Hedgehog small molecule agonist	Nervous system disorders	Wyeth	Mid-preclinical/ Discovery (2)
Hedgehog small molecule agonist	Hair growth	Procter & Gamble	Late preclinical
BMP-7 protein	Kidney disease and other disorders	Ortho Biotech Products/ Centocor	Mid preclinical
Discovery research	Spinal muscular atrophy	Spinal Muscular Atrophy Foundation	Discovery
Hedgehog agonist/gene	Cardiovascular disease	Internal development (3)	Mid preclinical
Discovery research	Various signaling pathways	Internal development	Discovery

- (1) Genentech has selected a lead clinical candidate for this program, a small molecule antagonist of the Hedgehog pathway. We currently expect that Genentech will file an IND for this program in the second half of 2006.
- (2) Curis and Wyeth are currently evaluating drug candidates in a particular class of agonist small molecule compounds. This class of compounds is currently in a mid-preclinical development status. Should the companies determine that this class of compounds will not generate a lead clinical development candidate, we expect that we will continue to seek a backup class of compounds. Our efforts to seek a backup class of compounds would initially be in discovery development.
- (3) We have incurred nominal expenses related to our cardiovascular disease program. Our preclinical data relating to this program has been primarily derived from studies conducted at Caritas St. Elizabeth's Medical Center in Boston, Massachusetts. Wyeth has a right of first negotiation to obtain an exclusive license to the cardiovascular applications. If Wyeth declines to exercise its option, or if we are unable to reach an agreement with Wyeth on terms within the contractually specified period, we are free to seek another collaborator for this program. In the event that Wyeth declines to exercise its option, we will actively explore other licensing opportunities for this program. Should we be successful in our efforts to license this program, either to Wyeth or to another collaborator, any investigational new drug filing will likely be the responsibility of the collaborator.

There is a risk that any drug discovery and development program may not produce products or revenues. Due to uncertainties inherent in drug discovery and development, including those factors described under Item 1A, "Risk Factors," we and our collaborators may not be able to successfully develop and commercialize any of the product candidates included in the table above.

Genentech and we are co-developing a Hedgehog small molecule antagonist formulated for the topical treatment of basal cell carcinoma. Genentech and we will share equally in all U.S. development costs. As a result of our election to exercise our co-development option, we expect that we would incur approximately \$20,000,000 in development costs through Phase II clinical trials and we anticipate that these trials will be completed in mid-2007, assuming the successful advancement of the basal cell carcinoma product candidate through Phase I and Phase II clinical trials. We expect to incur additional costs to complete Phase III clinical trials and the remainder of the regulatory approval process, assuming that Genentech and we successfully complete Phase II clinical trials. Due to the uncertainties that are inherent to the drug discovery process, as more fully described below, we are not currently able to estimate the cost and timing to complete the Phase III trial and receive regulatory approval of this product candidate, if ever.

Except for our basal cell carcinoma product candidate, all of our product development initiatives are in various stages of preclinical testing. Because of the early stages of all of our programs, including our basal cell carcinoma program, the successful development of our product candidates is highly uncertain. 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 product candidates due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, quality of data, rate of progress and cost of clinical trials and other research and development activities undertaken by us or our collaborators;
- the results of future 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;
- 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
- the cost and effectiveness of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

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 discussion of risks and uncertainties associated with completing our projects on schedule, or at all, and some consequences of failing to do so, are set forth in 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. Other costs include facility costs not otherwise included in research and development expense, insurance, and professional fees for legal, patent and accounting services. Within general and administrative expenses, we have recorded a \$500,000 charge resulting from a reduction in our expected loss of subtenant income on an operating lease for the remainder of the lease term at our facility at 61 Moulton Street, Cambridge, MA. This lease term ends on April 30, 2007.

Strategic Collaborations and License Agreements. Since inception, substantially all of our revenues have been derived from collaborations and other research and development arrangements with third parties. Our current strategic collaborations and key license agreements are with Genentech, Wyeth, Procter & Gamble and Ortho Biotech Products. These strategic license and collaboration agreements included \$18,500,000 in up-front payments, including \$6,629,000 from the sale of shares of our common stock, and also include approximately \$750,000,000 in contingent cash payments that are tied to future clinical development and regulatory approval objectives, assuming that all of the collaborations continue for their full terms, multiple products for multiple indications are successfully developed, and all milestone payments are received upon successful completion of specified research, development and regulatory approval objectives.

The collaborations and licenses are summarized as follows:

Genentech Hedgehog Antagonist Collaboration. In June 2003, we licensed our 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. Pursuant to the collaboration agreement, Genentech agreed to make specified cash payments including up-front payments 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 agreed to make license maintenance fee payments totaling \$4,000,000 over the first two years of the collaboration and contingent cash payments at various intervals during the clinical development and regulatory approval process of small molecule and antibody Hedgehog antagonist product candidates, assuming specified clinical development and regulatory approval objectives are met. In addition, Genentech will pay us a royalty on potential future net product sales, which increases with increasing sales volume. As described below, in December 2004, we entered into an amendment to this agreement that modified the maintenance fee payment arrangement.

In January 2005, pursuant to the collaboration agreement, we elected to exercise our co-development option and are now sharing equally in the U.S. development costs and will share in any future U.S. net profits or losses of the basal cell carcinoma program. As a result of participating in co-development, we will forego U.S. development contingent cash payments and royalty payments on potential future U.S. sales of the basal cell carcinoma product candidate. On June 8, 2005, we announced that the dosing of the first patient in the Phase I clinical trial for basal cell carcinoma was completed. This Phase I trial is being conducted by Genentech and Curis.

In addition to our co-development rights in the U.S. marketplace, in certain major international markets, we will receive cash payments if specific clinical development objectives are achieved and a royalty on any international sales of a basal cell carcinoma product candidate.

Under the systemic Hedgehog antagonist program of the collaboration, Genentech is obligated to make cash payments to us assuming the successful achievement of clinical development and drug approval objectives. In addition, Genentech will pay a royalty on potential future net product sales, which increases with increasing sales.

Amendments to the Genentech Hedgehog Antagonist Collaboration. In December 2004 and April 2005, we entered into separate amendments to our June 2003 agreement with Genentech. We considered the provisions of EITF 00-21 and determined that these agreements were separate contracts from our June 2003 agreement since these agreements were not contemplated at the time of the June 2003 arrangement, were separately negotiated in order to increase the number of full-time equivalents providing research and development services and to provide xenograft tumor samples to Genentech, and were not entered into at or near the time of the June 2003 agreement.

The December 2004 amendment, effective from June 12, 2004 to June 11, 2005, increased our commitment of full-time equivalents providing research and development services for the systemic Hedgehog antagonist program from eight to sixteen, including six full-time equivalents that are employed by a third party but are managed by us, and increased Genentech's funding commitment from \$2,000,000 to \$4,000,000 for this period of which Genentech paid us \$2,000,000 for research services in December 2004 and the remaining \$2,000,000 for subsequent research services was paid in June 2005. Pursuant to the agreement, we also agreed to provide xenograft tumor samples to Genentech during the research period for which Genentech paid us \$100,000 in December 2004. Also in accordance with the amendment, 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 us in December 2004.

The April 2005 amendment, effective from June 12, 2005 to June 11, 2006, provides for up to sixteen of our full-time equivalent researchers, including six full-time equivalents that are employed by a third party but are managed by us, to provide research and development services for the systemic Hedgehog antagonist program for the period of June 12, 2005 until December 11, 2005, in exchange for an additional \$2,000,000, which was paid in December 2005. The agreement also provided Genentech with the option to request that we provide up to sixteen full-time equivalent researchers to perform research services during the period of December 12, 2005 until June 11, 2006, provided that Genentech supplies us with adequate notice. In October 2005, Genentech requested that we provide ten full-time equivalent researchers, all of which are Curis employees, to work on the program from December 12, 2005 until June 11, 2006, in exchange for up to \$1,250,000. The six full-time third party equivalents that were previously involved in the program are no longer needed, based on the progress made under the program, which included the selection of a lead clinical candidate, a small molecule antagonist of the Hedgehog pathway. The remaining \$1,250,000 for subsequent research services is payable by Genentech in June 2006.

Genentech Discovery Research Collaboration. On April 1, 2005, we entered into a drug discovery collaboration agreement with Genentech for discovery and development of small molecule compounds that modulate a signaling pathway that plays an important role in cell proliferation. This pathway is a regulator of tissue growth, formation and repair, the abnormal activation of which is associated with certain cancers. 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 pathway. We have retained the rights for ex vivo cell therapy uses, except in the areas of oncology and hematopoiesis. Under the terms of the agreement, we have primary responsibility for drug discovery and research activities and Genentech will be responsible for clinical development, manufacturing, and commercialization of products that may result from the collaboration.

Genentech paid us an up-front license fee of \$3,000,000 and has agreed to fund up to \$6,000,000 for research activities during the initial two-year research term, subject to certain termination rights. Genentech has also agreed to make cash payments to us that are contingent upon the successful achievement of certain preclinical and clinical development and drug approval milestones. Excluding royalties on potential net product sales, the total potential cash payments from this collaboration could exceed \$140,000,000, assuming that two products are commercialized in two indications each. Genentech has an option to extend the initial two-year research term for up to two additional years in one-year increments. Genentech will also pay us royalties on net product sales if product candidates derived from the collaboration are successfully developed.

Wyeth Hedgehog Agonist Collaboration. On January 12, 2004, we licensed our Hedgehog proteins and small molecule Hedgehog pathway agonists to 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 our common stock.

Wyeth has agreed to assume all future responsibility for clinical development of the Hedgehog small molecule and protein agonists as systemic treatments for neurological and other disorders. Wyeth is also obligated to make cash payments that are contingent upon the successful achievement of clinical

development and drug approval objectives and to pay us a royalty on net product sales, if any should occur, that escalates with increasing sales volume. Our agreement with Wyeth includes more than \$170,000,000 in such contingent cash payments, assuming at least two products are successfully developed and commercialized.

In addition to these initial and potential future cash payments, Wyeth is obligated to provide financial support of our research under the collaboration, at \$250,000 per full-time equivalent researcher, for a period of up to two years based on the number of full-time equivalent researchers performing services under the collaboration. We are obligated to dedicate between five and ten full-time equivalents to this program, as determined by the steering committee in six-month intervals, for two years. After the initial two-year period, Wyeth can, at its option, elect to extend our research obligation, and Wyeth's funding thereof, for an initial one-year extension on the same terms and conditions as the initial two-year term. In November 2005, Wyeth exercised this option to extend the initial term. By exercising this option, Wyeth agreed to extend the research term by one year through February 9, 2007. After the initial one-year extension, the agreement may be extended for additional one-year periods with our consent upon recommendation of the steering committee with such full-time equivalent resources and related Wyeth funding obligations as may be consistent with fulfilling the objectives of the research plan.

As part of the agreement, we have retained development and licensing options for certain therapeutic applications of the Hedgehog agonist technologies, including topical treatment for skin diseases and disorders including hair growth regulation, ex vivo cell therapy, local delivery applications for treatment of cardiovascular disease, and those applications that qualify as orphan drug indications. Wyeth has a right of first negotiation to obtain an exclusive license to the orphan drug indications and the cardiovascular applications. If Wyeth declines to exercise its right, or if we are unable to reach an agreement with Wyeth on terms within the contractually specified period, we are free to seek another collaborator for these programs.

Procter & Gamble Hedgehog Agonist Collaboration for Hair Growth and Skin Disorders. On September 18, 2005, we entered into a collaboration, research and license agreement with Procter & Gamble, to evaluate and develop potential treatments for hair growth regulation and skin disorders utilizing our Hedgehog agonist technology.

Under the terms of the agreement, we granted to Procter & Gamble an exclusive, worldwide, royalty-bearing license for the development and commercialization of topical dermatological and hair growth products that incorporate our Hedgehog agonist technology. In accordance with the terms of the agreement, the parties shall jointly undertake a research program with the goal of identifying one or more compounds to be developed and commercialized by Procter & Gamble. Procter & Gamble is solely responsible for the cost of worldwide development and commercialization of any product candidates developed pursuant to the research program, provided however, that at the time that Procter & Gamble determines to file the first IND application with the FDA for a product candidate, we shall have the option, at our sole discretion, to co-develop a product candidate through Phases I and II of clinical development. We, however, would receive a higher royalty in the event that we exercise our co-development option and subsequently share in development expenses through Phase II clinical trials. Should we elect to exercise this co-development option, we will forego contingent cash payments that would otherwise be payable for the achievement of certain development objectives during the period from investigational new drug application filing through the completion of a Phase II clinical trial. Procter & Gamble has paid us an up-front license fee of \$500,000 and has agreed to fund up to \$600,000 for two of our full-time equivalent employees providing research and development activities during the initial one-year research term, subject to its termination rights. Procter & Gamble has an option to extend the initial one-year research term for up to three additional years in one-year increments.

Procter & Gamble 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. Procter & Gamble will also pay us royalties on net product sales if product candidates derived from the collaboration are successfully developed.

In March of 2006, we reached the first preclinical development objective in our hair growth program with Procter & Gamble Pharmaceuticals, a division of The Procter & Gamble Company. The program is focused upon the potential development of a topical Hedgehog agonist for hair growth disorders, such as male pattern baldness and female pattern hair loss. As part of the initial agreement signed in September of 2005, P&G agreed to pay Curis up to \$2,800,000 in cash payments that are contingent upon the achievement of certain preclinical development objectives. The first of two preclinical development objectives was successfully completed and resulted in a payment to Curis of \$1,000,000.

Ortho Biotech Products BMP License. In November 2002, we entered into an agreement with Ortho Biotech Products, a subsidiary of Johnson & Johnson, pursuant to which Ortho Biotech obtained the license rights to our BMP-7 technology and assumed control of the continued development of this product candidate. In 2005, Johnson & Johnson moved responsibility for the further development of BMP-7 to Centocor, another subsidiary of Johnson & Johnson, and Centocor has assumed all future costs and responsibility for BMP-based product development. We are entitled to receive a series of contingent cash payments that are tied to the achievement of clinical development and regulatory objectives payments, and royalties on product sales if any BMP-based products are successfully commercialized. Centocor has sole responsibility for deciding if and when human clinical trials of BMP-7 will begin.

The transaction relates to all of our proprietary BMP compounds including BMP-7, which has been studied in animal models in various disease indications, including 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. Use of our BMPs for the repair or regeneration of local musculoskeletal tissue defects and dental defects is the subject of an exclusive agreement with Stryker and is not included as part of this transaction.

Pursuant to the agreement, Ortho Biotech paid us an up-front payment of \$3,500,000, in December 2002, and has agreed to make contingent cash payments at various intervals during the U.S. and European regulatory approval process assuming the first two therapeutic indications are successfully developed. These contingent cash payments include a \$30,000,000 payment if Ortho Biotech achieves U.S. regulatory approval of a product for the treatment of kidney disease or associated complications. The agreement further specifies that we will receive a royalty on net sales of products that incorporate our BMP technologies. Unless terminated earlier, the agreement shall remain in effect until the expiration of Ortho Biotech's obligation to pay royalties to us under the agreement.

Centocor BMP Agonist Small Molecule Screening Program. In December 2005, we expanded our relationship with Centocor. Under a new agreement, we will screen for small molecule agonists that mimic the bioactivity of BMP-7 and activate the bone morphogenetic pathway. The screening effort is expected to last fifteen months. We will own any small molecule BMP agonist compounds that are discovered as part of this screening and Centocor will have an exclusive option to first negotiate a new collaboration and exclusive license agreement for the development of the small molecules.

Spinal Muscular Atrophy Program. Effective September 7, 2004, we entered into a sponsored research agreement with the Spinal Muscular Atrophy, or SMA, Foundation. Under the agreement, the SMA Foundation will grant Curis up to \$5,364,000 over a three-year period for the identification of therapeutic compounds to treat SMA, a neurological disease that is the leading genetic cause of infant and toddler death. The research will utilize our proprietary technologies and expertise to develop and refine assays in motor neurons and then use those assays to screen for potential drug candidates. We will own any compounds that we generate under this collaboration and will also have the ability to bring any such compounds into the clinic, either using our own resources or with a collaborating third party. If any drug candidates developed under the agreement are successfully commercialized, we will be required to make payments to the SMA Foundation if cumulative revenues from the sales of such products exceed \$100,000,000. Unless terminated earlier, the agreement will continue until the expiration of the research activities.

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 the following accounting policies to be 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)*.

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 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, then revenue is deferred until we can reasonably estimate when the performance obligation ceases or becomes inconsequential.

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.

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 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 would prevent us from concluding that subsequent milestone payments were substantive milestones and, as a result, any additional milestone payments would 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 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 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.

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.

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 twelve-month period ended December 31, 2006 are classified as long-term deferred revenue. As of December 31, 2005, we have short-term and long-term deferred revenue of \$1,757,000 and \$10,237,000, respectively, related to our collaborations.

Although we follow detailed guidelines in measuring revenue, certain judgments affect the application of our revenue policy. 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, 2006. Amounts that we expect will not be recognized prior to December 31, 2006 are classified as long-term deferred revenue. However, this estimate is based on our current operating plan as of December 31, 2005. If our operating plan should change in the future, we may recognize a different amount of deferred revenue over the twelve-month period from January 1, 2006 through December 31, 2006.

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. We issue stock options to employees under our stock option and employee stock purchase plans. These options are accounted for under APB Opinion No. 25, *Accounting for Stock Issued to Employees* and related interpretations, including FASB Interpretation No. 44. All stock-based awards to non-employees are accounted for at their fair value in accordance with SFAS No. 123, *Accounting for Stock-Based Compensation*, as amended by Financial Accounting Standards Board, or FASB, Interpretation No. 148, and EITF Issue No. 96-18, *Accounting for Equity Instruments that are Issued to Other than Employees*.

SFAS 123 requires that companies either recognize compensation expense for grants of stock options and other equity instruments based on fair value, or provide pro forma disclosure of net loss and net loss per share in the notes to the financial statements. At December 31, 2005, we had two stock-based compensation plans. We account for these plans under the recognition and measurement principles of APB Opinion No. 25 and related interpretations. Accordingly, no compensation cost has been recognized under SFAS 123 for our employee stock option plans.

Under SFAS No. 123, the fair value of stock-based awards to employees is calculated through the use of option pricing models, even though such models were developed to estimate the fair value of freely tradable, fully transferable options without vesting restrictions, which significantly differ from our stock option awards. These models also require subjective assumptions, including risk-free interest rates, future stock price volatility and expected time to exercise, which greatly affect the calculated values. We calculate compensation cost with the Black-Scholes option-pricing model.

Goodwill. At December 31, 2005, we have recorded \$8,982,000 in goodwill. As a result of the adoption of Statement of Financial Accounting Standards, or SFAS, No. 142, *Goodwill and Other Intangibles*, effective January 1, 2002, we ceased amortization of goodwill and have since performed at least annual assessments of goodwill impairment by comparing our fair value to our net assets. 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 2005, 2004 and 2003, 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 2005, 2004 or 2003.

Long-term receivables. During the year ended December 31, 2003, we recorded, in other expense, charges of \$1,708,000 related to the write-off of previously recorded interest income and foreign exchange gains on a euro-denominated note receivable that was originally due in June 2005 from Micromet, a former collaborator to whom we had licensed technology, and \$286,000 related to a reduction in the carrying value of Micromet equity securities held by us. We determined that this charge was necessary due to Micromet's announcement that it was terminating one-third of its workforce as the result of a contract dispute with a collaborator. Micromet had stated that this dispute would result in a significant decrease in previously budgeted cash inflows in 2004. We also wrote-off the note receivable and reduced deferred revenue by \$3,407,000 because we concluded that we were not reasonably assured of collecting the note.

On October 21, 2004, we amended our note receivable with Micromet, and, under the amended note, Micromet is obligated to pay us a total amount of EUR 4,500,000, subject to certain conditions. As a result of Micromet's financing in October 2004, we received a EUR 1,250,000 payment in November 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 we 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. The future amounts due to us under the amended note are not considered reasonably assured of collection at December 31, 2005 and, therefore, have not been recorded as revenue. We will record revenue when, and if, we conclude such amounts are reasonably assured of collection.

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, 2005 and 2004

Revenues

Total revenues are summarized as follows:

	For the Year Ended December 31,		Percentage Increase/ (Decrease)
	2005	2004 (as restated)	
Revenues:			
Research and development contracts			
Genentech	\$ 5,856,000	\$ 600,000	876%
Wyeth	2,327,000	2,256,000	3%
Spinal Muscular Atrophy Foundation	1,955,000	551,000	255%
Procter & Gamble	265,000	—	100%
Other	90,000	—	100%
Subtotal	10,493,000	3,407,000	208%
License fees			
Genentech	562,000	—	100%
Wyeth	272,000	242,000	12%
Procter & Gamble	24,000	—	100%
Micromet	1,400,000	—	100%
Subtotal	2,258,000	242,000	833%
Substantive milestones	250,000	50,000	400%
Gross Revenues	13,001,000	3,699,000	252%
Contra-revenues from co-development with Genentech	(6,999,000)	—	(100%)
Net Revenue	\$ 6,002,000	\$3,699,000	62%

The 62% increase in net revenues for the year ended December 31, 2005 as compared to the same period in the prior year, was primarily due to gross revenues from our research and development contracts, which increased from \$3,407,000 for the year ended December 31, 2004 to \$10,493,000 for the year ended December 31, 2005, an increase of \$7,086,000. Research and development contract revenues for the year ended December 31, 2005 increased \$2,141,000 from three new collaborations entered into during 2005—a new collaboration with Genentech entered into April 2005, a collaboration with Procter & Gamble entered into September 2005, and a collaboration with Centocor entered into December 2005. In addition, research services provided under our June 2003 collaboration, as amended in 2004 and 2005, with Genentech were \$4,006,000 for the year ended December 31, 2005 as compared to \$600,000 for the year ended December 31, 2004. In addition, our license fee revenues increased by \$2,016,000, to \$2,258,000 for the year ended December 31, 2005 as compared to \$242,000 for the same period in the prior year. This increase was mainly due to a \$1,400,000 payment received from Micromet, a former collaborator. This increase was offset by \$6,999,000 in contra-revenue, or a reduction to gross revenues, related to our co-development payments to Genentech. This reduction to gross revenue represents 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 therapeutic product candidate.

Operating Expenses

Research and development expenses are summarized as follows:

Research and Development Program	Primary Indication	For the Year Ended December 31,		Percentage Increase/ (Decrease)
		2005	2004 (as restated)	
Hh small molecule and antibody antagonist	Cancer	\$ 3,625,000	\$ 4,347,000	(17%)
Hh small molecule agonist	Nervous system disorders	2,912,000	2,831,000	3%
Hh small molecule agonist	Hair loss	1,061,000	835,000	27%
Discovery research	Spinal muscular atrophy	2,600,000	602,000	332%
Discovery research	Various	3,293,000	2,872,000	15%
Stock-based compensation	N/A	214,000	1,175,000	(82%)
Total research and development expense		<u>\$13,705,000</u>	<u>\$12,662,000</u>	8%

The increase of \$1,043,000, or 8%, in research and development expenses for the year ended December 31, 2005 was primarily due to increased spending on our discovery research programs of \$2,419,000 offset by decreased spending of \$722,000 on the Hedgehog, or Hh, small molecule and antibody antagonist program under collaboration with Genentech. In addition, stock-based compensation expense decreased \$961,000 during the year ended December 31, 2005 as compared to the prior year. The decrease in stock-based compensation was primarily attributable to a decrease of compensation expense recorded on options to purchase common stock that were issued to employees below fair market value on August 18, 2000. As of August 18, 2004, all of these options became fully vested; therefore, no related additional expense was recognized beyond August 2004. The decrease was also attributable to options issued to non-employees that are marked-to-market liabilities. As our stock price fluctuates, the liability and related expense either increases or decreases. Because our stock price declined, we recorded less stock-based compensation expense related to these options.

General and administrative expenses are summarized as follows:

	For the Year Ended December 31,		Percentage Increase/ (Decrease)
	2005	2004	
Personnel	\$3,251,000	\$2,959,000	10%
Occupancy and depreciation	1,111,000	641,000	73%
Legal services	1,510,000	1,727,000	(13%)
Consulting and professional services	1,081,000	1,445,000	(25%)
Insurance costs	424,000	484,000	(12%)
Settlement of notes receivable	—	(448,000)	100%
Other general and administrative expenses	706,000	752,000	(6%)
Stock-based compensation	7,000	197,000	(96%)
Total general and administrative expenses	<u>\$8,090,000</u>	<u>\$7,757,000</u>	4%

The increase of \$333,000, or 4%, in total general and administrative expenses for the year ended December 31, 2005 was primarily due to an increase in personnel costs of \$292,000 and occupancy costs of \$470,000, offset by decreases in legal, professional and consulting services of \$581,000. Occupancy costs for the year ended December 31, 2005 include the recognition of a \$500,000 charge resulting from the expected decrease in estimated subtenant income under an operating lease for the remainder of our lease term. The decrease in legal, professional and consulting services principally resulted from costs associated with various technology acquisition evaluations and expenses associated with financing-related activities during the first half of 2004. Stock-based compensation expense also decreased \$190,000 during the year ended December 31, 2005 as compared to the prior year period. The decrease in stock-based compensation was primarily attributable to a

decrease of compensation expense recorded on options to purchase common stock that were issued to employees below fair market value on August 18, 2000. As of August 18, 2004, all of these options became fully vested; therefore, no related additional expense was recognized beyond August 2004. We received \$558,000 from the settlement of notes receivable from former officers of a predecessor company that had a carrying value of \$110,000, resulting in a net gain of \$448,000 for the year ended December 31, 2004.

Amortization of intangible assets was \$75,000 for each of the years ended December 31, 2005 and 2004.

Other Income (Expense)

For the year ended December 31, 2005, interest income was \$1,196,000 as compared to \$540,000 for the year ended December 31, 2004, an increase of \$656,000, or 121%. The increase in interest income resulted from higher interest rates and a higher available investment balance for the year ended December 31, 2005, as compared to the year ended December 31, 2004.

For the year ended December 31, 2005, other income was \$125,000 as compared to \$1,592,000 for the year ended December 31, 2004, a decrease of \$1,467,000, or 92%. Other income for both years is primarily comprised of gains recognized on the collection of a note receivable from Micromet, a former collaborator.

For the year ended December 31, 2005, interest expense was \$308,000, as compared to \$411,000 for the year ended December 31, 2004, a decrease of \$103,000, or 25%. The decrease resulted from lower outstanding debt obligations during the year primarily due to the conversion of the note payable to Elan in January 2005.

Net Loss Applicable to Common Stockholders

As a result of the foregoing, we incurred a net loss applicable to common stockholders of \$14,855,000 for the year ended December 31, 2005, as compared to \$15,075,000 for the year ended December 31, 2004.

Years Ended December 31, 2004 and 2003

Revenues

Total revenues are summarized as follows:

	For the Year Ended December 31,		Percentage Increase/ (Decrease)
	2004	2003	
	(as restated)	(as restated)	
Revenues:			
Research and development contracts			
Genentech	\$ 600,000	\$ 58,000	934%
Wyeth	2,256,000	—	100%
Spinal Muscular Atrophy Foundation	551,000	—	100%
ES Cell International	—	1,470,000	(100%)
Other	—	101,000	(100%)
Subtotal	3,407,000	1,629,000	109%
License fees			
Wyeth	242,000	—	100%
Micromet	—	8,555,000	(100%)
ES Cell International	—	194,000	(100%)
Subtotal	242,000	8,749,000	(97%)
Substantial Milestones	50,000	—	100%
Total Revenues	<u>\$3,699,000</u>	<u>\$10,378,000</u>	(64%)

Revenues from research and development contracts increased by \$1,778,000 for the year ended December 31, 2004, as compared to the year ended December 31, 2003. Research and development contract revenues for the year ended December 31, 2004 were primarily derived from revenue recognized under our collaborations with Genentech and Wyeth of \$600,000 and \$2,256,000, respectively. In addition, we recognized revenue of \$551,000 for the year ended December 31, 2004 under our sponsored research agreement with the SMA Foundation.

For the year ended December 31, 2003, research and development contract revenues primarily consisted of \$1,470,000 recognized under a licensing agreement with ES Cell International. Effective December 2003, and consistent with the terms of this agreement, we are no longer providing research and development services for ES Cell International and will therefore not recognize future revenues related to this collaboration.

The decrease in revenue from license fees of \$8,507,000 for the year ended December 31, 2004, as compared to the year ended December 31, 2003, primarily consisted of \$8,555,000 in previously deferred revenue which was recognized upon the termination of our collaboration with Micromet during the third quarter of 2003. License fee revenues for the year ended December 31, 2004 were derived from revenue recognized under our collaboration with Wyeth of \$242,000.

Operating Expenses

Research and development expenses are summarized as follows:

<u>Research and Development Program</u>	<u>Primary Indication</u>	<u>For the Year Ended December 31,</u>		<u>Percentage Increase/ (Decrease)</u>
		<u>2004</u>	<u>2003</u>	
		<u>(as restated)</u>	<u>(as restated)</u>	
Hh small molecule and antibody antagonist	Cancer	\$ 4,347,000	\$ 4,094,000	6%
Hh small molecule agonist	Nervous system disorders	2,831,000	6,272,000	(55%)
Hh small molecule agonist	Hair loss	835,000	630,000	33%
Discovery research	Spinal muscular atrophy	602,000	—	100%
Discovery research	Various	2,872,000	—	100%
Other programs		—	2,125,000	(100%)
Stock-based compensation		1,175,000	1,267,000	(7%)
Total research and development expense		<u>\$12,662,000</u>	<u>\$14,388,000</u>	(12%)

The decrease of \$1,726,000 in research and development expenses for the year ended December 31, 2004 was primarily due to the net effect of changes in spending in our research programs. First, we decreased spending by \$2,125,000, or 100%, on other programs. Included in other programs were expenses incurred for contract research and development services performed under our diabetes cell therapy program that was under collaboration with ES Cell International. The contract research component of this collaboration ended in December 2003 and, accordingly, we are no longer incurring costs related to this program. In addition, costs related to our nervous system disorders program were significantly reduced as compared to 2003. These decreases were partially offset by increases in spending under our cancer program, which is under collaboration with Genentech. The increase in expenses was primarily attributable to a \$698,000 increase in chemistry expenses related to potential small molecule antagonist product candidates for the treatment of various cancers as well as increases in license fees, personnel costs and related lab supplies partially offset by a \$410,000 decrease in license fees charged to the program in 2004 as compared to 2003. Genentech reimbursed us for all chemistry costs incurred under our collaboration for 2004. In addition, we initiated new discovery research programs in 2004. We incurred costs of \$602,000 for our spinal muscular atrophy program, which is under collaboration with the SMA Foundation, and \$2,872,000 in expenses related to our other discovery research programs during the year ended December 31, 2004. We incurred no expenses for these programs during the same period in 2003.

General and administrative expenses are summarized as follows:

	For the Year Ended December 31,		Percentage Increase/ (Decrease)
	2004	2003	
Personnel	\$2,959,000	\$2,584,000	15%
Occupancy and depreciation	641,000	671,000	(4%)
Legal services	1,727,000	1,101,000	57%
Professional and consulting services	1,445,000	776,000	86%
Insurance costs	484,000	547,000	(12%)
Reserve against (settlement of) notes receivable	(448,000)	34,000	(1,418%)
Stock-based compensation	197,000	364,000	(46%)
Other general and administrative expenses	752,000	806,000	(7%)
Total general and administrative expenses	<u>\$7,757,000</u>	<u>\$6,883,000</u>	13%

The increase of \$874,000 in total general and administrative expenses for the year ended December 31, 2004 was primarily due to an increase in personnel costs of \$375,000, legal fees of \$626,000 and professional and consulting services of \$669,000. The increases principally resulted from costs associated with various technology acquisition evaluations, expenses associated with financing-related activities during the first half of 2004, an increase in legal patent expenses, an increase in personnel, and costs associated with compliance with the Sarbanes-Oxley Act. To offset these increases, we received \$558,000 during the fourth quarter of 2004 from the settlement of notes receivable from former officers of a predecessor company that had a carrying value of \$110,000, resulting in a net gain of \$448,000. The amount charged to reserve for the possible non-collection of these notes receivable was \$34,000 for the year ended December 31, 2003. The decrease in stock-based compensation was primarily attributable to a decrease of compensation expense recorded on options to purchase common stock that were issued to employees below fair market value on August 18, 2000. As of August 18, 2004, all of these options became fully vested; therefore, no related additional expense was recognized beyond August 2004.

Amortization of intangible assets was \$75,000 for each of the years ended December 31, 2004 and 2003.

Other Income (Expense)

For the year ended December 31, 2004, interest income was \$540,000 as compared to \$428,000 for the year ended December 31, 2003, an increase of \$112,000, or 26%. The increase in interest income resulted from a higher available investment balance for the year ended December 31, 2004, as compared to the year ended December 31, 2003.

For the year ended December 31, 2004, other income was \$1,592,000 as compared to other expense of \$1,445,000 for the year ended December 31, 2003, an increase of \$3,037,000. The increase was principally due to the receipt of \$1,604,000 on a note receivable from Micromet, a former collaborator, offset by a \$300,000 write-down of our investment in Micromet resulting in a net gain of \$1,304,000 in the fourth quarter of 2004. Previously recorded interest income and foreign exchange gains related to the note had been written off during the fourth quarter of 2003 resulting in a charge of \$1,708,000 for year ended December 31, 2003.

For the year ended December 31, 2004, interest expense was \$411,000, as compared to \$694,000 for the year ended December 31, 2003, a decrease of \$283,000, or 41%. The decrease in interest expense resulted from a decrease in the amount of interest expense that we paid under capital lease and debt obligations in 2004 as compared to 2003. We recorded interest expense under these obligations of \$35,000 for the year ended December 31, 2004 compared to \$244,000 for the year ended December 31, 2003.

Net Loss Applicable to Common Stockholders

As a result of the foregoing, we incurred a net loss applicable to common stockholders of \$15,075,000 for the year ended December 31, 2004, as compared to \$12,951,000 for the year ended December 31, 2003.

Liquidity and Capital Resources

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

At December 31, 2005, our principal sources of liquidity consisted of cash, cash equivalents, and marketable securities of \$44,209,000, excluding restricted long-term investments of \$196,000. Our cash and cash equivalents are highly liquid investments with a maturity of three months or less at date of purchase and consist of time deposits and investments in money market funds with commercial banks and financial institutions, short-term commercial paper, and government obligations. We 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 has primarily consisted of salaries and wages for our employees, facility and facility-related costs for our office and laboratory, fees paid in connection with preclinical studies, laboratory supplies, consulting fees, and legal fees. In addition, in 2005 we began incurring significant costs to fund the equal share of our co-development expenses of our basal cell carcinoma product candidate, which is under development with Genentech and is currently in a Phase I clinical trial. In 2005, we recorded \$6,999,000 in contra revenues at our consolidated statement of operations in connection with these co-development costs. To date, the source of our cash flows from operations has been payments received from our collaborators and licensors. In general, our only source of cash flows from operations for the foreseeable future will be the up-front license payments, if any, payments for the achievement of milestones, if any, and funded research and development that we may receive under collaboration agreements. The timing of any new collaboration agreements and any payments under collaboration agreements cannot be easily predicted and may vary significantly from quarter to quarter.

Net cash used in operating activities was \$8,139,000 for the year ended December 31, 2005 as compared to \$7,467,000 for the year ended December 31, 2004. Cash used in operating activities during the year ended December 31, 2005 was primarily the result of our net loss for the period of \$14,855,000, partially offset by non-cash charges of \$1,937,000 including depreciation, stock-based compensation, and non-cash interest expense. In addition, increases in operating cash resulted from changes in certain current assets and liabilities during the year ended December 31, 2005, including the receipt of payments from our collaborators highlighted by the following payments: a \$3,000,000 license fee and approximately \$2,000,000 in research funding from Genentech associated with our April 2005 discovery research agreement; \$4,000,000 from Genentech for our research and development services related to the development of Hedgehog antagonist candidates; \$2,000,000 from Wyeth for our research and development services related to the our broad Hedgehog agonist collaboration; a \$500,000 license fee and approximately \$170,000 in research funding from Procter & Gamble in connection with our September 2005 Hedgehog agonist collaboration for hair growth regulation; and \$2,018,000 received under our grant with the SMA Foundation. In addition, we received \$1,500,000 as a second payment on a previously written-off note receivable from a former collaborator.

Cash used in operating activities during the year ended December 31, 2004 was primarily to fund our net loss of \$15,075,000, partially offset by \$2,688,000 in non-cash charges including stock-based compensation expense, depreciation and amortization, non-cash interest expense on notes payable, amortization of intangible assets, a gain on recovery of officers' notes receivable relating to prior officers of a predecessor company and an

impairment of an investment in Micromet, a former collaborator of ours. In addition, a \$1,362,000 up-front payment received for a licensing agreement with Wyeth and a \$2,000,000 maintenance fee payment received from Genentech further offset our use of cash.

We expect to continue to use cash in operations as we continue to develop our products in clinical trials and advance new products into preclinical development. In addition, 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. We also expect that the increase in cash used will be partially offset by anticipated payments made under our collaborations with Genentech, Wyeth, Procter & Gamble and the SMA Foundation, assuming these collaborations continue in accordance with their terms.

Investing activities generated cash of \$4,709,000 for the year ended December 31, 2005 as compared to cash used of \$21,631,000 for the year ended December 31, 2004. Cash generated in investing activities resulted principally from \$7,583,000 in net investment sales offset by \$2,871,000 in fixed asset purchases for the year ended December 31, 2005. We expect that we will continue to use cash in our investing activities as we expand our infrastructure; however, we expect that our cash spend on fixed asset purchases will decline in 2006 since we currently do not expect to undertake any significant capital projects. Cash used in investing activities for the year ended December 31, 2004 resulted principally from \$19,714,000 in net investment purchases and \$1,917,000 in fixed asset purchases for the year ended December 31, 2004. The \$1,917,000 spent on fixed assets in 2004 related to equipment associated with a new screening program and to the partial completion of a laboratory build out that will be used to improve our capacity to conduct preclinical disease models.

Financing activities generated \$3,060,000 of net cash for the year ended December 31, 2005, as compared to net cash generated by financing activities of \$24,043,000 for the year ended December 31, 2004. The cash generated by financing activities during 2005 was principally the result of the sale of \$975,000 of our common stock, primarily as proceeds received upon stock option exercises. In addition, proceeds from the issuance of debt for the purchase of fixed assets provided \$2,585,000 for the year ended December 31, 2005. These increases were offset by \$500,000 in repayments of obligations under a note payable.

The cash generated by financing activities during 2004 was principally the result of the sale of \$22,678,000 of our common stock, including \$18,837,000 in net proceeds from a registered direct offering of 5,476,559 shares of newly issued common stock, and warrants to purchase an aggregate of 547,656 shares of common stock, in October 2004, \$1,638,000 from the sale of 315,524 shares of common stock to Wyeth and \$1,919,000 in proceeds received upon stock option exercises. In addition, proceeds from the issuance of debt for the purchase of fixed assets provided \$1,137,000 for the year ended December 31, 2004. These increases were offset in part by \$332,000 in repayments of obligations under capital leases.

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 the 36-month term. This loan is collateralized by all of our property, plant and equipment assets, except for fixtures and those that are purchased after March 23, 2005 under purchase money arrangements with equipment lenders. 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. 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 36-month term. This loan is collateralized by any equipment and leasehold improvements financed thereunder. As of December 31, 2005, we were in compliance with the sole covenant under each of the 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.

On June 26, 2001, we received \$2,000,000 from Becton Dickinson under a convertible subordinated note payable. The note was repayable at any time up to its maturity date of June 26, 2006 by us, at our discretion, in either cash or upon issuance to Becton Dickinson of shares of our common stock. The note bore interest at 7%. As of December 31, 2005, there was approximately \$2,632,000, including approximately \$632,000 in accrued interest, outstanding under the note. On January 20, 2006, we elected to prepay the then-outstanding principal and accrued interest due under the note in the amount of \$2,639,000 by issuing to Becton Dickinson 669,656 shares of our common stock, based on a conversion price of \$3.94 per share. We have no further obligations under this convertible note payable.

On May 16, 2003, we and affiliates of Élan Corporation entered into a termination agreement to conclude the joint venture that was originally formed in July 2001. As part of the termination, we entered into an amended and restated convertible note payable with EPIL with the principal amount of \$3,000,000. The terms of the amended and restated note were substantially the same as those under the original note, except that the interest rate was reduced from 8% to 6% and the conversion rate was increased from \$8.63 to \$10.00. As of December 31, 2004, there was approximately \$3,298,000, including approximately \$298,000 in accrued interest, outstanding under this convertible note payable. On January 7, 2005, Élan elected to convert the then-outstanding balance of \$3,305,523 into 330,552 shares of our common stock, based on a conversion price of \$10.00 per share. We have no further obligations under this convertible note payable.

Since August 2002, we have sublet 11,980 of the 17,800 square feet of our facility at 61 Moulton Street in Cambridge, Massachusetts. Under the terms of our sublease, as amended, we receive sublease payments that total approximately \$320,000 per year. In addition, we receive approximately \$50,000 for facilities-related services and also receive a pro-rata portion of the 61 Moulton Street facility overhead, including real estate taxes and utilities. In July 2005, our subtenant informed us that it was terminating approximately 50% of its workforce and that it may encounter difficulties meeting its sublease obligations beyond December 2005. Our lease obligation on our 61 Moulton Street facility extends to April 2007 and our lease obligation from January 2006 to April 2007 is approximately \$630,000, excluding real estate taxes and other operating costs. Should our current subtenant vacate the 61 Moulton facility, as expected, we will seek to sublet all or part of the facility. There is no guarantee that we will be able to sublease the premises or that any sublease would be on terms that are similar to our current sublease. Accordingly, we have recorded a \$500,000 charge to our "General and Administrative" expenses within the "Costs and Expenses" section of our consolidated statements of operation for the year ended December 31, 2005.

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 facilities, research services agreements, consulting agreements, and license agreements. The following table summarizes our contractual obligations due by the period indicated at December 31, 2005:

	(amounts in 000's)(1)						
	2006	2007	2008	2009	2010	Thereafter	Total
Convertible subordinated long-term debt (2) . . .	\$2,805	\$ —	\$ —	\$ —	\$ —	\$—	\$ 2,805
Debt obligations under note payable	1,436	1,342	758	—	—	—	3,536
Operating lease obligations	1,323	1,105	948	948	948	—	5,272
Outside service obligations (3)	288	—	—	—	—	—	288
Licensing obligations	292	—	—	—	—	—	292
Total future obligations (4)	<u>\$6,144</u>	<u>\$2,447</u>	<u>\$1,706</u>	<u>\$948</u>	<u>\$948</u>	<u>\$—</u>	<u>\$12,193</u>

(1) Obligations do not include amounts we will owe Genentech under our co-development arrangement. Assuming the successful advancement of the basal cell carcinoma product candidate through Phase I and Phase II clinical trials, we expect that we will incur approximately \$20,000,000 in development expenses

and that the Phase II clinical trial will be completed in mid-2007. Of this \$20,000,000, we have incurred \$6,999,000 through December 31, 2005.

On January 19, 2006, we received notification from Genentech that Genentech believed that it had improperly invoiced Curis for our share of basal cell carcinoma co-development costs. As a result of the invoicing errors, Genentech notified Curis that it believes that we owe Genentech an incremental \$667,000 for the reimbursement of costs that should have been charged by Genentech to Curis. Management believes that it is probable that we will owe Genentech some portion of this amount and has estimated that our liability will range from \$325,000 to \$667,000. Accordingly, we have recorded \$325,000 as "Contra revenues from co-development with Genentech" at our consolidated statement of operations for the year ended December 31, 2005. We have also recorded \$325,000 within "Accrued liabilities" at our consolidated balance sheet as of December 31, 2005.

- (2) Convertible subordinated debt is convertible into either shares of our common stock or cash at our option. On January 20, 2006, we elected to convert the then-outstanding balance of \$2,639,000 into 669,656 shares of our common stock, based on a conversion price of \$3.94 per share. We have no further obligations under this convertible note payable.
- (3) Outside service obligations consist of agreements we have with outside labs, consultants and various other service organizations.
- (4) 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, 2005, together with the payment of all contractually-defined payments under our collaborations and research programs with Genentech, Wyeth, Procter & Gamble and the SMA Foundation, assuming these contracts are not earlier terminated, should enable us to maintain current and planned operations into the second half of 2007, including spending related to the co-development of our basal cell carcinoma product candidate under development with Genentech. 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 the second half of 2007 is dependent upon the success of our collaborations, our ability to control our cash burn rate and our ability to raise additional funds through equity or debt financings, or from other sources of financing. Our ability to generate sufficient cash flows depends on a number of factors, including the ability of either us, or our collaborators, to obtain regulatory approval to market and commercialize products to treat indications in major commercial markets. We are seeking additional collaborative arrangements and also expect 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.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of December 31, 2005.

Inflation

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

New Accounting Pronouncements

In December 2004, the FASB issued SFAS No. 123 (revised 2004), *Share-Based Payment* (“SFAS No. 123R”), which replaces SFAS No. 123, *Accounting for Stock-Based Compensation*, and supersedes APB Opinion No. 25. SFAS No. 123R requires all share-based payments to employees, including grants of employee stock options and share-based payments granted to non-employee members of a company’s board of directors, to be recognized in the income statement based on their fair values using an option-pricing model, such as the Black-Scholes model, at the date of grant. The pro forma footnote disclosure alternative is no longer allowable under SFAS No. 123R. On March 29, 2005, the Securities and Exchange Commission (the “SEC”) issued Staff Accounting Bulletin No. 107 to express the SEC staff’s views regarding the interaction between SFAS No. 123R and certain SEC rules and regulations and provide the staff’s views regarding the valuation of share-based payment arrangements.

We are required to adopt SFAS 123R in the first quarter of fiscal 2006, beginning January 1, 2006. Under SFAS 123R, we must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at date of adoption. We are expecting to elect to use the modified prospective method for adoption, which requires compensation expense to be recorded for all unvested stock options and restricted shares beginning in the first quarter of adoption. For all unvested options outstanding as of January 1, 2006, compensation expense previously measured under SFAS No. 123, but unrecognized, will be recognized using the straight-line method 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, as defined by SFAS 123R, will be recognized using the straight-line method from the date of grant over the service period of the employee receiving the award.

SFAS 123R requires the estimation of forfeitures when recognizing compensation expense and that this estimate of forfeitures be adjusted over the requisite service period should actual forfeitures differ from such estimates. Changes in estimated forfeitures will be recognized through a cumulative catch-up adjustment, which will be recognized in the period of change and which will impact the amount of unamortized compensation expense to be recognized in future periods.

Prior to the adoption of SFAS No. 123R, we recognized share-based employee compensation expense for restricted stock awards and for stock issuances under our employee stock purchase plan. No share-based employee compensation cost for our stock option awards will have been reflected in net income prior to the adoption of SFAS No. 123R. Results for prior periods will not be restated. We are evaluating the requirements of SFAS 123R and expect that the adoption of SFAS 123R will have a material impact on our consolidated results of operations and earnings per share.

In March 2005, the FASB issued Interpretation No. 47, *Accounting for Conditional Asset Retirement Obligations*. This is an interpretation of SFAS No. 143, *Accounting for Asset Retirement Obligations* which applies to all entities and addresses the legal obligations with the retirement of tangible long-lived assets that result from the acquisition, construction, development or normal operation of a long-lived asset. The SFAS requires that the fair value of a liability for an asset retirement obligation be recognized in the period in which it is incurred if a reasonable estimate of fair value can be made. Interpretation No. 47 further clarifies what the term “conditional asset retirement obligation” means with respect to recording the asset retirement obligation discussed in SFAS No. 143. The provisions of FIN No. 47 are effective no later than December 31, 2005. We do not expect that the adoption of FIN No. 47 will have a material impact on our financial position and results of operations.

On June 2, 2005, the FASB issued FASB Statement No. 154, *Accounting Changes and Error Corrections* (FAS 154), which will require entities that voluntarily make a change in accounting principle to apply that change retrospectively to prior periods’ financial statements, unless this would be impracticable. FAS 154 supersedes APB Opinion No. 20, *Accounting Changes*, which previously required that most voluntary changes in accounting principle be recognized by including in the current period’s net income the cumulative effect of

changing to the new accounting principle. FAS 154 also makes a distinction between “retrospective application” of an accounting principle and the “restatement” of financial statements to reflect the correction of an error. Another significant change in practice under FAS 154 will be that if an entity changes its method of depreciation, amortization, or depletion for long-lived, non-financial assets, the change must be accounted for as a change in accounting estimate. Under APB 20, such a change would have been reported as a change in accounting principle. FAS 154 applies to accounting changes and error corrections that are made in fiscal years beginning after December 15, 2005.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We invest our cash balances in excess of operating requirements in cash equivalents and short-term marketable securities, generally money market funds, corporate debt and government 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 have operated primarily in the United States. Accordingly, we do not have any material exposure to foreign currency rate fluctuations.

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) and 15d-15(f) of 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, 2005. 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 (COSO).

Based on our assessment, we determined that, as of December 31, 2005, our internal control over financial reporting is effective based on the criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

Our management's assessment of the effectiveness of internal control over financial reporting as of December 31, 2005 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

Report of Independent Registered Public Accounting Firm

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

We have completed integrated audits of Curis, Inc.'s 2005 and 2004 consolidated financial statements and of its internal control over financial reporting as of December 31, 2005, and an audit of its 2003 consolidated financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

Consolidated financial statements

In our opinion, the consolidated financial statements listed in the index appearing under Item 15 (a)(1), present fairly, in all material respects, the financial position of Curis, Inc. and its subsidiary at December 31, 2005 and 2004, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2005 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit of financial statements includes 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. We believe that our audits provide a reasonable basis for our opinion.

As discussed in Note 2 to the consolidated financial statements, the Company has restated its consolidated financial statements for the years ended December 31, 2004 and 2003.

Internal control over financial reporting

Also, in our opinion, management's assessment, included in the accompanying Management's Report on Internal Control Over Financial Reporting, that the Company maintained effective internal control over financial reporting as of December 31, 2005 based on criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), is fairly stated, in all material respects, based on those criteria. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on criteria established in *Internal Control – Integrated Framework* issued by the COSO. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express opinions on management's assessment and on the effectiveness of the Company's internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. An audit of internal control over financial reporting includes obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance

with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

/s/ PRICEWATERHOUSECOOPERS LLP
Boston, Massachusetts
March 31, 2006

CURIS, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

	December 31,	
	2005	2004 (As Restated)
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 22,310,298	\$ 22,679,924
Marketable securities	21,899,024	26,834,038
Accounts receivable	1,002,511	1,226,460
Prepaid expenses and other current assets	680,320	796,618
Total current assets	45,892,153	51,537,040
Property and Equipment, net	5,347,639	3,416,620
Long-term investments	—	2,606,681
Long-term investment—restricted	195,998	193,166
Goodwill	8,982,000	8,982,000
Other intangible assets, net	27,050	102,122
Deposits and other assets, net	469,413	494,413
	\$ 60,914,253	\$ 67,332,042
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Debt, current portion	\$ 1,260,045	\$ 1,141,294
Convertible notes payable, current portion	2,605,280	—
Accounts payable	1,361,752	1,643,219
Accrued liabilities	2,897,042	1,078,687
Deferred revenue, current portion	1,756,959	819,640
Total current liabilities	9,881,078	4,682,840
Convertible notes payable, net of current portion	—	5,710,007
Debt obligations, net of current portion	1,966,667	—
Deferred revenue, net of current portion	10,236,725	8,356,134
Other long-term liabilities	830,204	271,058
Total liabilities	22,914,674	19,020,039
Commitments (Notes 9 and 10)		
Stockholders' Equity:		
Common stock, \$0.01 par value—125,000,000 shares authorized; 49,374,345 and 48,326,638 shares issued and outstanding, respectively, at December 31, 2005 and 48,565,120 and 47,517,413 shares issued and outstanding, respectively, at December 31, 2004	493,743	485,652
Additional paid-in capital	718,732,982	714,831,427
Treasury stock (at cost, 1,047,707 shares)	(891,274)	(891,274)
Deferred compensation	(242,297)	(834,157)
Accumulated deficit	(680,054,173)	(665,199,001)
Accumulated other comprehensive expense	(39,402)	(80,644)
Total stockholders' equity	37,999,579	48,312,003
	\$ 60,914,253	\$ 67,332,042

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

CURIS, INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Loss

	Years Ended December 31,		
	2005	2004	2003
		(As Restated)	(As Restated)
Revenues:			
Research and development contracts	\$ 10,493,077	\$ 3,406,612	\$ 1,628,724
License fees	2,258,677	242,467	8,749,526
Substantive milestones	250,000	50,000	—
Gross revenues	13,001,754	3,699,079	10,378,250
Contra-revenues from co-development with Genentech	(6,999,308)	—	—
Net revenues	6,002,446	3,699,079	10,378,250
Costs and Expenses:			
Research and development	13,705,074	12,661,870	14,388,126
General and administrative	8,089,738	7,757,052	6,883,100
Amortization related to intangible assets	75,072	75,071	75,079
Total costs and expenses	21,869,884	20,493,993	21,346,305
Loss from operations	(15,867,438)	(16,794,914)	(10,968,055)
Other Income (Expense):			
Interest income	1,195,727	539,853	427,912
Other income (expense)	124,958	1,591,681	(1,445,055)
Interest expense	(308,419)	(411,136)	(694,104)
Total other income (expense)	1,012,266	1,720,398	(1,711,247)
Net loss	(14,855,172)	(15,074,516)	(12,679,302)
Accretion on Series A Convertible Exchangeable Preferred Stock	—	—	(271,306)
Net loss applicable to common stockholders	\$(14,855,172)	\$(15,074,516)	\$(12,950,608)
Net Loss per Common Share (Basic and Diluted)	\$ (0.31)	\$ (0.35)	\$ (0.36)
Weighted Average Common Shares (Basic and Diluted)	48,074,181	42,685,594	36,015,610
Net Loss	\$(14,855,172)	\$(15,074,516)	\$(12,679,302)
Unrealized Gain (Loss) on Marketable Securities	41,242	(74,395)	(126,178)
Comprehensive loss	\$(14,813,930)	\$(15,148,911)	\$(12,805,480)

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

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

	Common Stock	Additional Paid-in Capital	Notes Receivable	Treasury Stock	Deferred Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount	(As Restated)			(As Restated)		(As Restated)
Balance, December 31, 2002	32,768,545	\$327,685	\$659,512,957	\$(143,898)	\$(869,384)	\$(2,037,230)	\$119,929	\$ 19,736,042
Issuance of common stock in connection with the cancellation of Series A preferred stock and forgiveness of debt	2,878,782	28,788	13,706,801	—	—	—	—	13,735,589
Issuance of common stock and warrants, net of issuance costs of \$1,107,000	3,589,700	35,897	9,769,491	—	—	—	—	9,805,388
Issuance of common stock under technology license agreement	200,000	2,000	1,005,000	—	—	—	—	1,007,000
Issuance of common stock to collaborator	1,323,835	13,239	4,977,981	—	—	—	—	4,991,220
Issuance of stock options to non-employees for services	—	—	99,108	—	—	—	—	99,108
Other issuances of common stock	847,836	8,479	1,450,354	—	—	—	—	1,458,833
Mark-to-market on stock options to non-employees	—	—	610,818	—	(610,818)	—	—	—
Amortization of deferred compensation	—	—	—	—	1,531,989	—	—	1,531,989
Reversal of deferred compensation related to forfeited options	—	—	(152,128)	—	152,128	—	—	—
Reserve on officer note receivable	—	—	—	33,530	—	—	—	33,530
Purchase of treasury stock	—	—	—	(21,890)	—	—	—	(21,890)
Realized gain on sale of investment	—	—	—	—	—	—	(96,597)	(96,597)
Unrealized loss on marketable securities	—	—	—	—	—	—	(29,581)	(29,581)
Accretion of Series A Convertible Exchangeable preferred stock dividend	—	—	—	—	—	(271,166)	—	(271,166)
Net loss	—	—	—	—	—	(12,679,302)	—	(12,679,302)
Balance, December 31, 2003, as restated	41,608,698	416,088	690,980,382	(110,368)	(891,274)	(963,931)	(6,249)	39,300,163
Issuance of common stock and warrants, net of issuance costs of \$1,262,000	5,476,559	54,766	18,782,026	—	—	—	—	18,836,792
Issuance of common stock to collaborator	315,524	3,155	1,634,845	—	—	—	—	1,638,000
Issuance of stock options to non-employees for services	—	—	18,000	—	—	—	—	18,000
Other issuances of common stock	1,164,339	11,643	2,191,903	—	—	—	—	2,203,546
Mark-to-market on stock options to non-employees	—	—	1,265,659	—	(1,265,659)	—	—	—
Amortization of deferred compensation	—	—	—	—	1,354,045	—	—	1,354,045
Reversal of deferred compensation related to forfeited options	—	—	(41,388)	—	41,388	—	—	—
Settlement of officer note receivable	—	—	—	110,368	—	—	—	110,368
Unrealized loss on marketable securities	—	—	—	—	—	—	(74,395)	(74,395)
Net loss	—	—	—	—	—	(15,074,516)	—	(15,074,516)
Balance, December 31, 2004, as restated	48,565,120	485,652	714,831,427	(891,274)	(834,157)	(665,199,001)	(80,644)	48,312,003

CURIS, INC. AND SUBSIDIARIES

Consolidated Statements of Stockholders' Equity—(Continued)

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Notes Receivable	Treasury Stock	Deferred Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
Balance, December 31, 2004, as restated	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 6(a))	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

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

CURIS, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows

	Years Ended December 31,		
	2005	2004	2003
		(As Restated)	(As Restated)
Cash Flows from Operating Activities:			
Net loss	\$(14,855,172)	\$(15,074,516)	\$(12,679,302)
Adjustments to reconcile net loss to net cash used in operating activities—			
Depreciation and amortization	939,619	1,000,740	1,425,842
Stock-based compensation expense	221,202	1,372,045	1,631,096
Reserve on loss of subtenant income (Note 10)	500,000	—	—
Amortization of intangible assets	75,072	75,071	75,079
Noncash interest expense on notes payable	200,796	387,869	461,377
Gain on recovery of officer notes receivable	—	(448,074)	—
Loss on property and equipment	—	—	281
Impairment of long-term receivable	—	—	1,708,433
Impairment of investment	—	300,000	286,349
Foreign currency exchange gain	—	—	(452,857)
Changes in operating assets and liabilities:			
Accounts receivable	223,949	(1,041,487)	2,292,355
Prepaid expenses and other assets	141,298	285,869	(7,437)
Due from joint venture	—	—	210,207
Accounts payable and accrued and other liabilities	1,596,034	8,321	(965,149)
Deferred contract revenue	2,817,910	5,666,774	(5,238,030)
Total adjustments	6,715,880	7,607,128	1,427,546
Net cash used in operating activities	(8,139,292)	(7,467,388)	(11,251,756)
Cash Flows from Investing Activities:			
Purchase of marketable securities	(36,184,927)	(34,341,678)	(21,063,891)
Sale of marketable securities	41,161,182	14,844,444	23,176,683
(Increase) decrease in restricted cash/restricted long-term investments	(2,832)	—	4,212,527
Purchase of long-term investments	—	(7,823,521)	(2,389,742)
Sale of long-term investments	2,606,681	7,606,582	—
Expenditures for property and equipment	(2,870,637)	(1,916,657)	(152,057)
Increase in other long-term assets	—	—	(2,138,794)
Net cash provided by (used in) investing activities	4,709,467	(21,630,830)	1,644,726
Cash Flows from Financing Activities:			
Proceeds from issuance of common stock, net of issuance costs	—	18,836,792	9,805,388
Proceeds from other issuances of common stock	974,781	3,841,545	7,457,052
Proceeds from officers' notes receivable	—	558,442	—
Repayment of convertible notes payable	—	—	(1,601,563)
Purchases of treasury stock	—	—	(21,890)
Proceeds from issuance of debt	2,585,418	1,138,871	—
Repayments of notes payable and capital leases	(500,000)	(332,056)	(5,218,014)
Net cash provided by financing activities	3,060,199	24,043,594	10,420,973
Net (Decrease) Increase in Cash and Cash Equivalents	(369,626)	(5,054,624)	813,943
Cash and Cash Equivalents, beginning of period	22,679,924	27,734,548	26,920,605
Cash and Cash Equivalents, end of period	\$ 22,310,298	\$ 22,679,924	\$ 27,734,548
Supplemental cash flow data			
Cash paid during the year for:			
Interest	\$ 144,083	\$ 30,690	\$ 255,079
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 5(a))	\$ 3,305,523	\$ —	\$ —
Issuance of common stock in connection with cancellation of Series A preferred stock and forgiveness by Elan Pharma International, Limited of a portion of convertible note payable	\$ —	\$ —	\$ 13,735,589

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

CURIS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

(1) OPERATIONS

Curis, Inc. (the “Company” or “Curis”) is a therapeutic drug development company principally focused on the discovery, development and future commercialization of products that modulate key regulatory signaling pathways controlling the growth, repair and regeneration of human tissues and organs. The Company’s product development approach involves using small molecules, proteins or antibodies to modulate these regulatory signaling pathways, for example, to increase the pathway signals when they are insufficient or to decrease them when they are excessive or unregulated. The Company has successfully used its product development approach to produce multiple compounds with potential use for several different disease indications. The Company has also developed several promising preclinical product candidates in various fields, including cancer, neurological disorders and hair growth regulation. 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, 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) RESTATEMENT OF FINANCIAL STATEMENTS

The Company has restated its financial results for 2004 and 2003. The restatement adjusts the Company’s 2004 consolidated balance sheet contained herein to correct amounts in prepaid expenses and other current asset, deposits and other assets, short-term and long-term deferred revenues, additional paid-in capital, and accumulated deficit and to restate the Company’s consolidated 2004 and 2003 statements of operations to correct amounts reported in gross revenues and research and development expenses. As a result of these restatements, amounts in the consolidated statement of cash flows for the years ended December 31, 2004 and 2003 have also been corrected. These adjustments are more fully described below:

- *Genentech license fee payments:* The Company had been recognizing revenue in connection with \$7,509,000 in payments received from Genentech as part of the June 2003 Hedgehog antagonist collaboration between the parties over an eight-year period based on the Company’s belief that its participation on the steering committees 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. The Company has determined that it should not have recognized any of this revenue in 2005, 2004, and 2003. Instead, the Company will defer the \$7,509,000 in payments and recognize this amount as revenue only when it can reasonably estimate when its contractual steering committee obligations will cease or after the Company no longer has contractual steering committee obligations under this agreement with Genentech. The contractual term of the Company’s steering committee obligations extends for as long as Hedgehog antagonist products subject to this collaboration are being developed or commercialized by either of the parties. Accordingly, the contractual term of the Company’s steering committee obligations is indefinite and the Company expects it will not record any revenue related to these payments for at least several years. The consolidated financials statements for 2004 and 2003 have been restated to reverse all revenue recognized

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

related to the amortization of this up-front payment and to correct the related deferred revenue balances at December 31, 2004 and 2003.

- *Expenses due to university licensors:* The Company is restating reported research and development expenses associated with \$410,000 in license fee payments that were payable by the Company to university licensors in connection with the June 2003 Hedgehog antagonist collaboration with Genentech. The Company had previously capitalized this amount as “Prepaid expenses and other current assets” and “Deposits and other assets” in its consolidated balance sheets and amortized this amount to research and development expense as the related license fee revenue was recognized. The Company has determined that it should have instead recognized the entire \$410,000 immediately as research and development expense in June 2003. The consolidated financial statements for 2004 and 2003 have been restated to reverse \$83,000 of expense recorded in 2004, to expense the entire payment of \$410,000 in 2003 and to correct “Prepaid expenses and other current assets” and “Deposits and other assets” at December 31, 2004 to reflect the expensing of these payments.
- *Correction of previously identified immaterial errors:*
 - *Allocation of up-front payments received from Genentech and Wyeth:* In connection with the restatement, the Company will also correct other previously identified immaterial errors which had previously been corrected through a cumulative adjustment to the consolidated financial statements in the Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2005. The restatement will allocate the adjustment among the correct periods.

These errors relate to the Company’s sale of shares of its common stock in connection with the June 2003 Genentech and January 2004 Wyeth collaboration agreements. In each case, the Company calculated the value of the common stock using the negotiated price, which was less than the closing market price on the agreement date. Because of this, the Company understated additional paid-in capital and overstated deferred revenues by \$1,629,000. During the third quarter of 2005, prior to restating, the Company recorded a cumulative adjustment as a result of these errors to reverse previously recorded license fee revenue of \$460,000 for the years ended December 31, 2004 and 2003 and through the nine-month period ended September 30, 2005. The overstatement of deferred revenues resulted in an overstatement of license fee revenues of \$124,000 and \$233,000 in 2003 and 2004, respectively, because, in each case, the Company amortized deferred revenue over the estimated performance period to revenues in its consolidated statements of operations. The consolidated financial statements for 2004 and 2003 have been restated to: (i) reverse all revenue recognized related to the amortization of the deferred revenue related to the June 2003 Genentech Hedgehog antagonist collaboration, (ii) correct revenue recognized related to the amortization of the deferred revenue related to the 2004 Wyeth collaboration, (iii) correct additional paid-in capital at December 31, 2004 and 2003, to reflect the fair value on the date of issuance of the common stock issued to Genentech and Wyeth and (iv) correct deferred revenue at December 31, 2004 and 2003 to reflect the impact of these adjustments. The correction of the accounting for the January 2004 Wyeth collaboration agreement resulted in a \$138,000 increase in net cash used in operating activities and a corresponding increase in net cash provided by financing activities for the year ended December 31, 2004. The correction of the accounting for the June 2003 Genentech collaboration agreement resulted in a \$1,491,000 increase in net cash used in operating activities and a corresponding increase in net cash provided by financing activities for the year ended December 31, 2003.

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

- *Recording of \$4 million in annual maintenance fee payments as accounts receivable:* The Company mistakenly treated two \$2,000,000 annual maintenance payments payable under its June 2003 Genentech collaboration as accounts receivable. The Company subsequently determined that there were contingencies relating to its receipt of each payment and, therefore, these amounts should not have been reflected in the Company's consolidated balance sheet until the cash payments were received. As a result of the error, the Company's consolidated balance sheet reflected excess accounts receivable and corresponding deferred revenues in the amount of \$4,000,000 in the third quarter of 2003. As the contingencies expired, the receivable balances were paid and the overstatement of accounts receivable declined to \$2,000,000 in the second quarter of 2004. This error had corrected itself by the fourth quarter of 2004 and, as such, the Company's accounts receivable balances were appropriately recorded on its December 31, 2004 consolidated balance sheet and at all subsequent consolidated balance sheets. This error had no effect on the Company's consolidated statements of operations. The correction of the accounting for the June 2003 Genentech collaboration agreement resulted in a \$4,000,000 increase in the change in the Company's accounts receivable balances and a corresponding decrease in the change in the Company's deferred revenue balances in its statement of cash flows for the year ended December 31, 2003. The net effect of these changes did not impact the Company's cash balances or cash flow from operations in any period.

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

The following is a summary of the effects of the changes described above:

	<u>As Previously Reported</u>	<u>Adjustments</u>	<u>As Restated</u>
<u>Consolidated Balance Sheet</u>			
December 31, 2004			
Prepaid expenses and other current assets . . .	\$ 843,198	\$ (46,580)	\$ 796,618
Total current assets	51,583,620	(46,580)	51,537,040
Deposits and other assets	750,604	(256,191)	494,413
Total other assets	12,634,573	(256,191)	12,378,382
Total assets	67,634,813	(302,771)	67,332,042
Deferred revenue, current portion	1,939,708	(1,120,068)	819,640
Total current liabilities	5,802,908	(1,120,068)	4,682,840
Deferred revenue, net of current portion	6,941,545	1,414,589	8,356,134
Additional paid-in capital	713,202,427	1,629,000	714,831,427
Accumulated deficit	(662,972,709)	(2,226,292)	(665,199,001)
Total stockholders' equity	48,909,295	(597,292)	48,312,003
Total liabilities and stockholders' equity . . .	67,634,813	(302,771)	67,332,042
	<u>As Previously Reported</u>	<u>Adjustments</u>	<u>As Restated</u>
<u>Consolidated Statements of Operations</u>			
Year ended December 31, 2004			
License fee revenues	\$ 1,496,003	\$(1,253,536)	\$ 242,467
Gross revenues	4,952,615	(1,253,536)	3,699,079
Net revenues	4,952,615	(1,253,536)	3,699,079
Research and development expenses	12,745,164	(83,294)	12,661,870
Total costs and expenses	20,577,287	(83,294)	20,493,993
Loss from operations	(15,624,672)	(1,170,242)	(16,794,914)
Net loss applicable to common stockholders	(13,904,274)	(1,170,242)	(15,074,516)
Net loss per common share (basic and diluted)	\$ (0.33)	\$ (0.02)	\$ (0.35)
	<u>As Previously Reported</u>	<u>Adjustments</u>	<u>As Restated</u>
Year ended December 31, 2003			
License fee revenues	\$ 9,419,509	\$ (669,983)	\$ 8,749,526
Gross revenues	11,048,233	(669,983)	10,378,250
Net revenues	11,048,233	(669,983)	10,378,250
Research and development expenses	14,002,059	386,067	14,388,126
Total costs and expenses	20,960,238	386,067	21,346,305
Loss from operations	(9,912,005)	(1,056,050)	(10,968,055)
Net loss	(11,623,252)	(1,056,050)	(12,679,302)
Net loss applicable to common stockholders	(11,894,558)	(1,056,050)	(12,950,608)
Net loss per common share (basic and diluted)	\$ (0.33)	\$ (0.03)	\$ (0.36)

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

<u>Consolidated Statements of Cash Flows</u>	<u>As Previously Reported</u>	<u>Adjustments</u>	<u>As Restated</u>
Year ended December 31, 2004			
Net loss	\$(13,904,274)	\$(1,170,242)	\$(15,074,516)
Changes in operating assets and liabilities:			
Collection of long-term receivable	2,000,000	(2,000,000)	—
Accounts receivable	1,171,346	(2,212,833)	(1,041,487)
Prepaid expenses and other assets	56,332	229,537	285,869
Accounts payable and accrued liabilities	108,321	(100,000)	8,321
Deferred revenue	551,236	5,115,538	5,666,774
Total adjustments	6,574,886	1,032,242	7,607,128
Net cash used in operating activities	(7,329,388)	(138,000)	(7,467,388)
Proceeds from other issuances of common stock	3,703,545	138,000	3,841,545
Net cash provided by financing activities	23,905,594	138,000	24,043,594
Year ended December 31, 2003			
Net loss	\$(11,623,252)	\$(1,056,050)	\$(12,679,302)
Changes in operating assets and liabilities:			
Accounts receivable	(1,738,120)	4,030,475	2,292,355
Prepaid expenses and other assets	(263,029)	255,592	(7,437)
Accounts payable and accrued liabilities	(1,065,149)	100,000	(965,149)
Deferred revenue	(417,013)	(4,821,017)	(5,238,030)
Total adjustments	1,862,496	(434,950)	1,427,546
Net cash used in operating activities	(9,760,756)	(1,491,000)	(11,251,756)
Proceeds from other issuances of common stock	5,966,052	1,491,000	7,457,052
Net cash provided by financing activities	8,929,973	1,491,000	10,420,973

(3) FINANCIAL STATEMENT RECLASSIFICATIONS

The Company has reclassified \$1,372,000 and \$1,631,000, respectively, for the years ended December 31, 2004 and 2003, respectively, from “Stock-based compensation expense” to “Research and development expenses” and “General and administrative expenses” in the Company’s Costs and Expenses section of its Consolidated Statements of Operations and Comprehensive Loss to conform with the current period presentation. Of these amounts, \$1,175,000 and \$1,267,000 were reclassified to “Research and development expenses” and \$197,000 and \$364,000 were reclassified to “General and administrative expenses” for the years ended December 31, 2004 and 2003, respectively (see Note 14).

(4) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The following are the Company’s 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

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

assumptions that affect the reported amounts and disclosure of certain assets and liabilities at the balance sheet date. Such estimates include 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, beginning May 16, 2003, Curis Newco, Ltd. Intercompany balances have been eliminated in consolidation. Curis Newco was dissolved on November 5, 2004 and is no longer a subsidiary of the Company as of December 31, 2004.

(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)*.

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.

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.

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

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 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 the Company expects to complete its performance obligations. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the straight-line basis, as of the period ending date.

If the Company cannot reasonably estimate when its performance obligation either ceases or becomes inconsequential, then revenue is deferred until the Company can reasonably estimate when the performance obligation ceases or becomes inconsequential.

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. In addition, 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 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 the Company expects to complete its aggregate performance obligations.

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

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Notes to Consolidated Financial Statements—Continued

that one such payment was not a substantive milestone would prevent the Company from concluding that subsequent milestone payments were substantive milestones and, as a result, any additional milestone payments would 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 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 is recognized upon the sale of the related products, provided that the royalty amounts are fixed or determinable, collection of the related receivable is reasonably assured and the Company has no remaining performance obligations under the arrangement. If royalties are received when the Company has remaining performance obligations, the royalty payments would be attributed to the services being provided under the arrangement and therefore would be recognized as such performance obligations are performed under either the relative performance or straight line methods, as applicable, and in accordance with these policies as described above.

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. 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 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.

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 ended December 31, 2006 are classified as long-term deferred revenue. As of December 31, 2005, the Company has short- and long-term deferred revenue of \$1,757,000 and \$10,237,000, respectively, related to its collaborations (see Note 5).

The Company received a grant award during 2004 from the Spinal Muscular Atrophy Foundation. Revenue under this grant is being recognized as the services are provided and when payment is reasonably assured under the terms of the grant.

During the years ended December 31, 2005, 2004, and 2003, total gross revenues from major customers as a percent of total gross revenues of the Company were as follows:

	Year Ended December 31,		
	2005	2004 (as restated)	2003 (as restated)
Genentech	49%	16%	1%
Wyeth Pharmaceuticals	22%	68%	—%
Spinal Muscular Atrophy Foundation	15%	15%	—%
Procter & Gamble	2%	—%	—%
Micromet AG	11%	—%	82%
ES Cell International	—%	—%	16%

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Notes to Consolidated Financial Statements—Continued

(d) RESEARCH AND DEVELOPMENT

Research and development costs, including internal and external costs, are charged to operations as incurred. Certain research and development projects are, or have been, partially funded by research and development contracts, and the expenses related to these activities are included in research and development costs. Research and development costs include personnel costs, lab supplies, outside services including medicinal chemistry, sponsored research agreements, allocations of facility costs and fringe benefits, and other costs.

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

Cash equivalents consist of short-term, highly liquid investments purchased with original 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 losses and fair value of marketable securities available-for-sale as of December 31, 2005, with maturity dates ranging between one and 12 months and with a weighted average maturity of 4.0 months are as follows:

	Amortized Cost	Unrealized Loss	Fair Value
U.S. government obligations	\$ 2,045,000	\$ (1,000)	\$ 2,044,000
Asset-backed securities	3,886,000	(6,000)	3,880,000
Corporate bonds and notes	16,008,000	(33,000)	15,975,000
Total marketable securities	\$21,939,000	\$(40,000)	\$21,899,000

The Company had no long-term investments as of December 31, 2005.

The amortized cost, unrealized losses and fair value of marketable securities available-for-sale as of December 31, 2004, with maturity dates ranging between one and 12 months and with a weighted average maturity of 5.1 months are as follows:

	Amortized Cost	Unrealized Loss	Fair Value
U.S. government obligations	\$ 3,721,000	\$ —	\$ 3,721,000
Corporate bonds and notes	23,181,000	(68,000)	23,113,000
Total marketable securities	\$26,902,000	\$(68,000)	\$26,834,000

As of December 31, 2004, the Company recorded long-term investments of \$2,607,000 on its Consolidated Balance Sheet. This amount is comprised of corporate debt securities with maturities ranging from January 2006 to April 2006 and with amortized cost totaling \$2,620,000, less unrealized losses of \$13,000.

The Company considers its unrealized losses to be temporary because it has the ability to hold the 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. Accordingly, the Company has not recorded an impairment loss on its investments.

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Notes to Consolidated Financial Statements—Continued

The 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.

(f) FAIR VALUE OF FINANCIAL INSTRUMENTS

The Company's financial instruments consist mainly of cash and cash equivalents, marketable securities, short- and long-term accounts receivable, long-term investments, common stock in privately-held companies, accounts payable, convertible notes 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. Notes receivable are recorded at the lesser of cost or net realizable value, which approximates the fair value of these instruments.

The fair values of marketable securities and short- and long-term investments are based on current quoted market values. Equity investments in privately-held companies are reflected in the accompanying consolidated financial statements at a value based on the Company's best estimate of the fair value of such equity investments. When determining the fair values of such investments, the Company generally considers such factors as the fair value paid by outside investors for similar equity in such companies, the liquidity of the investment and both company-specific and macroeconomic factors that may have affected values since the last such investment by other outside investors. 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 fourth quarter of the year ended December 31, 2003, the Company wrote down the carrying value of its investment in Micromet equity securities by \$286,000 from \$686,000 to \$400,000. In October 2004, Micromet completed a financing and the Company believed that the terms of Micromet's financing adversely affected the carrying value of the equity investment in Micromet. As a result, during the fourth quarter of the year ended December 31, 2004, the Company wrote down the carrying value of the investment in Micromet to \$100,000, recognizing a charge to other expense of \$300,000.

As of December 31, 2005 and 2004, the value of the Company's investments in privately-held companies was \$417,000, and these amounts are included in "Deposits and other assets" in the Consolidated Balance Sheets.

The convertible note payable and debt obligations have fixed rates of interest and will be subject to fluctuations in fair value during their terms. As of December 31, 2005, the Company estimates that the fair values of these instruments approximate their carrying amounts.

(g) PROPERTY AND EQUIPMENT

Purchased equipment is recorded at cost. Leased equipment is recorded at the lesser of cost or the present value of the minimum lease payments. Depreciation and amortization are provided on the

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Notes to Consolidated Financial Statements—Continued

straight-line method over the estimated useful lives of the related assets or the remaining terms of the leases, whichever is shorter, as follows:

<u>Asset Classification</u>	<u>Estimated Useful Life</u>
Laboratory equipment and computers	3-5 years
Leasehold improvements	Lesser of life of the lease or the life of the asset
Office furniture and equipment	5 years
Equipment under lease obligations	Life of the lease

(h) LONG-LIVED ASSETS OTHER THAN GOODWILL

Long-lived assets other than goodwill consist of long-term investments in corporate debt securities, investments in certain of the Company's former and strategic collaborators, and long-term deposits. The aggregate balances for these long-lived assets were \$692,000 and \$3,396,000 as of December 31, 2005 and 2004, respectively. The Company applies SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, which requires companies to (1) recognize an impairment loss only if the carrying amount of a long-lived asset is not recoverable based on its undiscounted future cash flows and (2) measure an impairment loss as the difference between the carrying amount and fair value of the asset. In addition, SFAS No. 144 provides guidance on accounting and disclosure issues surrounding long-lived assets to be disposed of by sale.

During the fourth quarter of the year ended December 31, 2003, the Company recorded an impairment charge of approximately \$1,708,000 related to the write-off of a note receivable that was originally due in June 2005 from Micromet, a former collaborator (see Note 6(b)). On October 21, 2004, the Company amended its note receivable with Micromet, and, under the amended note, Micromet is 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 November 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 future amounts due to the Company under the amended note are not considered reasonably assured of collection at December 31, 2005 and, therefore, have not been recorded as revenue. The Company will record revenue when, and if, it concludes such amounts are reasonably assured of collection. 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.

(i) GOODWILL

As of December 31, 2005 and 2004, 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 December of 2005, 2004 and 2003, the Company completed its annual goodwill

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Notes to Consolidated Financial Statements—Continued

impairment tests and determined that as of those dates the fair value of the Company exceeded the carrying value of its net assets. Accordingly, no goodwill impairment was recognized in 2005, 2004 or 2003.

(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. Since May 31, 2002, the Company has repurchased 1,047,707 shares of its common stock at a cost of \$891,000 pursuant to this repurchase program.

(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 loss per share were determined by dividing net loss, after giving effect to the accretion on Series A Convertible Exchangeable Preferred Stock, if any, by the weighted average common shares outstanding during the period. As of May 16, 2003, the Series A Convertible Exchangeable Preferred Stock was cancelled as part of the termination of the collaboration with affiliates of Elan Corporation (see Note 6(a)). 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, which consist of stock options, warrants, convertible debt and, until May 16, 2003, Series A Convertible Exchangeable Preferred Stock, that were not included in diluted net loss per common share were 11,737,856, 11,459,030, and 11,070,422 as of December 31, 2005, 2004 and 2003, respectively.

(l) STOCK-BASED COMPENSATION

The Company has two stock option plans, which are described more fully in Note 14. In December 2004, the FASB issued SFAS No. 123(R), *Accounting for Stock-Based Compensation*, which establishes standards for the accounting of transactions in which an entity exchanges its equity instruments for goods or services. This Statement focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions. SFAS No. 123(R) requires that the fair value of such equity instruments be recognized as an expense in the historical financial statements as services are performed. Prior to adopting SFAS No. 123(R), only certain pro forma disclosures of fair value are required.

The provisions of SFAS No. 123(R) are effective for the first annual reporting period beginning after June 15, 2005. Early adoption is encouraged and retroactive application of the provisions of SFAS 123(R) to the beginning of the fiscal year that includes the effective date is permitted, but not required. The Company is expecting to use the modified prospective method for adoption, which requires compensation expense to be recorded for all unvested stock options and restricted shares beginning in the first quarter of adoption. For all unvested options outstanding as of January 1, 2006, compensation expense previously measured under SFAS No. 123, but unrecognized, will be recognized using the straight-line method 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, as defined by

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Notes to Consolidated Financial Statements—Continued

SFAS 123R, will be recognized using the straight-line method from the date of grant over the service period of the employee receiving the award.

SFAS 123R requires the estimation of forfeitures when recognizing compensation expense and that this estimate of forfeitures be adjusted over the requisite service period should actual forfeitures differ from such estimates. Changes in estimated forfeitures will be recognized through a cumulative catch-up adjustment, which will be recognized in the period of change and which will impact the amount of unamortized compensation expense to be recognized in future periods.

Prior to the adoption of SFAS No. 123R, the Company recognized share-based employee compensation expense for stock issuances under our employee stock purchase plan. No share-based employee compensation cost for our stock option awards will have been reflected in net income prior to the adoption of SFAS No. 123R. Results for prior periods will not be restated.

The Company will implement the revised standard in the first quarter of fiscal year 2006. Currently, the Company accounts for its share-based payment transactions under the provisions of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, which does not necessarily require the recognition of compensation cost in the financial statements. The Company is evaluating its current compensation strategies as they relate to stock-based compensation. Management expects that this revised standard will materially impact the Company's results of operations in the first quarter of fiscal year 2006 and thereafter.

For the years ended December 31, 2005, 2004 and 2003, the Company applied APB No. 25 and related interpretations, including FASB Interpretation No. 44, in accounting for qualifying options granted to its employees and directors under its plans and applies SFAS No. 123, as amended by FASB No. 148, for disclosure purposes only. The SFAS 123 disclosures include pro forma net loss and net loss per share as if the fair value method of accounting had been used. Stock issued to non-employees is accounted for in accordance with SFAS 123 and related interpretations.

Under SFAS No. 123, the fair value of stock-based awards to employees is calculated through the use of option pricing models, even though such models were developed to estimate the fair value of freely tradable, fully transferable options without vesting restrictions, which significantly differ from the Company's stock option awards. These models also require subjective assumptions, including future stock price volatility and expected time to exercise, which greatly affect the calculated values. The Company's calculations were made using the Black-Scholes option-pricing model with the following assumptions and weighted average values:

	<u>Year Ended December 31,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
Risk-free interest rate	3.8%	3.7%	3.1%
Expected dividend yield	—	—	—
Expected lives	5.0	5.0	7.0
Expected volatility	95%	95%	121%
Weighted average grant date fair value	\$2.89	\$3.37	\$2.44

The risk-free interest rate is based on the U.S. treasury security rate estimated for the expected life of the options at the date of grant. Due to limited historical data, the expected lives of options are based on the Company's historical data and compared to relevant industry data. The Company determined that a blend of implied volatility and historical volatility is more reflective of market conditions and a better indicator of expected volatility than using purely historical volatility. Forfeitures for grants to employees are recognized as they occur. If the computed fair values of the 2005, 2004 and 2003 awards

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Notes to Consolidated Financial Statements—Continued

had been amortized to expense over the vesting period of the awards consistent with SFAS No. 123, pro forma net loss and net loss per common share would have been as follows:

	Year Ended December 31,		
	2005	2004	2003
		(As Restated)	(As Restated)
Net loss applicable to common stockholders as reported	\$(14,855,000)	\$(15,075,000)	\$(12,951,000)
Add back: employee stock based compensation included in net loss, as reported	7,000	639,000	838,000
Less: stock-based employee compensation expense determined under fair value based methods for all awards	<u>(4,814,000)</u>	<u>(7,212,000)</u>	<u>(7,552,000)</u>
Pro forma net loss	<u><u>\$(19,662,000)</u></u>	<u><u>\$(21,648,000)</u></u>	<u><u>\$(19,665,000)</u></u>
Net loss per common share (basic and diluted)—			
As reported	\$ (0.31)	\$ (0.35)	\$ (0.36)
Pro forma	(0.41)	(0.51)	(0.55)

The effects on the years ended December 31, 2005, 2004 and 2003 pro forma net loss and net loss per share of the estimated fair value of stock options are not necessarily representative of the effects on the results of operations in the future. In addition, the estimates made utilize a pricing model developed for traded options with relatively short lives. The Company's option grants typically have a life of up to ten years and are generally not transferable, therefore, the actual fair value of a stock option grant may be different from these estimates. The Company believes that its estimates incorporate all relevant information and represent a reasonable approximation in light of the difficulties involved in valuing non-traded stock options.

(m) OPERATING LEASES

The Company has three facilities which are located at 25, 45 and 61 Moulton Street in Cambridge, Massachusetts under noncancellable operating lease agreements for office and laboratory space. The rent payments for the 25 and 61 Moulton Street locations are fixed over the lease term. The rent payments for the 45 Moulton Street facility escalate over the lease term. The Company expenses its obligations under these lease agreements on a straight-line basis over the term of each lease (see Note 10).

The Company currently leases a portion of its facility at 61 Moulton Street for which it receives sublease income. The term of the sublease extends through the Company's original lease term of April 2007, and the Company records sublease income as a reduction to its rent expense when the payments are received. In July 2005, the subtenant notified the Company that it expected that it would no longer be able to meet its obligations under the sublease. The Company does not expect to utilize the space, if vacated by the current tenant due to default of the amended sublease terms, for its current or future operations. In addition, the Company believes that its costs under the lease will exceed any future sublease income for the duration of the lease. Based on these factors and the expected decline in sublease income, the Company recorded a charge of \$500,000 in the "General and administrative expense" line item of its Consolidated Statement of Operations during the second quarter of 2005.

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(n) DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES

SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, as amended by SFAS No. 137 and SFAS No. 138, establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities. As of December 31, 2005, 2004 and 2003, the Company did not have any derivative instruments.

(o) NEW ACCOUNTING PRONOUNCEMENTS

In December 2004, the FASB issued SFAS No. 123 (revised 2004), "*Share-Based Payment*" ("SFAS No. 123R"), which replaces SFAS No. 123, "*Accounting for Stock-Based Compensation*," and supersedes APB Opinion No. 25. SFAS No. 123R requires all share-based payments to employees, including grants of employee stock options and share-based payments granted to non-employee members of a company's board of directors, to be recognized in the income statement based on their fair values using an option-pricing model, such as the Black-Scholes model, at the date of grant. The pro forma footnote disclosure alternative is no longer allowable under SFAS No. 123R. On March 29, 2005, the Securities and Exchange Commission (the "SEC") issued Staff Accounting Bulletin No. 107 to express the SEC staff's views regarding the interaction between SFAS No. 123R and certain SEC rules and regulations and provide the staff's views regarding the valuation of share-based payment arrangements.

The Company is required to adopt SFAS 123R in the first quarter of fiscal 2006, beginning January 1, 2006. Under SFAS 123R, the Company must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at date of adoption. The Company is expecting to use the modified prospective method for adoption, which requires compensation expense to be recorded for all unvested stock options and restricted shares beginning in the first quarter of adoption. For all unvested options outstanding as of January 1, 2006, compensation expense previously measured under SFAS No. 123, but unrecognized, will be recognized using the straight-line method 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, as defined by SFAS 123R, will be recognized using the straight-line method from the date of grant over the service period of the employee receiving the award.

SFAS 123R requires the estimation of forfeitures when recognizing compensation expense and that this estimate of forfeitures be adjusted over the requisite service period should actual forfeitures differ from such estimates. Changes in estimated forfeitures will be recognized through a cumulative catch-up adjustment, which will be recognized in the period of change and which will impact the amount of unamortized compensation expense to be recognized in future periods.

Prior to the adoption of SFAS No. 123R, the Company recognized share-based employee compensation expense for stock issuances under our employee stock purchase plan. No share-based employee compensation cost for our stock option awards will have been reflected in net income prior to the adoption of SFAS No. 123R. Results for prior periods will not be restated. The Company is evaluating the requirements of SFAS 123R and expects that the adoption of SFAS 123R will have a material impact on its consolidated results of operations and earnings per share.

In March 2005, the FASB issued Interpretation No. 47, "*Accounting for Conditional Asset Retirement Obligations*." This is an interpretation of SFAS No. 143, "*Accounting for Asset Retirement Obligations*" which applies to all entities and addresses the legal obligations with the retirement of tangible long-lived assets that result from the acquisition, construction, development or normal operation of a long-lived asset. The SFAS requires that the fair value of a liability for an asset retirement obligation be recognized in the period in which it is incurred if a reasonable estimate of fair

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Notes to Consolidated Financial Statements—Continued

value can be made. Interpretation No. 47 further clarifies what the term “conditional asset retirement obligation” means with respect to recording the asset retirement obligation discussed in SFAS No. 143. The provisions of FIN No. 47 are effective no later than December 31, 2005. The Company does not expect that the adoption of FIN No. 47 will have a material impact on its financial position and results of operations.

On June 2, 2005, the Financial Accounting Standards Board (FASB) issued FASB Statement No. 154, *Accounting Changes and Error Corrections* (FAS 154), which will require entities that voluntarily make a change in accounting principle to apply that change retrospectively to prior periods’ financial statements, unless this would be impracticable. FAS 154 supersedes Accounting Principles Board Opinion No. 20, *Accounting Changes* (APB 20), which previously required that most voluntary changes in accounting principle be recognized by including in the current period’s net income the cumulative effect of changing to the new accounting principle. FAS 154 also makes a distinction between “retrospective application” of an accounting principle and the “restatement” of financial statements to reflect the correction of an error. Another significant change in practice under the FAS 154 will be that if an entity changes its method of depreciation, amortization, or depletion for long-lived, non-financial assets, the change must be accounted for as a change in accounting estimate. Under APB 20, such a change would have been reported as a change in accounting principle. FAS 154 applies to accounting changes and error corrections that are made in fiscal years beginning after December 15, 2005.

(5) 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. Pursuant to the collaboration agreement, Genentech agreed to make specified cash payments including up-front payments 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 agreed to make license maintenance fee payments totaling \$4,000,000 over the first two years of the collaboration and cash payments at various intervals during the clinical development and regulatory approval process of small molecule and antibody Hedgehog antagonist product candidates, assuming specified clinical development and regulatory approval objectives are met. In addition, Genentech will pay a royalty on potential future net product sales, which increases with increasing sales volume.

Under the collaboration agreement, the Company has the option to elect to co-develop Hedgehog antagonist products in the field of basal cell carcinoma in the U.S. In January 2005, the Company elected to exercise this co-development option and will now share equally in both U.S. development costs and any future U.S. net profits and/or losses resulting from the development and commercialization of its basal cell carcinoma product candidate. This co-development right includes basal cell carcinoma and any additional indications for which this product candidate may be developed in the U.S. As a result of participating in co-development, the Company will forego contingent cash payments, U.S. development and regulatory approval objectives and royalty payments on potential future U.S. sales of the basal cell carcinoma product candidate. Should the Company determine that it cannot continue funding its equal share of the development expenses, the Company may opt out of the

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Notes to Consolidated Financial Statements—Continued

co-development structure and receive certain contingent cash payments upon achieving specified development and regulatory approval objectives and royalties on sales of the basal cell carcinoma product candidate, should any ever occur. In addition, in certain major international markets, the Company will receive cash payments if specific clinical development objectives are achieved and a royalty on any international sales of any basal cell carcinoma product candidate.

Under the systemic Hedgehog antagonist program of the collaboration, Genentech is also obligated to make cash payments to the Company assuming the successful achievement of clinical development and drug approval objectives. In addition, Genentech will pay a royalty on potential future net product sales, which increases with increasing sales volume.

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) Genentech may terminate the agreement without cause, effective no earlier than June 12, 2004, upon six months prior written notice. Genentech may also terminate the agreement solely with respect to a particular compound, indication or country no earlier than June 12, 2004, upon six months prior written notice.
- (iii) If Genentech terminates the agreement for cause, all licenses granted by Genentech to the Company automatically terminate and revert to Genentech and specified licenses granted by Curis to Genentech shall survive so long as Genentech is not then in breach under the Agreement. The consideration for any product that the Company shares gross profits and losses with Genentech through a co-development structure (i.e., the basal cell carcinoma product candidate) will be modified so that the Company will no longer receive its share of gross profits and losses. The Company will instead receive clinical development and drug approval milestones and royalties on product sales for such product.
- (iv) 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.

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.

(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 steering committees. The Company applied the provisions of EITF 00-21 to determine whether the performance obligations under this collaboration

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Notes to Consolidated Financial Statements—Continued

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, does not have stand-alone value to Genentech without the Company's research and development services and steering committee participation and because 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's ongoing performance obligations under this collaboration consist of participation on two steering committees. The steering committees are comprised of an equal number of employees from the Company and Genentech. Each member of the steering committees receives the right to cast one vote, but Genentech has the final decision making authority in most matters. The development of Hedgehog antagonist product candidates are generally managed by the Joint Steering Committee, with the development of any product that is being co-developed by Genentech and Curis being managed by a Co-Development Steering Committee. The Joint Steering Committee is required to meet on at least a quarterly basis until the filing of the first investigational new drug application for a hedgehog antagonist product candidate that is managed by the joint steering committee. The Joint Steering Committee is currently managing the development of a systemically administered small molecule Hedgehog antagonist for the treatment of certain solid tumor cancers. After the investigational new drug application has been filed, the Joint Steering Committee will meet as often as it deems necessary. The Co-Development Steering Committee meets as often as it deems necessary.

The Company has 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 4). The Company is deferring the entire \$7,509,000 in total payments and will only recognize this amount as revenue when it can reasonably estimate when its contractual steering committee obligations will cease or after the Company no longer has contractual steering committee obligations under this agreement with Genentech. The contractual term of the Company's steering committee obligations extends for as long as Hedgehog antagonist products subject to this collaboration are being developed or commercialized by either of the parties. Accordingly, the contractual term of the Company's steering committee obligations is indefinite and the Company expects it will not record any revenue related to these payments for at least several years.

In July 2004, the Company received the first maintenance fee payment in the amount of \$2,000,000. The second \$2,000,000 maintenance payment was replaced by a \$2,000,000 payment for research services in December 2004 as part of an amendment to the collaboration in December 2004.

The Company expects that some of the contingent payments that are tied to clinical development and drug approval objectives under this collaboration with Genentech would be substantive milestones provided that the successful achievement of these objectives meets each of the criteria set forth in the Company's revenue recognition policy related to substantive milestones. For example, the Company believes that a cash payment for the filing of an investigational new drug application would be substantive since the requirements of its revenue recognition policy would have been met. Should the company ever successfully achieve any substantive milestones under this collaboration agreement, any related cash payments would be recorded as revenue upon achievement of the objective in "Substantive objectives" in the Revenues section of its Consolidated Statement of Operations.

The Company believes that certain contingent payments tied to later stage clinical development and drug approval objectives under this collaboration may not constitute substantive milestones since the

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Notes to Consolidated Financial Statements—Continued

successful achievement of these objectives will not meet each of the criteria set forth in the Company's revenue recognition policy related to substantive milestones (i.e., the Company does not expect to incur substantive effort in achieving late-stage clinical and drug approval objectives). Accordingly, all such contingent payments would be deferred until the Company can reasonably estimate when its contractual steering committee obligations will cease or after it no longer has contractual steering committee obligations under this agreement with Genentech.

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 and was exercisable only at the Company's option and, therefore, did not impact the initial accounting for this arrangement. As a result of its decision to exercise its right to co-development the basal cell carcinoma product candidate, the Company expects to make significant cash payments to Genentech during the period of clinical development. The Company has recorded \$6,999,000 in co-development payments to Genentech for the year ended December 31, 2005, as contra-revenues at its Consolidated Statement of Operations. The Company will follow the provision of EITF 01-09 and expects to record its future co-development payments first as a reduction of revenue, to the extent of both cumulative revenue recorded to date and of probable future revenues, which includes any unamortized deferred revenue balances, under all arrangements with Genentech (including those described below) and then as an expense.

(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, increases the Company's commitment of full-time equivalents providing research and development services for the systemic Hedgehog antagonist program from eight to sixteen and increases Genentech's funding commitment from \$2,000,000 to \$4,000,000 for this period. The agreement also provides 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, and 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 are to provide research services and xenograft tumor samples to Genentech through June 2005. The Company has applied the provisions of SAB No. 104 and is recognizing the \$2,000,000 in incremental funding as revenues under this collaboration as the incremental research services are performed from December 2004 through June 2005. The amount payable to the Company and, accordingly, the amount of revenue to be recognized will vary if the Company provides less than sixteen full-time equivalents through June 2005. During the years ended

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December 31, 2005 and 2004, the Company recorded \$1,674,000 and \$220,000, respectively, 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 2003. As of December 31, 2005, the Company had no amounts receivable from Genentech under this collaboration in “Accounts receivable” in the Company’s Current Assets section of its Consolidated Balance Sheets.

(c) GENENTECH, INC. APRIL 2005 AGREEMENT

(i) *Agreement Summary*

On April 13, 2005, the Company entered into a second amendment to its June 2003 agreement with Genentech. The effective date of the amendment was April 11, 2005.

Under the terms of the amendment, Genentech will provide to the Company \$2,000,000 of funding to continue development of therapeutics to treat solid tumor cancers, and the research term has been extended until December 11, 2005 (previously June 11, 2005), at which time the \$2,000,000 will be paid. At Genentech’s option, the research term may 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 will now fund ten Curis full-time equivalents through June 11, 2006. Genentech will pay the Company \$1,250,000 in June 2006, provided that Curis has performed the required research services. Other than the change to the period of the research term and payments associated with such research, the amendment has not changed 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 are 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 would extend for an additional period from December 2005 through June 2006. The Company has applied the provisions of SAB No. 104 and is recognizing the research funding as revenues under this collaboration as such research services are performed. The amount payable to the Company and, accordingly, the amount of revenue to be recognized will vary if the Company provides less than the required sixteen full-time equivalents through December 2005 or the ten full-time equivalents through June 2006. During the year ended December 31, 2005, the Company recorded \$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 or 2003. As of December 31, 2005, the Company had recorded \$17,000 as unbilled accounts receivable from Genentech under this agreement in the Company’s Current Assets section of its Consolidated Balance Sheet.

(d) GENENTECH APRIL 2005 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 a signaling pathway

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that plays an important role in cell proliferation. This pathway 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 will have primary responsibility for research and development activities and Genentech will be 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 has agreed to fund up to \$6,000,000 for research and development activities during the initial two-year research term, subject to its termination rights described below. 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 has an option to extend the initial two-year research term for up to two additional years in one-year increments. Genentech will also pay the Company royalties on net product sales if product candidates derived from the collaboration are successfully developed.

Each party has the right to terminate the agreement for uncured material breach by the other party. Genentech has the right to terminate the agreement without cause at any time after the first anniversary of the effective date, upon six months prior written notice, if such termination is to be effective prior to the end of the initial research term, and upon sixty days prior written notice otherwise. In the event of termination by Genentech without cause or if the agreement is terminated by Genentech due to material breach, the Company would be entitled to receive only a reduced royalty for those products that are covered by a subset of certain intellectual property rights, in lieu of the standard contract royalties that would otherwise apply.

(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 ongoing performance obligations under this collaboration consist of participation on a steering committee and the performance of research services. Because the Company believes that it can reasonably estimate its level of effort over the term of the arrangement, the Company is accounting for the arrangement under the relative performance method. In developing its 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 can be no assurance Genentech will, in fact, make such an election. The Company estimates that it will 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 will maintain its initially elected number of twelve full-time equivalent researchers throughout the four-year period. The steering committee effort is 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

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funding which the Company will be entitled to for providing twelve full-time equivalents at \$250,000 each over four years, is therefore being attributed to the research services. Revenue is being recognized as the research services are provided over the four-year period through March 2009 at a rate of \$312,500 per full-time equivalent. If the research period is changed or the number of full-time equivalents requested by Genentech changes, then the Company will update its estimated level of effort and total expected payments under the arrangement.

The Company recorded revenue under this collaboration of \$2,412,000 during the year ended December 31, 2005. Of this amount, approximately \$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 year ended December 31, 2005. The remaining \$1,849,000 was related to research services performed by the Company’s full-time equivalent researchers and is included within “Research and development contracts” within the Revenues section of the Company’s Consolidated Statement of Operations.

The Company expects that some of the contingent payments that are tied to preclinical, clinical development and drug approval objectives under this collaboration with Genentech would be substantive milestones provided that the successful achievement of these objectives meets each of the criteria set forth in the Company’s revenue recognition policy related to substantive milestones. For example, the Company believes that a cash payment for the achievement of a preclinical milestone or Genentech’s filing of an investigational new drug application would be substantive since the requirements of its revenue recognition policy would have been met. Should the company ever successfully achieve any substantive milestones under this collaboration agreement, any related cash payments would be recorded as revenue upon achievement of the objective in “Substantive milestones” in the Revenues section of its Consolidated Statement of Operations.

The Company believes that contingent payments tied to certain later stage clinical development and drug approval objectives under this collaboration may 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 (i.e., the Company does not expect to incur substantive effort in achieving late-stage clinical and drug approval objectives). Accordingly, the Company would recognize such contingent payments as revenue ratably over the remaining performance period at the time such contingent payment is received.

As of December 31, 2005, the Company has 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.

(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 our common stock. Wyeth is also obligated to make cash payments if the licensed programs successfully achieve clinical development and drug approval objectives and to pay the Company a royalty on net product sales, if any should occur, that escalates with increasing sales volume.

As part of the agreement, the Company has retained development and licensing options for certain therapeutic applications of the Hedgehog agonist technologies, including topical applications for hair

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growth and local delivery applications for treatment of cardiovascular disease. Wyeth has a right of first negotiation to obtain an exclusive license to the orphan drug indications and the cardiovascular applications. If Wyeth declines to exercise its right, or if the Company is unable to reach an agreement with Wyeth on terms within the contractually specified period, the Company is free to seek another collaborator for this program.

Unless terminated earlier, the agreement shall expire on the expiration of Wyeth's obligation to pay royalties to the Company under the agreement. Early termination provisions are as follows:

- Either party may terminate the agreement unilaterally, in whole or in relevant part, during the research program in the event of issuance of third party patents that block Wyeth's right to use the licensed technology. If the agreement is terminated under this provision, license rights will revert to the respective parties and no royalties will be due and payable unless products continue to be sold after termination. In such event, Wyeth would continue to pay royalties as defined in the agreement.
- Wyeth may terminate the agreement at any time upon ninety days written notice, for safety reasons, if Wyeth concludes that a major mechanism-based toxicological finding would preclude the development of licensed technology products for use in humans. If the agreement is terminated under this provision, license rights will revert to the respective parties and no royalties will be due and payable unless products continue to be sold after termination. In such event, Wyeth would continue to pay royalties as defined in the agreement.
- Upon sixty days written notice and subject to an additional thirty day period of discussion between the parties, Wyeth may terminate its research funding of Company personnel upon the acquisition of the Company by a third party. Unless the agreement is terminated under another provision, this provision would permit Wyeth to retain the licenses granted provided that it continued to fulfill its non-research funding obligations to the Company, including payment of milestones and royalties on product sales.
- Wyeth may terminate the agreement without cause, for any reason in its entirety or on any compound, product, or country basis upon sixty days written notice, provided that such complete or partial termination cannot occur before February 2006. If a termination occurs under this provision, any terminated license rights would revert to the respective party. If the Company were to subsequently sell products that were subject to these reverted license rights, royalties would be due Wyeth in accordance with the terms of the agreement. In addition, Wyeth would continue to pay royalties to the Company on sales of specified compounds or products that were not terminated as well as on sales of specified terminated compounds or products that Wyeth continued to sell despite such earlier termination.
- Either party may terminate the agreement in the event of uncured material default by the other party. Depending upon the nature of the default, the cure period may be extended from ninety days to as long as one year. Subject to the restrictions described in the agreement, the non-defaulting party may terminate the agreement in its entirety or only with respect to the compound or product that is affected by the default. If the Company elected to terminate the agreement, either partially or in its entirety, the relevant license rights would revert to the Company. In the event the Company subsequently sold terminated compounds or products that were subject to both reverted license rights and certain Wyeth intellectual property rights, the Company would owe Wyeth a royalty for such product sales, in accordance with the terms of the agreement. In the event of partial termination by the Company, Wyeth's obligations with respect to those compounds or products that were not terminated would continue. If Wyeth terminates the agreement, all license rights become fully paid up and perpetual provided that

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Wyeth pays the reduced royalty rate on product sales, as described in the termination provisions of the agreement.

- To the extent permitted by applicable law, either the Company or Wyeth may exercise certain rights upon the occurrence of the other party's bankruptcy, insolvency, dissolution, winding up or assignment of assets for the benefit of creditors. Wyeth may terminate the research program or elect to keep the agreement in effect. The Company may terminate the agreement. If either party terminates the agreement, the licenses granted to Wyeth by the Company under the agreement will terminate and revert to the Company.

In addition, as part of a termination agreement entered into between the Company and Elan Corporation, the Company will pay 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 receives from Wyeth. The Company and Elan had previously collaborated on the development of the Hedgehog agonist technologies currently under development with Wyeth. The Company is also obligated to make payments to various university licensors when certain payments are received from Wyeth. These obligations totaled \$125,000 in payments to university licensors for the up-front license fee.

(ii) Accounting Summary

The Company considers its arrangement with Wyeth to be a revenue arrangement with multiple deliverables, or performance obligations. The Company's performance obligations under this collaboration include an exclusive license to its Hedgehog agonist technologies and performing services, including research and development services for at least two years and participation on a steering committee. The Company applied the provisions of EITF 00-21 to determine whether the performance obligations under this collaboration could be accounted for separately or as a single unit or multiple units of accounting. The Company determined that these performance obligations represented a single unit of accounting, research and steering committee services, since the Company believes that the license does 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 consist of participation on a steering committee and the performance of research services. Because the Company can reasonably estimate its level of effort over the term of the arrangement, the Company is accounting for the arrangement under the relative performance method. In developing its 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 provides for a one-year evaluation period immediately following the end of the research term, during which time the Company may be obligated to serve on the steering committee and may be required, at Wyeth's expense, to perform additional research and development services. The Company estimates that it will 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 will maintain its initially elected number of eight full-time equivalents throughout the five-year period. The steering committee effort is also expected to be consistent over the five-year period. The \$1,362,000 up-front license fee plus \$10,000,000, the total amount of research funding which the Company will be entitled to for providing eight full-time equivalents at \$250,000 each over five years, is therefore being attributed to the research services. Revenue is being recognized as the research services are provided over the five-year period through February 2009 at a rate of \$284,000 per full-time equivalent. If the

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research period is shortened or the number of full-time equivalents requested by Wyeth decreases, then the Company will update its estimated level of effort and total expected payments under the arrangement.

During the years ended December 31, 2005 and 2004, the Company recorded revenue of \$2,849,000 and \$2,498,000, respectively, related to the Company's research efforts under the Wyeth arrangement, of which \$272,000 and \$242,000, respectively, were recorded in "License Fees" and \$2,327,000 and \$2,256,000, 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 \$327,000 and \$476,000 for the years ended December 31, 2005 and 2004, respectively, as revenue related to expenses incurred on behalf of Wyeth that were paid by the Company and for which Wyeth is obligated to reimburse the Company. 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. No revenues were recognized under this collaboration in 2003. As of December 31, 2005, the Company had recorded \$173,000 as amounts receivable from Wyeth in "Accounts receivable" in the Company's Current Assets section of its Consolidated Balance Sheets.

The Company expects that some of the contingent payments that are tied to preclinical, clinical development and drug approval objectives under this collaboration with Wyeth would be substantive milestones provided that the successful achievement of these objectives meets each of the criteria set forth in the Company's revenue recognition policy related to substantive milestones. For example, the Company believes that a cash payment for the achievement of a preclinical objective or Wyeth's filing of an investigational new drug application would be substantive since the requirements of its revenue recognition policy would have been met. Should the company ever successfully achieve any substantive milestones under this collaboration agreement, any related cash payments would be recorded as revenue upon achievement of the objective in "Substantive milestones" in the Revenues section of its Consolidated Statement of Operations.

The Company believes that certain contingent payments tied to later stage clinical development and drug approval objectives under this collaboration may 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 (i.e., the Company does not expect to incur substantive effort in achieving late-stage clinical and drug approval objectives). Accordingly, the Company would recognize such contingent payment as revenue ratably over the remaining performance period at the time such payment is received.

As of December 31, 2005, the Company has not provided any consideration to Wyeth.

(f) 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 will 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 that is the leading genetic cause of infant and toddler death.

The research will utilize the Company's proprietary technologies and expertise to develop and refine assays in motor neurons and then use those assays to screen for potential drug candidates. The

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Company will own any compounds that it generates under this collaboration and will also have the ability to bring any such compounds into the clinic, either using the Company's own resources or with a collaborating third party. If any drug candidates developed under the agreement are successfully commercialized, the Company will be required to make payments to the SMA Foundation if cumulative revenues from the sales of such products exceed \$100,000,000. Unless terminated earlier, the agreement will continue until the expiration of the research activities. The Company or the SMA Foundation may terminate this agreement upon sixty days' prior written notice upon the occurrence of bankruptcy, insolvency, dissolution or winding up of the other party; or upon the breach of any material provision of the sponsored research agreement by the other party, provided that the other party has not cured such breach within the 60-day period following written notice of termination. Termination of the agreement will not relieve either party of obligations that have accrued prior to termination, including the SMA Foundation's obligation to make payments for research activities. In addition, the Company remains obligated to make payments to the SMA Foundation in the event the Company recognizes an aggregate of \$100,000,000 in revenues on products containing any drug candidates developed under the agreement.

(ii) Accounting Summary

The Company's sole deliverable under this sponsored research agreement is to provide research services. The Company has applied the provisions of SAB No. 104 for recognizing revenue under this collaboration. The Company is recognizing revenues under this collaboration as the services are performed, provided that payment is reasonably assured under the terms of the grant. For the years ended December 31, 2005 and 2004, the Company recognized \$1,955,000 and \$551,000, respectively, related to our research and development efforts under this sponsored research agreement. This amount is included in "Research and development contracts" in the Company's Revenues section of its Consolidated Statement of Operations.

Should the Company ever generate over \$100,000,000 in cumulative future revenues from products developed under this agreement, we expect to record any payments to the SMA Foundation as contra-revenues in accordance with EITF 01-9.

As of December 31, 2005, the Company has not provided any consideration to the SMA Foundation.

(g) PROCTER & GAMBLE

(i) Agreement Summary

On September 18, 2005, the Company entered into a collaboration, research and license agreement with The Procter & Gamble Company, or 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 shall jointly undertake a research program with the goal of identifying one or more compounds to be developed and commercialized by Procter & Gamble. Procter & Gamble is solely responsible for the cost of worldwide development and commercialization of any product candidates developed pursuant to the research program. At the time that Procter & Gamble determines to file the first investigational new drug application with the FDA for a product candidate, the Company shall have the option, at its sole discretion, to co-develop a product candidate

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

through Phases I and II of clinical development at a 20% or 50% participation rate. Should the Company elect to exercise its co-development option, the Company will forego contingent cash payments that would otherwise be payable for the achievement of certain development objectives during the period from investigational new drug application filing through the completion of a Phase II clinical trial. The Company, however, would receive a higher royalty in the event that it exercises its co-development option and subsequently shares in development expense through Phase II clinical trials. The amount of the royalty increase is based on the co-development percentage elected by the Company. Under the agreement, Procter & Gamble paid the Company an up-front license fee of \$500,000 and has 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 has an option to extend the initial one-year research term for up to three additional years in one-year increments. Procter & Gamble has also agreed to make cash payments to the Company that are contingent upon the successful achievement of certain research, development, clinical and drug approval milestones, including \$2,800,000 upon the achievement of certain preclinical development objectives. Procter & Gamble will also pay the Company royalties on net product sales if product candidates derived from the collaboration are successfully developed.

Unless terminated earlier in accordance with the terms of the agreement, the agreement shall continue until six months after the expiration of the last to expire of any patent rights covering a product being sold under the agreement. Early termination rights are as follows:

- During the first twelve months, the agreement may not be terminated by either party, except in the case of breach, as discussed below, or failure of all, or all but one, of the licensed compounds to demonstrate acceptable results in certain tests as specified in the agreement and the research plan. In the event of such failure, Procter & Gamble may terminate the agreement and the related research obligations (full-time equivalent reimbursement) without cause, with 45 days prior written notice.
- Following the initial twelve-month period, Procter & Gamble shall have the right to terminate the agreement without cause upon at least six months prior written notice.
- Upon or after the uncured breach of any material provision of the agreement by a party, the other party may terminate the agreement immediately upon written notice to the defaulting party.

If Procter & Gamble terminates the agreement without cause or the Company terminates the agreement as a result of Procter & Gamble's material breach, then, among other things, all licenses granted to Procter & Gamble shall terminate. The Company shall have the exclusive option to acquire from Procter & Gamble all data generated by Procter & Gamble and all regulatory approvals and other regulatory filings and submissions, clinical data, promotional, advertising, marketing and distribution rights or contracts, and other similar information and items related to the compounds developed during the collaboration by Procter & Gamble, on commercially reasonable terms to be mutually agreed to by the parties. Upon termination of the agreement by Procter & Gamble as a result of a material breach by the Company, all rights and licenses granted to Procter & Gamble under the agreement shall terminate.

(ii) Accounting Summary

The Company considers its arrangement with Procter & Gamble to be a revenue arrangement with multiple deliverables. The Company's deliverables under this collaboration include 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 for at least one year and participation on at least one steering committee. The Company does not consider its co-development option to be a deliverable. The Company applied the provisions of Emerging Issues Task Force Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* (EITF 00-21) to

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

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 performance obligations represented a single unit of accounting, since the Company believes that the license does 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.

The Company's ongoing performance obligations under this collaboration consist of participation on a steering committee and the performance of preclinical research services. The Company cannot reasonably estimate the total level of effort required over the performance period and, therefore, is recognizing revenue on a straight-line basis over the performance period, which it has estimated to be six years. In developing its estimate of the period to complete its performance obligations, the Company estimates the time required to complete Phase II clinical trials of a product candidate under the collaboration to be six years. The performance period was determined based on management's estimate of its involvement through co-development of Phase II clinical trials since, should Curis exercise its co-development option, Curis' last deliverable under this arrangement would be its participation on the clinical development steering committee through Phase II clinical trials. The steering committee effort is also expected to be consistent over the six-year period.

The Company has attributed the \$500,000 up-front fee plus \$600,000, the total amount of currently committed research funding which the Company expects to receive for providing two full-time equivalents at \$300,000 each over the first year of the collaboration, to the undelivered research and steering committee services. The \$1,100,000 in total payments is being recognized as revenue over the Company's performance period of six years under the collaboration. If the research period, number of full-time equivalents requested by Procter & Gamble, or the estimate to complete Phase II clinical trials changes, then the Company will update its estimated level of effort and total expected payments under the arrangement. During the year ended December 31, 2005, the Company recorded revenue of \$289,000. Of this amount, \$24,000 was attributed to the amortization of the up-front license fee and is included in the "License fees" line item within the Revenues section of the Company's Consolidated Statement of Operations for the year ended December 31, 2005. Of the remaining \$265,000, \$28,000 was related to research services performed by the Company's two full-time equivalents and the remaining \$237,000 was 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, 2005, the Company had recorded \$237,000 as amounts receivable from Procter & Gamble in "Accounts receivable" in the Company's Current Assets section of its Consolidated Balance Sheets.

The Company expects that some of the contingent cash payments that are tied to preclinical, clinical development and drug approval objectives under this collaboration with Procter & Gamble would be substantive milestones provided that the successful achievement of these objectives meets each of the criteria set forth in the Company's revenue recognition policy related to substantive milestones. For example, the Company believes that a milestone payment for the achievement of a preclinical development objective or Procter & Gamble's filing of an investigational new drug application would be substantive since the requirements of its revenue recognition policy would have been met. Should the company ever successfully achieve any substantive milestones under this collaboration agreement, any related cash payments would be recorded as revenue upon achievement of the milestone in "Substantive milestones" in the Revenues section of its Consolidated Statement of Operations.

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

The Company believes that certain contingent payments tied to later stage clinical development and drug approval objectives under this collaboration may 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 (i.e., the Company does not expect to incur substantive effort in achieving late-stage clinical and drug approval objectives). Accordingly, the Company would recognize such contingent payment as revenue ratably over the remaining performance period at the time such payment is received.

As of December 31, 2005, the Company has not provided any consideration, such as payments under co-development arrangements, to Procter & Gamble.

(h) ORTHO BIOTECH PRODUCTS, L.P.

(i) *Agreement Summary*

In November 2002, the Company licensed its broad bone morphogenetic protein, or BMP, technology portfolio to Ortho Biotech Products, L.P., a member of the Johnson & Johnson family of companies. Two of Ortho Biotech Products' research affiliates, Johnson & Johnson Pharmaceutical Research & Development, L.L.C. and Centocor Research & Development, also members of the Johnson & Johnson family of companies, will have joint responsibility for further research and development of the Company's licensed BMP technology portfolio.

The transaction relates 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. Use of the Company's BMPs for the repair or regeneration of local musculoskeletal tissue defects and dental defects is the subject of an exclusive agreement with Stryker and is not included as part of this transaction.

The agreement provides for Ortho Biotech to pay the Company an up-front payment of \$3,500,000, which was paid in December 2002, and contingent cash payments at various intervals during the U.S. and European regulatory approval process assuming the first two therapeutic indications are successfully developed. These contingent cash payments include a \$30,000,000 payment if Ortho Biotech achieves U.S. regulatory approval of a product for the treatment of kidney disease or associated complications. The agreement further specifies that the Company will receive a royalty on net sales of products that incorporate the Company's BMP technologies.

Unless terminated earlier, the agreement shall remain in effect until the expiration of Ortho Biotech's obligation to pay royalties to the Company under the agreement. Early termination provisions are as follows:

- Ortho Biotech Products may terminate the agreement, for any reason, upon ninety days written notice to the Company.
- Either the Company or Ortho Biotech Products may terminate the agreement immediately for cause upon the occurrence of bankruptcy, insolvency, or if the other party assigns substantially all of its assets for the benefit of creditors.
- Either the Company or Ortho Biotech may terminate the agreement upon ninety days' prior written notice if the other party has materially breached or defaulted on any material obligations under the contract, provided that the other party has not cured such breach within the ninety-day period following written notice of termination.
- Ortho Biotech may terminate the agreement upon thirty days written notice if the Company breaches its representation to Ortho Biotech that certain of the Company's other license

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

agreements do not contain restrictions which would restrict Ortho Biotech from exercising its license rights under the agreement.

If Ortho Biotech terminates the agreement for cause, the licenses granted by the Company to Ortho Biotech shall survive such termination and the royalty rates owed to the Company would be reduced. If the Company terminates the agreement for cause or if Ortho Biotech terminates upon thirty days written notice without cause, the licenses granted by the Company to Ortho Biotech shall terminate.

(ii) Accounting Summary

The Company has no future deliverables under the license agreement and has 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 the fourth quarter of 2002 because the Company has no continuing performance obligations under the contract.

The Company does not view the contingent payments that are tied to clinical development and drug approval objectives under its collaboration with Ortho Biotech to be 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 (i.e., the Company does not expect to incur substantive effort in achieving these objectives). The Company has no future deliverables under the license agreement, and, therefore the Company 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. The Company has not recognized any revenues under its arrangement with Ortho Biotech for the years ended December 31, 2005, 2004, or 2003.

As of December 31, 2005, the Company has not provided any consideration to Ortho Biotech Products.

(i) CENTOCOR

(i) Agreement Summary

Effective December 7, 2005, the Company entered into a Screening and Option Agreement with Centocor under which the Company will screen its small molecule libraries for BMP-7 agonists and perform subsequent validation of any assay hits. The purpose of the research is to identify compounds that are BMP-7 agonists. The screening effort will occur at the Company using its personnel and technology. Except for the Centocor license to use BMP-7 protein technology, which will be used in assay development, all the technology that will be used in the development effort is novel Curis technology that has not been licensed to Centocor or other third parties. Under the SOA, Centocor will pay the Company \$500,000 up-front to fund the research efforts performed by the Company.

The agreement permits the Company to identify potential BMP-7 small molecule agonists. No licenses to potential small molecule agonists are provided by the Company to Centocor under the terms of the agreement. Rather, the Company has granted Centocor an exclusive option to negotiate a separate, subsequent collaboration and license agreement with Curis for the development and commercialization of such BMP-7 small molecule agonists. Should Centocor exercise its option, the Company and Centocor will have three months to separately negotiate and sign a collaboration agreement. If the parties are unable to sign an agreement within three months, then the Company shall have the right to negotiate with other third parties.

(ii) Accounting Summary

The Company considers this agreement to be a revenue arrangement with multiple deliverables. The Company's deliverables under this collaboration include research and development services for a

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

maximum of fifteen months as well as participation on a joint steering committee. The Company does not consider Centocor's option to negotiate a separate, subsequent collaboration and license agreement as a deliverable. The Company applied the provisions of EITF 00-21 to determine whether the deliverables under this collaboration can be accounted for separately or can be accounted for as a single unit of accounting. The Company determined that these deliverables, the research and steering committee services, represented a single unit of accounting because objective and reliable evidence of the fair value of the Company's research and steering committee services could not be determined.

The Company determined that the performance period is fifteen months based on management's estimate that the agreement would continue to its full term of fifteen months. Should the agreement terminate prior to March 2007, no amount would be refundable to Centocor, and the Company would recognize any remaining deferred revenue. Curis' two deliverables under the agreement, its steering committee service and its research and development services, both expire at the end of the term of the agreement, after which the Company has no remaining deliverables.

Under the agreement, revenue is generated solely from the research and development services. The Company has attributed the \$500,000 of committed research funding for two full-time equivalents at \$250,000 each, to the undelivered research and steering committee services. The \$500,000 is being recognized as revenue over the Company's performance period of fifteen months under the collaboration. The Company cannot reasonably estimate the total level of effort required over the performance period (or the allocation between steering committee and research services) and, therefore, is recognizing the \$500,000 on a straight-line basis over the performance period. For the year ended December 31, 2005, the Company recorded revenue of \$27,000 related to the Company's research efforts under the Centocor arrangement, which was recorded in "Research and development contracts" in the Company's Revenues section of its Consolidated Statement of Operations. As of December 31, 2005, the Company had recorded \$500,000 as amounts receivable from Centocor in "Accounts receivable" in the Company's Current Assets section of its Consolidated Balance Sheets.

As of December 31, 2005, the Company has not provided any consideration to Centocor.

(6) FORMER COLLABORATIONS

(a) 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, including disease targets such as Parkinson's Disease and diabetic neuropathy. 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 no longer a subsidiary of the Company as of December 31, 2004.

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 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

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

interest rate was reduced from 8% to 6% and the conversion rate was increased to \$10.00 from \$8.63. On January 7, 2005, Elan Pharma International Limited, or EPIL, elected to convert the entire balance of its outstanding convertible note into shares of the Company's common stock. As of January 7, 2005, the outstanding balance of the EPIL note, including interest, was \$3,305,523. 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.

In July 2001, the Company issued to Elan shares of its Series A convertible/exchangeable preferred stock valued at \$12,015,000 to fund the Company's pro rata share of the initial capitalization of Curis Newco. The Company recorded a charge to accumulated deficit of \$271,000 for the year ended December 31, 2003, for the accretion of a mandatory 6% dividend on the preferred stock. Such amounts are included in the net loss applicable to common stockholders for the year ended December 31, 2003. The preferred stock, which had a carrying value of \$13,336,000, was cancelled on the May 16, 2003 termination date. As partial consideration for the rights and benefits described in the termination agreement, including the cancellation of the preferred stock, the Company issued 2,878,782 shares of its common stock to Elan, having a fair value of \$8,377,000 based on the May 16, 2003 closing price of the Company's common stock on the Nasdaq National Market. Upon the termination of the Elan agreement, the Company recorded a credit to additional paid-in-capital of \$13,736,000 to reflect the cancellation of the Preferred Stock and the forgiveness of debt in exchange for the issuance of the Company's common stock.

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, both in its own right and as sole shareholder of Curis Newco. 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.

(b) 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 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.

The Company was recognizing revenue under these contracts as services were performed under the product development agreement. The Company recognized approximately \$183,000 in revenue over the course of its relationship with Micromet through July 31, 2003. In addition, the Company recognized approximately \$1,708,000 in interest income and foreign currency gains for the year ended December 31, 2003.

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

Effective July 31, 2003, the Company and Micromet entered into agreements to terminate the target research and license agreement and the product development agreement. As a result of the termination of these agreements, the Company will no longer perform any services under its arrangement with Micromet. Accordingly, the Company immediately recognized as revenue \$8,555,000 of previously deferred revenue related to its agreements with Micromet.

As of the July 31, 2003 termination date, the Company had continued to defer \$3,407,000 in revenues related to the long-term note receivable from Micromet and had intended to recognize this as revenue when amounts become reasonably assured of collection. During the year ended December 31, 2003, the Company recorded, in other expense, charges of \$1,708,000 related to the write-off of previously recorded interest income and foreign exchange gains on a euro-denominated note receivable that was originally due in June 2005 from Micromet, a former collaborator to whom the Company had licensed technology, and \$286,000 related to a reduction in the carrying value of Micromet equity securities that the Company holds. The Company determined that this charge was necessary due to Micromet's announcement that it was terminating one-third of its workforce as the result of a contract dispute with a collaborator. Micromet had stated that this dispute would result in a significant decrease in previously budgeted cash inflows in 2004. The Company also wrote-off the note receivable and reduced deferred revenue by \$3,407,000 because it concluded that it was not reasonably assured of collection the note.

On October 21, 2004, the Company amended its note receivable with Micromet, and, under the amended note, Micromet is 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 November 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. The future amounts due to the Company under the amended note are not considered reasonably assured of collection at December 31, 2005 and, therefore, have not been recorded as revenue. The Company will record revenue when, and if, it concludes such amounts are reasonably assured of collection.

(c) ES CELL INTERNATIONAL, PTE, LTD.

On December 17, 2002, the Company assigned and licensed its patent rights related to the development of cellular therapeutics for the treatment of diabetes to ES Cell International pte, Ltd. in exchange for an up-front fee and an equity position in ES Cell International. As of December 17, 2002, ES Cell International has assumed all responsibility for future development of the Company's diabetes stem-cell technologies, including the funding of six of the Company's scientists through December 17, 2003 at a rate of \$250,000 per scientist per year. For the year ended December 31, 2003, the Company recognized \$1,470,000 in revenue related to its contract research performed by these six scientists. Because the funding portion of this program ended on December 17, 2003, the Company will not recognize future revenues under this collaboration.

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

Since the Company had a performance obligation to employ six scientists through December 17, 2003, as part of this transaction, the Company recognized as revenue the up-front cash payment and the value of the equity received over the one-year term of its obligation.

The Company maintains an equity position in ES Cell International. As of December 31, 2005 and 2004, the Company has recorded this investment at a carrying value of \$150,000, included within the “Deposits and other assets” section of its Consolidated Balance Sheets.

(7) PROPERTY AND EQUIPMENT

Property and equipment consist of the following:

	December 31,	
	2005	2004
Laboratory equipment and computers	\$ 7,337,000	\$ 7,076,000
Laboratory equipment and computers under notes payable	2,077,000	948,000
Leasehold improvements	5,037,000	5,046,000
Leasehold improvements under notes payable	1,682,000	189,000
Office furniture and equipment	938,000	942,000
	17,071,000	14,201,000
Less—Accumulated depreciation and amortization	(11,723,000)	(10,784,000)
Total	\$ 5,348,000	\$ 3,417,000

The Company recorded depreciation and amortization expense of \$940,000, \$1,001,000, and \$1,426,000 for the years ended December 31, 2005, 2004 and 2003, respectively. In 2005, the Company capitalized \$59,000 in interest costs incurred in financing leasehold improvements.

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.

(8) ACCRUED LIABILITIES

Accrued liabilities consist of the following:

	December 31,	
	2005	2004
Collaboration and clinical costs	\$ 35,000	\$ 162,000
Accrued co-development expenses	1,301,000	—
Professional fees	262,000	114,000
Accrued compensation	626,000	336,000
Facility-related costs	445,000	—
Other	228,000	467,000
Total	\$2,897,000	\$1,079,000

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

(9) LONG-TERM DEBT OBLIGATIONS

Long-term debt consists of the following at December 31, 2005 and 2004:

	December 31,	
	2005	2004
Notes payable to financing agencies for capital purchases, including \$27,000 and \$4,000 of accrued interest at December 31, 2005 and 2004, respectively	\$ 3,227,000	\$ 1,141,000
Convertible promissory note agreement with Elan Pharma International, Limited including \$298,000 of accrued interest at December 31, 2004	—	3,298,000
Convertible subordinated note payable to Becton Dickinson, net of \$27,000 and \$80,000 discount and including \$632,000 and \$492,000 of accrued interest at December 31, 2005 and 2004, respectively	2,605,000	2,412,000
	5,832,000	6,851,000
Less—current portion	(3,865,000)	(1,141,000)
Total long-term debt obligations	\$ 1,967,000	\$ 5,710,000

Effective June 9, 2005, the Company entered into a loan agreement with the Boston Private Bank & Trust Company to finance up to \$1,450,000 in purchases of equipment and facility leasehold improvements. Under the terms of the loan agreement, the Company could request periodic financings for qualifying purchases of equipment and leasehold improvements during the period from June 9, 2005 until December 9, 2005. Until December 9, 2005, the Company paid interest only on any borrowings on a monthly basis in arrears. On December 9, 2005, the Company drew down the remaining balance under this agreement bringing the total amount financed to \$1,450,000 and exercised its option to convert the outstanding balance 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 extending through the 36-month term. The loan is collateralized by any equipment and leasehold improvements financed thereunder. As of December 31, 2005, the Company was in compliance with the sole covenant under this agreement. This 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 this agreement, the entire obligation becomes immediately due at the option of the Boston Private Bank & Trust Company.

On March 23, 2005, the Company drew down the remaining balance under an amended loan agreement with the Boston Private Bank & Trust Company, bringing the total amount financed to \$2,250,000 and exercised its option to convert the outstanding balance into a 36-month term note that bears interest at a fixed rate of 7.36% for the repayment period. These funds were used for qualifying purchases of equipment and facility leasehold improvements. 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 extending through the 36-month term. The loan is collateralized by all property, plant and equipment assets, except for fixtures and those that are purchased after March 23, 2005 under purchase money arrangements with equipment lenders. As of December 31, 2005, the Company was in compliance with the sole covenant under this agreement. This 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 this agreement, the entire obligation becomes immediately due at the option of the Boston Private Bank & Trust Company.

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Notes to Consolidated Financial Statements—Continued

On July 18, 2001, the Company entered into a convertible promissory note agreement with Elan Pharma International Limited, or EPIL, an affiliate of Elan Corporation in the amount of \$8,010,000. This note agreement was amended as part of the termination of the Company's collaboration with Elan Corporation on May 16, 2003 as described in Note 6(a). At the May 16, 2003 termination date, there was \$4,900,000 outstanding under the note agreement. As part of the termination, 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. Under the terms of the amended and restated note agreement the default maturity was July 18, 2007. However, EPIL had the option to convert all or any portion of the outstanding principal amount into the Company's common stock at any time until July 18, 2007. In addition, the interest rate was reduced from 8% at the original note agreement to 6% at the amended and restated note agreement and the conversion rate was increased to \$10.00 from \$8.63. On January 7, 2005, Elan Pharma International Limited, or EPIL, elected to convert the entire balance of its outstanding convertible note into shares of the Company's common stock. As of January 7, 2005, the outstanding balance of the EPIL note, including interest, was \$3,305,523. 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.

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 is repayable, at the option of the Company, in either cash or issuance of the Company's common stock at any time up to its maturity date of June 26, 2006. The note bears interest at 7%, which was below the fair market interest rate on the date of issue. The Company estimated the fair market interest rate to be 11%. The difference between the fair market interest rate of 11% and the coupon interest rate of 7% is being amortized as interest expense over the term of the note payable. As of December 31, 2005, \$2,632,000, including \$632,000 of accrued interest, was outstanding under the note payable. 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 conversion price of \$3.94 per share. The Company has no further obligations under this convertible note payable.

Maturities of short- and long-term debt are as follows:

<u>Year Ending December 31,</u>	
2006	\$4,139,000
2007	1,342,000
2008	758,000
Thereafter	<u>—</u>
Total minimum payments	6,239,000
Less—Amount representing interest	<u>(407,000)</u>
Principal obligation, including accrued interest as of December 31, 2005	<u>\$5,832,000</u>

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

(10) 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:

<u>Year Ending December 31,</u>	
2006	\$1,323,000
2007	1,105,000
2008	948,000
2009	948,000
2010	948,000
Thereafter	—
Total minimum payments	<u>\$5,272,000</u>

Rent expense for all operating leases was \$871,000, \$588,000 and \$339,000 for the years ended December 31, 2005, 2004 and 2003, respectively, net of facility sublease income of \$412,000, \$563,000 and \$583,000 in 2005, 2004 and 2003, respectively.

Effective August 15, 2002, the Company sublet 11,980 square feet, or 67%, of the rentable square footage of its facility at 61 Moulton Street, Cambridge, MA. The original subtenant's lease had a contracted rate of \$40.00 per square foot through the end of the Company's lease term of April 30, 2007. In addition to the sublease payments, the subtenant is required to pay its pro rata share of all building operating costs. The sublease income exceeded the Company's cost of the sublet space so the Company did not record a loss on the lease at the time the Company ceased using the space. The Company has continued to use a portion of the remaining 33% of the leased space.

In July 2005, the subtenant notified the Company that it expected that it would no longer be able to meet its obligations under the sublease. Effective August 1, 2005, the Company amended its sublease agreement to lower the monthly sublease rent payments to an amount equal to the rate the Company must pay through the remainder of the lease term of April 30, 2007. No other terms of the sublease agreement were changed. Should the tenant fail to comply with the lease as amended, the Company will seek to sublease the 61 Moulton Street facility to a new subtenant but is uncertain that its efforts will be successful. Further, the Company expects that, should it be successful in its subleasing efforts, the sublease rent may be lower than the Company's cost to lease the space, based on an analysis of rental rates for similar space in the area.

The Company does not expect to utilize the space, if vacated by the current tenant due to default of the amended sublease terms, for its current or future operations. In addition, the Company believes that its costs under the lease will exceed the estimated future sublease income for the duration of the lease. Based on these factors and the expected decline in sublease income, the Company recorded a charge of \$500,000 in the "General and administrative expense" line item of its Consolidated Statement of Operations during the second quarter of 2005. There has been no change in the Company's estimate of the \$500,000 liability, of which \$400,000 and \$100,000 are included as current and long-term liabilities, respectively, in the Company's balance sheet as of December 31, 2005.

During the twelve months ending December 31, 2005, 2004 and 2003, the Company received sublease payments of \$412,000, \$410,000 and \$370,000, respectively. The Company's lease obligation for its 61 Moulton Street facility ends on April 30, 2007 and the future minimum rentals due from the subtenant total \$317,000 and \$106,000 for 2006 and 2007, respectively.

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

Effective March 1, 2002 and ending on September 15, 2004, the Company sublet approximately 5,000, or 15%, of the rentable square footage of its facility at 45 Moulton Street, Cambridge, MA, at a rate of \$37.00 per square foot. The Company's cost of the sublet space is \$8.85 per square foot. During the twelve months ending December 31, 2004 and 2003, the Company received sublease payments of \$153,000 and \$213,000, respectively. In addition to the sublease payments, the subtenant was required to pay its pro rata share (approximately 15%) of all building operating costs. The Company is now using this space and its lease obligation ends on December 30, 2010.

(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 expenses royalty payments as related product sales 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 \$190,000, \$602,000 and \$1,650,000 for the years ended December 31, 2005, 2004 and 2003, respectively. During the years ending December 31, 2004 and 2003, the Company incurred \$106,000 and \$74,000, respectively, in expenses associated with development milestone payments or royalties on licensed technology. The Company did not incur any such expenses for the year ended December 31, 2005.

During the year ended December 31, 2003, the Company amended its license agreements with Harvard University and Johns Hopkins University. These contracts were amended to reduce future royalties and milestone payments payable on future revenues generated by the Company on the licensed technology, including revenues derived from the Company's corporate collaborators. During the year ended December 31, 2003, the Company recorded \$1,007,000 in non-cash expense associated with the issuance of an aggregate of 200,000 shares of common stock pursuant to the terms of these amended license agreements. The fair value of the common stock issued was charged to research and development expense because the technology covered under the amended license agreement was in preclinical development and is not currently commercializable. The terms of the amended license agreements also state that the Company is obligated to issue up to an aggregate of 200,000 additional shares of common stock if there is a change of control in the Company (i.e., acquisition) or if any product candidate covered under these amended license agreements should advance into Phase III clinical trials. The Company has not recorded any expense associated with the potential future issuance of its common stock since such issuance is contingent upon future events.

(11) NOTES RECEIVABLE—FORMER OFFICERS OF PREDECESSOR COMPANY

On February 8, 2000, Creative BioMolecules loaned to two executive officers an aggregate of \$1,131,000, which was equal to the aggregate exercise price of incentive stock options exercised by them on the same date. The officers immediately used these funds to pay Creative the exercise price of such incentive stock options. Neither of these executive officers became officers or employees of the Company after the merger of Creative into Curis on July 31, 2000. The underlying notes were full recourse loans

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

that each bore interest at an annual rate of 7.0%. All principal and interest was due and payable on the earlier of May 8, 2002, or 30 days following the sale of the stock purchased with these funds.

The total principal and accrued interest of the notes was \$1,338,000 as of December 31, 2003. The notes were included as “Notes receivable” in the Company’s Stockholders’ Equity section of its Consolidated Balance Sheet and were presented net of a reserve for the estimated uncollectible portion of the notes. The reserve on the notes was \$1,229,000 as of December 31, 2003. The reserve was recorded as a charge to general and administrative expenses.

On October 22, 2004, the Company entered into settlement agreements regarding the notes receivables with these former executive officers of Creative. Under the terms of the settlement agreement, the notes were cancelled, the underlying 139,707 common shares were sold in November 2004, and the resulting proceeds were remitted to the Company. The proceeds of the transaction, net of all brokerage commissions, totaled \$558,000. In the fourth quarter of 2004, the Company recorded the net proceeds, less the current book value of the notes of \$110,000, as a credit of \$448,000 in “General and administrative expenses” of its Consolidated Statement of Operations and Comprehensive Loss.

(12) SERIES A PREFERRED STOCK

On July 18, 2001, the Company issued to Elan shares of its Series A convertible/exchangeable preferred stock valued at \$12,015,000 to fund the Company’s pro rata share of the initial capitalization of Curis Newco. The Company recorded charges to accumulated deficit for the accretion of a mandatory 6% dividend on the preferred stock of \$271,000 for the year ended December 31, 2003. Such amounts are included in the net loss applicable to common stockholders for the years ended December 31, 2003.

As part of a termination agreement entered into between the Company and Elan (see Note 5(a)), the preferred stock, which had a carrying value of \$13,336,000, was cancelled on May 16, 2003. Accordingly, no accretion was recorded for the years ended December 31, 2005 and 2004.

(13) WARRANTS

The Company has a total of 1,680,976 warrants to purchase its common stock outstanding as of December 31, 2005. These warrants are summarized as follows:

- (a) 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, 2005, none of these warrants have been exercised.
- (b) 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, 2005, none of these warrants have been exercised.
- (c) On July 18, 2001, and in connection with its common stock issuance to an affiliate of Elan Corporation, the Company issued a warrant to purchase up to 50,000 shares of the Company’s common stock at \$10.46 per share. The warrant expires on July 18, 2006. As of December 31, 2005, the warrant has not been exercised.
- (d) At December 31, 2005, other warrants to purchase 6,410 shares of common stock with prices ranging from \$9.76 to \$19.51 per share are outstanding. These warrants expire at various dates, ranging from October 2007 until December 2009.

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

(14) STOCK PLANS

(a) **OPTION PLANS**

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 stock options as well as the issuance of restricted shares. On the first day of January each year beginning on January 1, 2001 continuing through January 1, 2010, the number of shares of common stock reserved for issuance under the 2000 Plan is automatically increased by the lesser of 1,000,000 shares or 4% of outstanding stock on January 1 of each year. As of December 31, 2005, the number of shares of common stock subject to issuance under the 2000 Plan is 15,000,000. At December 31, 2005, 3,230,079 shares are available for grant under the 2000 Plan.

The 2000 Plan permits the granting of incentive and nonqualified 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.

In March 2000, the 2000 Director Stock Option Plan (the 2000 Director Plan) was adopted by the Board of Directors and in June 2000, was approved by the stockholders. The 2000 Director Plan provides for the granting of options to non-employee directors. As of December 31, 2005, the number of shares of common stock subject to issuance under the 2000 Director Plan is 500,000. As of December 31, 2005, 140,000 shares are available for grant under the 2000 Director Plan.

Activity under both the 2000 Plan and 2000 Director Plan is summarized as follows:

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price per Share</u>
Outstanding, December 31, 2002 (4,220,759 exercisable at weighted average price of \$5.38 per share)	8,704,892	8.30
Granted	3,351,445	2.65
Exercised	(797,119)	1.73
Cancelled	<u>(2,141,969)</u>	4.06
Outstanding, December 31, 2003 (4,186,437 exercisable at weighted average price of \$5.37 per share)	<u>9,117,249</u>	<u>4.01</u>
Granted	1,362,600	4.54
Exercised	(1,091,227)	1.76
Cancelled	<u>(392,457)</u>	3.46
Outstanding, December 31, 2004 (5,018,605 exercisable at weighted average price of \$5.45 per share)	<u>8,996,165</u>	<u>4.39</u>
Granted	1,153,000	3.99
Exercised	(416,443)	1.88
Cancelled	<u>(391,953)</u>	6.82
Outstanding, December 31, 2005 (6,071,189 exercisable at weighted average price of \$4.90 per share)	<u><u>9,340,769</u></u>	<u><u>\$4.35</u></u>

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

The table below summarizes options outstanding and exercisable at December 31, 2005:

<u>Exercise Price Range</u>	<u>Options Outstanding</u>			<u>Options Exercisable</u>	
	<u>Number of Shares</u>	<u>Weighted Average Remaining Contractual Life (in years)</u>	<u>Weighted Average Exercise Price per Share</u>	<u>Number of Shares</u>	<u>Weighted Average Exercise Price per Share</u>
\$ 0.56 - \$ 1.32	595,026	6.56	\$ 1.03	460,362	\$ 1.04
1.50 - 1.95	1,268,875	5.92	1.52	838,249	1.54
2.12 - 3.95	3,625,905	6.50	2.97	2,712,866	3.08
4.03 - 7.30	2,862,857	8.17	4.44	1,071,606	4.71
10.00 - 17.94	909,543	4.57	13.59	909,543	13.59
20.00 - 31.15	78,563	1.51	28.60	78,563	28.60
	<u>9,340,769</u>	<u>6.71</u>	<u>\$ 4.35</u>	<u>6,071,189</u>	<u>\$ 4.90</u>

(b) 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 ESPP period, as defined. During the years ended December 31, 2005, 2004 and 2003, 62,230, 43,112, and 50,717 shares, respectively, were issued under the ESPP. As of December 31, 2005, 732,057 shares are available for future purchase under the ESPP.

(c) STOCK-BASED COMPENSATION

The Company accounts for its stock-based awards using the intrinsic value method in accordance with APB Opinion No. 25 and its related interpretations. Accordingly, no compensation expense has been recognized in the consolidated financial statements at the date of grant for employee stock option arrangements for which the exercise price is equal to the fair market value of the underlying shares at that date.

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

In connection with stock options granted to employees and non-employees during the year ended December 31, 2000, the Company recorded deferred compensation of approximately \$17,330,000, which represents the aggregate difference between the option exercise price and the fair market value of the common stock on the grant date. The deferred compensation was being recognized as an expense on a straight-line basis over the vesting period, generally four years, of the underlying stock options for options granted to employees and as earned for non-employees in accordance with EITF 96-18. The options granted to non-employees were valued based upon the fair value of the options granted. These options became fully vested during the year ended December 31, 2004 and, therefore, no compensation expense was recorded for the year ended December 31, 2005 related to these options. The Company recorded compensation expense related to these options for the years ended December 31, 2004 and 2003, per the following table:

	For the Year ended December 31,	
	2004	2003
Employees	\$599,000	\$1,076,000
Non-employees	—	24,000
Total	\$599,000	\$1,100,000

During the years ended December 31, 2004 and 2003, the Company reversed \$41,000 and \$152,000, respectively, of unamortized deferred compensation related to options which were forfeited by terminated employees. The deferred compensation balance at December 31, 2005, relating to stock options held by existing employees was \$5,000.

For the years ended December 31, 2005, 2004 and 2003, the Company recorded stock-based compensation expense to the following line items in its Costs and Expenses section of the Consolidated Statements of Operations and Comprehensive Loss:

	For the Year ended December 31,		
	2005	2004	2003
Research and development expenses	\$214,000	\$1,175,000	\$1,267,000
General and administrative expenses	7,000	197,000	364,000
Total stock-based compensation expense	\$221,000	\$1,372,000	\$1,631,000

During the year ended December 31, 2005, the Company granted stock options to a non-employee for services. These options were issued at their fair market value on the date of grant and have various vesting dates up to 3.5 years from date of grant.

(15) INCOME TAXES

For the years ended December 31, 2005, 2004 and 2003, the Company did not record any federal or state tax expense given its continued net operating loss position.

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

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

	For the Year Ended December 31,	
	2005	2004
	(As restated)	
Statutory federal income tax rate	34.0%	34.0%
State income taxes, net of federal benefit	4.5%	8.6%
Research and development tax credits	4.1%	3.4%
Deferred compensation	(0.5%)	(3.1%)
NOL expirations	(11.5%)	(6.0%)
Other	4.9%	(1.4%)
Net increase in valuation allowance	<u>(35.5%)</u>	<u>(35.5%)</u>
Effective income tax rate	<u>—%</u>	<u>—%</u>

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, 2005 and 2004, respectively are as follows:

	December 31,	
	2005	2004
	(As restated)	
Deferred Tax Assets:		
Net operating loss carryforwards	\$ 70,022,000	\$ 66,491,000
Research and development tax credit carryforwards	8,940,000	8,528,000
Depreciation and amortization	2,565,000	1,794,000
Capitalized research and development expenditures	23,032,000	21,544,000
Deferred revenue	4,711,000	5,637,000
Impairment of investments	482,000	1,086,000
Accrued expenses and other	365,000	106,000
Total Gross Deferred Tax Asset	<u>110,117,000</u>	<u>105,186,000</u>
Valuation Allowance	<u>(110,117,000)</u>	<u>(105,186,000)</u>
Net Deferred Tax Asset	<u>\$ —</u>	<u>\$ —</u>

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

	December 31,	
	2005	2004
	(As restated)	
Deferred Tax Assets:		
Current deferred tax assets	\$ 416,000	\$ 89,000
Non-current deferred tax assets	109,701,000	105,097,000
Valuation Allowance	<u>(110,117,000)</u>	<u>(105,186,000)</u>
Net Deferred Tax Asset	<u>\$ —</u>	<u>\$ —</u>

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

As required by Statement of Financial Accounting Standards No. 109, management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are comprised principally of net operating losses, capitalized research and development expenditures and research and development credits. Management has determined that it is more likely than not that the Company will not recognize the benefits of federal and state deferred tax assets and, as a result, a valuation allowance of approximately \$110,117,000 has been established at December 31, 2005.

As of December 31, 2005, the Company had federal and state net operating loss carryforwards of approximately \$198,030,000 and \$42,930,000, respectively, and federal and state research and development credit carryforwards of approximately \$7,576,000 and \$2,036,000, respectively, which may be available to offset future federal and state income tax liabilities which expire at various dates starting in 2006 and going through 2025. The future realization, if any amount, of deferred tax asset attributable to disqualifying dispositions of incentive stock options and the exercise of nonqualified stock options will not be recognized as a tax benefit in the statement of operations, but rather as a component of stockholder's equity.

Previous ownership changes, as defined in the Internal Revenue Code, may have limited the amount of net operating loss carryforwards and research and development credits that can be utilized annually to offset future taxable income. Subsequent ownership changes could further affect the limitation in future years.

The American Jobs Creation Act of 2004 (the "Act") was signed into law on October 22, 2004. The Act contains numerous amendments and additions to the U.S. corporate income tax rules. None of these changes, either individually or in the aggregate, is expected to have a significant effect on the Company's income tax liability.

The Company is involved in tax proceedings arising in the ordinary course of business and periodically assesses its liabilities and contingencies in connection with these matters based upon the latest information available. For those matters where it is probable that the Company has incurred a loss due to potential tax liabilities and the loss or range of loss can be reasonably estimated, reserves have been recorded in the consolidated balance sheets. In other instances, the Company is unable to make a reasonable estimate of any liability because of the uncertainties related to both the probable outcome and amount or range of loss. As additional information becomes available, the Company adjusts its assessment and estimates of such liabilities accordingly.

(16) 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, 2005, 2004 and 2003, the Board of Directors authorized matching contributions of \$114,000, \$126,000 and \$184,000, respectively.

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

(17) RELATED PARTY TRANSACTIONS

During the years ended December 31, 2005, 2004 and 2003, the Company made consulting payments to one of its directors for service as chairman on our Scientific Advisory Board. These payments were in addition to compensation earned in his capacity as a director. These consulting payments totaled \$75,000 for each of the years ended December 31, 2005, 2004 and 2003. As of December 31, 2005 and 2004, there were no amounts payable to or due from this director.

(18) SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

The following are selected quarterly financial data for the years ended December 31, 2005 and 2004:

	Quarter Ended			
	March 31, 2005	June 30, 2005	September 30, 2005	December 31, 2005
	(as restated)	(as restated)	(as restated)	
Net revenues	\$ (812,748)	\$ 1,240,625	\$ 2,065,125	\$ 3,509,444
Loss from operations	(5,584,191)	(5,052,001)	(3,477,706)	(1,753,540)
Net loss applicable to common stockholders	(5,381,314)	(4,857,936)	(3,251,341)	(1,364,581)
Basic and diluted net loss per share	\$ (0.11)	\$ (0.10)	\$ (0.07)	\$ (0.03)
Shares used in computing basic and diluted net loss per share	47,846,903	47,964,360	48,178,626	48,298,273
	Quarter Ended			
	March 31, 2004	June 30, 2004	September 30, 2004	December 31, 2004
	(as restated)	(as restated)	(as restated)	(as restated)
Net revenues	\$ 541,593	\$ 802,823	\$ 1,168,981	\$ 1,185,682
Loss from operations	(4,491,172)	(4,581,416)	(4,311,936)	(3,410,390)
Net loss applicable to common stockholders	(4,341,343)	(4,526,009)	(4,258,552)	(1,948,612)
Basic and diluted net loss per share	\$ (0.11)	\$ (0.11)	\$ (0.10)	\$ (0.02)
Shares used in computing basic and diluted net loss per share	41,105,756	41,467,655	41,620,123	48,298,273

The net loss amounts presented above for the quarters ending December 31, 2005 and 2004 included \$1,400,000 of license fee revenue and \$1,708,000 of other income, respectively, related to the recovery of a previously written-off note receivable and previously written-off interest income and foreign exchange gains.

As discussed in Note 2, the Company restated its financial results for each quarter ended March 31, 2005, June 30, 2005 and September 30, 2005 and for the years ended December 31, 2004 and 2003.

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

(19) SUBSEQUENT EVENTS

(a) *Loss contingency for additional basal cell carcinoma co-development costs*

The Company accrues loss contingencies when such costs are probable and estimable. If the Company identifies a loss contingency that is not both probable and estimable, the Company does not accrue for the loss contingency. However, if the Company's management believes that it is reasonably possible that the loss contingency will be realized, the Company would disclose the nature and, if possible, the estimated amount of the loss contingency. If the Company's management believes that the likelihood of the loss contingency being realized is remote, it would not disclose the loss contingency.

As discussed in Note 5(a), beginning in 2005, the Company and Genentech have been sharing equally in the development expenses related to a basal cell carcinoma product candidate. For the year ended December 31, 2005, the Company recorded \$6,999,000 as contra revenues associated with its equal share of the development expenses.

On January 19, 2006, the Company received notification from Genentech that Genentech believed that it had improperly invoiced the Company for the Company's share of basal cell carcinoma co-development costs. As a result of the invoicing errors, Genentech notified the Company that it believes that the Company owes Genentech an incremental \$667,000 for the reimbursement of costs that should have been charged by Genentech to the Company. Management believes that it is probable that the Company will owe Genentech some portion of this amount and has estimated that its liability will range from \$325,000 to \$667,000. Accordingly, the Company has recorded \$325,000 as "Contra revenues from co-development with Genentech" at its Consolidated Statement of Operations for the year ended December 31, 2005. The Company has also recorded \$325,000 within "Accrued liabilities" at its Consolidated Balance Sheet as of December 31, 2005.

(b) *Preclinical Milestone received from Procter & Gamble*

In March 2006, the Company reached the first preclinical milestone in its hair growth program with Procter & Gamble Pharmaceuticals, a division of The Procter & Gamble Company. The program is focused upon the potential development of a topical Hedgehog agonist for hair growth disorders, such as male pattern baldness and female pattern hair loss. As part of the initial agreement signed in September of 2005, Procter & Gamble agreed to pay the Company up to \$2,800,000 in preclinical milestones. The first of two preclinical milestones was successfully completed and will result in a payment to the Company of \$1,000,000.

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, 2005. 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, 2005, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective.

Management’s report on internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, and the related audit report of our independent registered public accounting firm are included in Item 8 of this annual report on Form 10-K and are 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, 2005 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

Information concerning directors that is required by this Item 10 is set forth in our proxy statement for our 2006 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 2006 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 2006 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

Information required by this Item 13 is set forth in our proxy statement for our 2006 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 2006 annual meeting of stockholders under the heading “Independent Auditor’s Fees,” which information is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) *Financial Statements.*

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

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

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

EXHIBIT INDEX

Exhibit No.	Description	Incorporated by Reference			
		Form	SEC Filing Date	Exhibit Number	Filed with this 10-K
<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	
<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, effective as of September 20, 2001, between Curis and Daniel R. Passeri	10-Q	11/14/01	10.3	
#10.2	Employment Agreement, effective as of November 27, 2003, between Curis and Michael P. Gray	10-K	03/01/04	10.4	
#10.3	Employment Agreement, effective as of September 1, 2002, between Curis and Mary Elizabeth Potthoff	10-K	03/01/04	10.5	
#10.4	Board of Director and Scientific Advisory Board Services Agreement, effective as of August 11, 2000, between Curis and Douglas A. Melton	10-K	03/01/04	10.6	
#10.5	Consulting Agreement entered into by Curis and Dr. Joseph M. Davie on September 23, 2004 with an effective date of February 2, 2004	8-K	11/18/04	10.1	
#10.6	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	
#10.7	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	
#10.8	Curis 2000 Stock Incentive Plan	S-4/A (333-32446)	05/31/00	10.71	
#10.9	Curis 2000 Director Stock Option Plan	S-4/A (333-32446)	05/31/00	10.72	
#10.10	Curis 2000 Employee Stock Purchase Plan	S-4/A (333-32446)	05/31/00	10.73	
#10.11	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	

<u>Exhibit No.</u>	<u>Description</u>	<u>Incorporated by Reference</u>			
		<u>Form</u>	<u>SEC Filing Date</u>	<u>Exhibit Number</u>	<u>Filed with this 10-K</u>
#10.12	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	
#10.13	Form of Non-statutory Stock Option Agreement granted to non-employee directors under Curis' Director Stock Option Plan	10-Q	10/26/04	10.4	
#10.14	Compensation of Named Executive Officers of Curis, Inc.				X
#10.15	Compensation of Directors of Curis, Inc.				X
	<i>Material contracts—Leases</i>				
10.16	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	
10.17	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	
10.18	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	
10.19	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>				
10.20	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	
10.21	Security Agreement, dated restated on September 23, 2004, between Curis and Boston Private Bank & Trust Company	10-K	03/15/05	10.19	

<u>Exhibit No.</u>	<u>Description</u>	<u>Incorporated by Reference</u>			
		<u>Form</u>	<u>SEC Filing Date</u>	<u>Exhibit Number</u>	<u>Filed with this 10-K</u>
10.22	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	
10.23	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	
10.24	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	
10.25	Security Agreement (Equipment), between Curis, Inc. and Boston Private Bank & Trust Company, dated June 9, 2005	8-K	06/15/05	10.3	
<i>Material contracts—License and Collaboration Agreements</i>					
10.26	Master Restructuring Agreement, dated as of October 15, 1998, between Creative and Stryker Corporation	10-K	03/30/99	10.10	
†10.27	Second Amendment to Master Restructuring Agreement, dated October 1, 2002, between Curis and Stryker Corporation	10-Q	11/12/02	10.5	
10.28	Irrevocable License Agreement, dated November 20, 1998, between Creative and Stryker Corporation	10-K	03/13/00	10.7	
10.29	Stryker Irrevocable License Agreement, dated November 20, 1998, between Creative and Stryker Corporation	10-K	03/13/00	10.8	
10.30	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	
†10.31	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	
†10.32	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	
†10.33	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	

<u>Exhibit No.</u>	<u>Description</u>	<u>Incorporated by Reference</u>			
		<u>Form</u>	<u>SEC Filing Date</u>	<u>Exhibit Number</u>	<u>Filed with this 10-K</u>
†10.34	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	
†10.35	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	
†10.36	Agreement, dated as of November 27, 2002, by and between Curis and Ortho Biotech Products, L.P.	8-K	12/09/02	10.1	
†10.37	Collaborative Research, Development and License Agreement, dated June 11, 2003, between Curis and Genentech, Inc.	8-K	07/10/03	10.1	
10.38	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	
10.39	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	
†10.40	Drug Discovery and Collaboration Agreement dated April 1, 2005 by and between Curis, Inc. and Genentech, Inc.	10-Q	4/29/05	10.1	
†10.41	Collaboration, Research and License Agreement, dated January 12, 2004, between Curis and Wyeth	10-K	03/01/04	10.29	
†10.42	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>					
†10.43	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	
10.44	Registration Rights Agreement, dated June 13, 2003, between Curis and Genentech, Inc.	8-K	07/10/03	10.3	

<u>Exhibit No.</u>	<u>Description</u>	<u>Incorporated by Reference</u>			
		<u>Form</u>	<u>SEC Filing Date</u>	<u>Exhibit Number</u>	<u>Filed with this 10-K</u>
10.45	Common Stock Purchase Agreement, dated June 11, 2003, between Curis and Genentech, Inc.	8-K	07/10/03	10.2	
10.46	Common Stock Purchase and Registration Rights Agreement, dated January 9, 2004, between Curis and Wyeth	10-K	03/01/04	10.34	
10.47	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	
10.48	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	
<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.

MANAGEMENT

Daniel R. Passeri
President and Chief Executive Officer

Lee L. Rubin, Ph.D.
*Executive Vice President of Research
and Chief Scientific Officer*

Michael P. Gray
*Vice President of Finance, Chief
Financial Officer and Treasurer*

Mark W. Noel
*Vice President of Technology
Management and Business Development*

M. Elizabeth Potthoff, Esq.
*Vice President, General Counsel
and Secretary*

BOARD OF DIRECTORS

Susan B. Bayh
*Distinguished Visiting Professor,
College of Business Administration,
Butler University; Director, Dyax
Corporation, Dendreon Corporation,
Novovax, Inc., Wellpoint, Inc. and
Emmis Communications, Inc.*

Joseph M. Davie, Ph.D., M.D.
*Director, Inflazyme Pharmaceuticals, Inc.
and Targeted Genetics, Inc.; elected to
Institute of Medicine*

Martyn D. Greenacre
*Chairman of the Board, Beijing Med-Pharm
Corporation and Life Mist, L.L.C.;
Director, Cephalon, Inc., Acusphere, Inc.
and The Immune Response Corporation*

Kenneth I. Kaitin, Ph.D.
*Director of the Tufts Center for the
Study of Drug Development; Associate
Professor of Medicine at Tufts University
School of Medicine*

James R. McNab, Jr.
*Chairman of the Board, Curis, Inc.;
Chairman and Chief Executive Officer
of eNOS Pharmaceuticals, Inc.*

Douglas A. Melton, Ph.D.
*Chairman of the Scientific Advisory
Board, Curis, Inc.; Thomas Dudley
Cabot Professor of the Natural Sciences,
Harvard University; Investigator,
Howard Hughes Medical Institute*

Daniel R. Passeri
*President and Chief Executive Officer,
Curis, Inc.*

James R. Tobin
*President and Chief Executive Officer,
Boston Scientific Corporation; Director,
Applera Corporation and Boston
Scientific Corporation*

MARKET INFORMATION

Our common stock has traded on the NASDAQ National Market since August 1, 2000. Our trading symbol is "CRIS". There were 306 shareholders of record as of March 22, 2006. 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 National Market:

FY 2005	High	Low
1st Quarter	\$ 5.32	\$ 3.27
2nd Quarter	\$ 4.35	\$ 3.23
3rd Quarter	\$ 4.94	\$ 3.81
4th Quarter	\$ 4.69	\$ 3.50

FY 2004	High	Low
1st Quarter	\$ 6.59	\$ 4.50
2nd Quarter	\$ 5.17	\$ 3.51
3rd Quarter	\$ 4.95	\$ 2.46
4th Quarter	\$ 5.94	\$ 3.14

We have never declared or paid any cash dividends on our common stock and we do not anticipate paying cash dividends in the foreseeable future.

CORPORATE HEADQUARTERS

Curis, Inc.
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Cambridge, MA 02138
P: 617.503.6500
F: 617.503.6501
www.curis.com

TRANSFER AGENT

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85 Challenger Road
Ridgefield Park, NJ 07660
P: 800.288.9541
www.melloninvestor.com

INDEPENDENT ACCOUNTANTS

PricewaterhouseCoopers LLP
125 High Street
Boston, MA 02110
P: 617.530.5000
www.pwcglobal.com

LEGAL COUNSEL

Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109
P: 617.526.6000
www.wilmerhale.com

ANNUAL MEETING

The annual meeting of shareholders will be held at 10:00 a.m. on June 1, 2006, at the offices of Wilmer Cutler Pickering Hale and Dorr LLP 60 State Street, Boston, MA 02109.

SEC FORM 10-K

A copy of our 2005 annual report on Form 10-K, without exhibits, is available without charge upon written request to: Investor Relations, Curis, Inc., 61 Moulton Street, Cambridge, MA 02138

CAUTIONARY NOTE

This Annual Report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements concerning Curis' financial results and expected year-end cash position, the potential effectiveness of its technologies under development and the Company's belief that it can grow as a company through its co-development arrangements and the clinical expertise of its collaborators. Forward-looking statements used in this press release may contain the words "believes", "expects", "anticipates", "plans", "seeks", "estimates" or similar expressions. These forward-looking statements are not guarantees of future performance and involve risks, uncertainties, assumptions and other factors that may cause Curis' actual results to be materially different from those indicated by such forward-looking statements. Actual results can be affected by a number of important factors including, among other things: adverse results in Curis' and its strategic collaborators' and licensees' product development programs; delays in enrolling patients for its basal cell carcinoma clinical trial, difficulties or delays in obtaining or maintaining required regulatory approvals for products being developed by Curis' and its collaborators and licensees; Curis' ability to obtain or maintain the patent and other proprietary intellectual property protection necessary for the development and commercialization of products based on its technologies; changes in or Curis' inability to execute its business plan; the risk that Curis does not obtain the additional funding required to conduct research and development of its product candidates, fund its co-development obligations under its collaboration with Genentech and execute its business plan; unplanned cash requirements and expenditures; risks relating to Curis' ability to enter into and maintain important strategic collaborations, including its ability to maintain its current collaboration agreements with Genentech, Procter & Gamble, Wyeth and Ortho Biotech Products; the risk that competitors will discover and develop signaling pathway-based or other competing therapeutics faster and more successfully than Curis and its collaborators are able to; and other risk factors identified in Curis' most recent Annual Report on Form 10-K, Quarterly Report on Form 10-Q and subsequent reports periodically filed with the Securities and Exchange Commission. In addition, any forward-looking statements represent the Company's views only as of today and should not be relied upon as representing its views as of any subsequent date. Curis disclaims any intention or obligation to update any of the forward-looking statements after the date of this press release whether as a result of new information, future events or otherwise.



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