



2003 Annual Report

SHAREHOLDER INFORMATION

Curis, Inc. and Subsidiaries

MANAGEMENT

Daniel R. Passeri
President and Chief Executive Officer

Lee L. Rubin, Ph.D.
Senior Vice President, Research and Chief Scientific Officer

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

Marc F. Charette, Ph.D.
Vice President, Corporate Communications

Mark W. Noel
Vice President, Technology Management and Business Development

Mary Elizabeth Potthoff, Esq.
Vice President, General Counsel and Secretary

Christopher U. Missling, Ph.D.
Senior Vice President of Strategic Analysis and Planning

MARKET INFORMATION

Our common stock was first traded on the NASDAQ National Market on August 1, 2000. Our trading symbol is "CRIS." There were 318 shareholders of record as of February 28, 2004. 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 2003 | High | Low |
|-------------------|-------------|------------|
| 1st Quarter | \$1.25 | \$0.65 |
| 2nd Quarter | \$5.60 | \$0.76 |
| 3rd Quarter | \$5.34 | \$2.80 |
| 4th Quarter | \$5.92 | \$4.34 |

| FY 2002 | High | Low |
|-------------------|-------------|------------|
| 1st Quarter | \$5.68 | \$1.96 |
| 2nd Quarter | \$2.24 | \$1.00 |
| 3rd Quarter | \$1.37 | \$0.51 |
| 4th Quarter | \$1.28 | \$0.50 |

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.
61 Moulton Street
Cambridge, MA 02138
P• 617.503.6500
F• 617.503.6501
www.curis.com

TRANSFER AGENT

Mellon Investor Service LLC
85 Challenger Road
Ridgefield Park, NJ 07660
P• 800.288.9541
www.melloninvestor.com

BOARD OF DIRECTORS

Susan B. Bayh
Distinguished Visiting Professor, College of Business Administration, Butler University; Director, Cubist Pharmaceuticals, Inc., Anthem, 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 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; serves on faculty of European Center for Pharmaceutical Medicine at the University of Basel

James R. McNab, Jr.
Chairman of the Board, Curis, Inc.; Chairman of eNOS Pharmaceuticals, Inc. and Sontra Medical Corporation

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

INDEPENDENT ACCOUNTANTS

PricewaterhouseCoopers LLP
One Post Office Square
Boston, MA 02109
P• 617.428.8400
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LEGAL COUNSEL

Hale and Dorr LLP
60 State Street
Boston, MA 02109
P• 617.526.6000
www.haledorr.com

ANNUAL MEETING

The annual meeting of shareholders will be held at 10:00 a.m. on June 2, 2004, at the offices of Hale and Dorr LLP, 60 State Street, Boston, MA 02109

SEC FORM 10-K

A copy of our 2003 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
info@curis.com

FORWARD-LOOKING INFORMATION

This annual report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements about Curis' drug discovery and development programs. Such statements 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 partners' product development programs; difficulties or delays in obtaining or maintaining required regulatory approvals; 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 realigned business strategy; the risk that Curis does not obtain the additional funding required to conduct research and development of its product candidates and execute on its business plan; unplanned cash requirements and expenditures; risks relating to Curis' ability to enter into and maintain important strategic partnerships, including its ability to maintain its current collaboration agreements with Genentech, Ortho Biotech and Wyeth; the risk that competitors will discover and develop signaling pathway-based 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 10-Q and any subsequent reports 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, whether as a result of new information, future events or otherwise.

Annual Report 2004 – Shareholders Letter

Dear Shareholders:

2003 has been a successful year for Curis. Our lead research programs have moved closer to reaching human clinical trials either through collaborations with top-tier biotechnology and pharmaceutical companies or through our internal efforts. Our financial stability is greatly improved and our stock price appreciated substantially. These results are due to a strategic plan that was adopted by senior management and the board of directors during 2002.

In the first quarter of 2002, we embarked on a strategy of focusing our resources on the research and development of regulatory signaling pathway product candidates and the establishment of strategic corporate collaborations. The principle objectives of this strategy were to concentrate on our core competencies in regulatory signaling pathways in order to provide our most advanced programs with access to collaborators' development and clinical trial expertise and to obtain the financial resources required to enable us to further advance our development programs and pursue our internal research initiatives.

The implementation of this strategic plan has been successful to date. During the last eighteen months, we have established major strategic corporate relationships with Ortho Biotech (a subsidiary of Johnson & Johnson) in the field of kidney disease in November of 2002, Genentech in the field of cancer in June of 2003, and Wyeth Pharmaceuticals in the field of neurological disorders in January of 2004. These three transactions resulted in a strengthened balance sheet due to initial payments totaling \$15 million. In addition, our collaborations with Genentech and Wyeth will provide us with additional payments over the first two years of each collaboration that we expect to use to help offset certain research costs associated with these programs. Lastly, each of these collaborations provides significant potential future milestone and royalty revenue if product candidates under the collaboration are successfully developed. For example, our collaboration with Wyeth includes milestone payments of more than \$170 million, assuming at least two products are successfully developed.

The establishment of these strategic corporate collaborations has enabled us to diversify our product candidate portfolio and associated revenue opportunities, while at the same time providing us with ongoing relationships with leaders in pharmaceutical product development and clinical trial management. Because our collaborators are leaders in clinical development, we anticipate that these relationships may increase the likelihood that our product candidates will ultimately be successfully developed. Additionally, we expect that our collaborators will complement our current preclinical expertise by providing us with valuable development and clinical experience.

During the next twelve months, we expect that at least one of our corporate collaborators will file an investigational new drug application to initiate a human clinical trial. We believe that such a filing would provide evidence that our licensed technology has the potential to progress towards commercialization. In addition, any such filing would result in a meaningful cash milestone to us.

During 2003, our research team made several important scientific advances in the fields of cancer and neurological disorders. We also were issued several key U.S. patents involving our core regulatory signaling pathway technologies. The scientific advances of our research team and our intellectual property position were key factors in the establishment of both the Genentech and Wyeth collaborations.

The \$15 million in payments received under our collaboration agreements, coupled with \$10.9 million received through a private placement of our common stock in August of 2003, have increased our financial strength. Our improved financial flexibility should allow us to add depth to our product development candidate portfolio through our internal efforts and, potentially, through external technology acquisitions. For example, while our corporate partners are advancing our programs in kidney disease, cancer, and neurological disorders, we are continuing to develop programs in the fields of hair growth regulation and cardiovascular disease. Within the next twelve months, we hope to announce the selection of a clinical candidate for the hair growth program.

In summary, Curis has established itself as a company with strong top-tier corporate collaborations that we believe provide validation of our technology platform and research direction. We believe that we are in a position to be able to advance our promising internal programs as well as explore related technology acquisitions during 2004. Our long-term goal is to create a consistently productive and, ultimately, profitable biotechnology company. We anticipate a successful 2004, marked by the continued progression of our product candidates and the expansion of our technology portfolio.

Lastly, I would like to thank our shareholders for their confidence, our board of directors for their support, and our employees for their hard work, dedication, and significant achievements.

Sincerely,

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

**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, 2003

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 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 an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes No

As of June 30, 2003, the aggregate market value of the common stock held by non-affiliates of the registrant was approximately \$106,073,000 based on the closing sale price of the registrant's common stock on The NASDAQ National Market on such date.

As of February 23, 2004, there were 41,359,136 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 2, 2004, 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, 2003 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 “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Factors That May Affect Future Results” 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 have successfully used this product development approach to produce multiple compounds for several different disease indications. For example, we have developed several promising preclinical product candidates in the fields of kidney disease, cancer, neurological disorders, cardiovascular disease and hair growth regulation.

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 are developing our product candidate programs around several major signaling pathways including the Hedgehog and Bone Morphogenetic Protein pathways. We have substantial intellectual property rights 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. In addition, we intend to expand our technology offerings and associated intellectual property portfolio through in-licensing arrangements and the acquisition of complimentary technologies, including additional signaling pathways.

Our research programs are conducted both internally and through strategic alliances and collaborations. We currently have strategic collaborations with Ortho Biotech, Genentech and Wyeth. Our strategic alliances and collaborations generally provide for our research, development and commercialization programs to be 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. In some cases, we have retained development and commercialization rights in areas where we believe we can attain the greatest potential long-term value through the application of our own internal resources. We believe that our approach allows us to augment our development capabilities and capacities through collaborations with leading pharmaceuticals companies and also provides us with the opportunity to discover and develop products while reducing our internal product development costs and related risks.

In the future, we plan to continue to seek corporate partners for the further development and commercialization of some of our technologies. Even though we are seeking partners to help develop some of our technologies, we expect to select at least one program that we will develop further on our own.

Regulatory Signaling Pathways Background

Regulatory signaling pathways are the means by which tissues and organs 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 and Bone Morphogenetic pathways, which act by initiating cascades of other pathways required for tissue formation and regulation. Later in life, the body uses these master pathways to repair damage and regenerate tissues. For example, in damaged nerve tissue, we have demonstrated in preclinical models 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 pathways that promote the growth of new cells and blood vessels.

The ability to activate certain signaling pathways is of great interest to biotechnology and pharmaceutical companies as many diseases and disorders are now known to be associated with insufficient or damaged signaling pathways. For example, one of the most successful biotechnology-derived drugs is a formulation of a signaling protein called erythropoietin. Erythropoietin is made in the kidney and controls a pathway that instructs the bone marrow to make new red blood cells. In dialysis patients with end-stage kidney disease, in which their kidneys have mostly or completely stopped functioning, the kidneys are unable to make erythropoietin. These patients therefore develop severe anemia, a critical medical condition caused by a lack of sufficient red blood cells. Administration of erythropoietin restores normal levels of red blood cells thus alleviating the patient's anemia. The erythropoietin market for dialysis patients in the U.S. is estimated to be over \$2 billion annually.

Our BMP-7 program, which is partnered with Ortho Biotech, is similar to erythropoietin in several respects. BMP-7 is also a signaling protein made in the kidney that regulates several important tissue repair and maintenance pathways. Dialysis patients develop several other serious complications in addition to severe anemia, including bone diseases and blood vessel calcification resulting in life-threatening cardiovascular complications. In preclinical models, administration of BMP-7 has been shown to prevent the bone and blood vessel complications that are associated with chronic kidney disease. Preclinical studies also suggest that BMP-7 may delay progression of kidney disease, delay the need for dialysis and stabilize kidney function for dialysis patients. If successfully developed, we estimate that the market size for BMP-7 in dialysis patients may approximate the market size for erythropoietin in dialysis patients.

There is also significant pharmaceutical interest in the inhibition of abnormally or inappropriately activated signaling pathways which have been implicated in certain cancers. For instance, Novartis Inc.'s Gleevec® is a small molecule drug that inhibits a signaling pathway that is abnormally expressed in certain cancers. Gleevec® is among the first signaling pathway inhibitors to be approved by the FDA and is Novartis' second largest-selling drug with estimated annual worldwide sales of more than \$1 billion.

Abnormal expression of the Hedgehog signaling pathway has been shown to be associated with certain cancers, including basal cell carcinoma, small cell lung cancer and pancreatic cancer. We have also developed small molecule Hedgehog pathway inhibitors and Hedgehog blocking antibodies. Our Hedgehog pathway inhibitors and antibodies, which are partnered with Genentech, have been demonstrated to slow or halt the growth of these 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 pathway inhibitors may be applicable to a broad array of cancers.

We believe that our focus on developing drugs based primarily on the master signaling pathways will give us a competitive advantage over similar efforts by other biotechnology and pharmaceutical companies. Our approach has already enabled us to develop a diverse portfolio of preclinical product candidates in several

important therapeutic areas including kidney disease, cancer, neurological disorders, cardiovascular disease and hair growth regulation.

Our Strategy

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

- ***Focus on large 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 attractive markets with unmet medical needs. We are principally focused on developing proprietary regulatory signaling pathway-based drugs for large markets including kidney disease, cancer, neurological disorders, cardiovascular disease and hair growth regulation where we believe our product candidates can provide compelling clinical advantages over existing products. For example, BMP-7 is a signaling protein that is synthesized in the kidney and has been implicated in the maintenance of the normal health of the kidney, the skeleton, and the vascular system. We estimate that the U.S. market potential for our BMP-7 product, if approved for the dialysis market, would be more than \$2 billion annually in the U.S.
- ***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 drug development companies are better qualified and experienced to develop and run clinical trials, these collaborations will better allow our product candidates to potentially enter large markets. 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 alliances and co-development agreements, we believe we will be able to strengthen our capabilities and capacities for developing and managing clinical trials.
- ***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 can 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. For instance, we believe that topically applied or locally delivered drug candidates may be a more appropriate match with our development capabilities. We are considering the independent development of our two Hedgehog topically-applied small molecule product candidates, including a small molecule antagonist for inhibition of unwanted hair growth and a small molecule agonist to promote hair growth. In addition, we have retained the right to independently develop our Hedgehog locally-delivered agonist for selected cardiovascular indications.
- ***Acquire and develop additional intellectual property around other key regulatory signaling pathways.*** We currently own or have rights to approximately 164 issued and 121 pending patent applications in the United States and have foreign counterpart patent filings. 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 by investing in selected research and development efforts and potentially acquiring complementary intellectual property.

Product Development Programs

We are developing product candidates in several important medical fields where there is substantial unmet therapeutic need. These product development initiatives, described in the chart below, are being pursued using our internal resources or through partnering and licensing arrangements with pharmaceutical or biotechnology firms that are able to dedicate additional resources and clinical development expertise. 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 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, and 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 application, or IND, filing with the FDA seeking to commence a phase I clinical trial to assess safety in humans.

| <u>Product Candidate</u> | <u>Primary Indication</u> | <u>Partner/Licensee</u> | <u>Status</u> |
|------------------------------|-------------------------------------|-------------------------|-------------------|
| BMP-7 protein | Kidney disease | Ortho Biotech | Late preclinical |
| Hh small molecule antagonist | Basal cell carcinoma | Genentech | Late preclinical |
| Hh small molecule antagonist | Cancer | Genentech | Mid preclinical |
| Hh antibody antagonist | Cancer | Genentech | Mid preclinical |
| Hh small molecule agonist | Central nervous system disorders | Wyeth | Mid preclinical |
| Hh small molecule agonist | Peripheral nervous system disorders | Wyeth | Mid preclinical |
| Hh small molecule agonist | Hair loss | In-house development | Late preclinical |
| Hh agonist/protein/gene | Cardiovascular disease | In-house development | Mid preclinical |
| Hh small molecule antagonist | Hair growth inhibition | In-house development | Early preclinical |
| PYY peptide | Obesity | Amylin Pharmaceuticals | IND filed |

BMP-7 Program

BMP-7 is a signaling protein that is synthesized in the kidney and has been implicated in the maintenance of the normal health of the kidney, the skeleton, and the vascular system. Prior to November 2002, we had been developing BMP-7 as a therapeutic compound to halt the progression of chronic kidney failure and to prevent skeletal and vascular complications that are associated with chronic kidney disease.

During 2003, several academic researchers published reports concluding that BMP-7 may be an effective therapy for chronic kidney disease. These reports, from the Beth Israel Deaconess Medical Center, the Harvard Medical School and the Washington University School of Medicine, have demonstrated the potential of using BMP-7 as a potential treatment to both halt the progression and reverse the effects of chronic progressive kidney disease. These reports are published in *Nature Medicine* 2003 July 9(7): 964-8 and *The Journal of the American Society of Nephrology* 2003 June 14(6): 1559-67.

These data suggest that BMP-7 may be similar in some respects to erythropoietin, believed to be one of the most successful biotechnology-derived drugs. Erythropoietin is a signaling protein that is made in the kidney. It is secreted into the blood system and controls the process that instructs bone marrow to make new red blood cells. In dialysis patients with end-stage kidney disease, in which their kidneys have mostly or completely stopped functioning, the kidneys are unable to make erythropoietin. These patients therefore develop severe anemia, a critical medical condition caused by a lack of sufficient red blood cells. Administration of erythropoietin restores normal levels of red blood cells thus alleviating the patient's severe anemia. Dialysis patients develop several other serious complications in addition to severe anemia, including bone disease and severe blood vessel calcification resulting in life-threatening cardiovascular complications. The preclinical demonstration that BMP-7 prevents the bone and blood vessel complications that are associated with chronic

kidney disease suggests that the market size for BMP-7 in dialysis patients may approximate the market size for erythropoietin in dialysis patients, which is currently estimated to be over \$2 billion in the U.S.

In November 2002, we entered into an agreement with Ortho Biotech for the continued development of this kidney disease product candidate. Ortho Biotech is a pharmaceutical company with broad expertise in protein-based therapeutic drug development and has an established presence in the kidney disease marketplace. Ortho Biotech will assume all future costs and responsibility for BMP-based product development, and we will receive clinical milestone payments and royalties on product sales if clinical evaluations of any BMP-based products are successful. Ortho Biotech has sole responsibility for deciding if and when human clinical trials of BMP-7 will begin.

Hedgehog Small Molecule and Antibody Antagonist Cancer Programs

The Hedgehog signaling pathway controls the development and growth of many kinds of tissues in the body by activating other secondary 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 certain cancers, such as basal cell carcinoma, are expressing abnormally high concentrations of Hedgehog protein, thereby creating local environments favorable to the rapid growth of cancerous tissue. Furthermore, in 2003, several academic researchers published reports that also noted the link between abnormal expression of the Hedgehog signaling pathway and the malignant growth of other tumors, including small cell lung cancer and certain tumors of the gastrointestinal tract. These reports, from the Johns Hopkins University School of Medicine, University of California, San Francisco, Massachusetts General Hospital, and the Harvard Medical School were published in *Nature* 2003 October 23 425(6960): 846-51 and 851-6.

Our preclinical evidence indicates that inhibition of the Hedgehog pathway, in cells where it is being abnormally activated, results in the selective and specific death of the tumor cells while conferring no harm to adjacent normal cells. This selectivity contrasts with more traditional cancer treatments that often kill both cancer cells and normal cells. We believe that the ability to selectively kill cancer cells while leaving healthy cells intact represents the next generation of cancer treatments that are in development.

In June 2003, we established a collaboration with Genentech for the continued development of these anti-cancer drug candidates. Genentech is a pharmaceutical company with broad expertise in the development of cancer therapeutics. Except for the co-development option described below, Genentech will assume all future responsibility for the clinical development of the Hedgehog small molecule and antibody antagonists as cancer drugs for solid tumors. We will receive clinical milestone payments and royalties on product sales if clinical evaluations of any Hedgehog antagonist and antibody technology-based products are successful. We have retained a co-development option in the field of basal cell carcinoma, a type of skin cancer.

Hedgehog Small Molecule Agonist Neurological Disorders Programs

The Hedgehog signaling pathway is essential for the formation of normal nerves in the central and peripheral nervous systems. Our scientists and academic collaborators have shown that treatment with a Hedgehog protein accelerates 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. During 2003, our scientists and several academic researchers presented reports concluding that activation of the Hedgehog pathway promotes improved recovery from stroke, Parkinson's disease, and spinal cord injury. In addition to findings reported by us, reports were also made by researchers at the Université Victor Segalen in France, the University of Manchester in the United Kingdom, the Toronto Western Research Institute in Canada, the California Institute of Technology in Pasadena, California, and at Case

Western Reserve University. The stroke data were presented by our scientists at the 2003 Society for Neuroscience conference, the Parkinson's data were published in the *FASEB Journal* 2003 December 17(15): 2337-8, and the spinal cord injury data were presented at the 2003 meeting of the North American Spine Society.

Our scientists have developed a series of small molecule Hedgehog agonists that, in preclinical models, have 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 brain tissue. Small molecules that cross this blood brain barrier can reach and treat damaged brain tissue, therefore making them attractive product development candidates.

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 also know that activation of the Hedgehog pathway results in an increased proliferation of brain stem cells. We are currently exploring the possibility that this may enable to develop drugs that can promote the replacement of brain cells lost as a result of injury or disease.

In January 2004, we entered into a collaboration agreement with Wyeth Pharmaceuticals to continue the development of these promising drug candidates for the treatment of neurological disorders and other potential indications. 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. Under the terms of the collaboration, Wyeth paid us an up-front license fee and is obligated to provide two years of research funding. In addition, if clinical evaluations of any Hedgehog agonist technology-based products are successful, Wyeth is obligated to pay us clinical milestone payments and royalties on product sales.

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. As part of the agreement, we have retained development and licensing options for certain therapeutic applications of Hedgehog agonist technologies, including those applications that qualify as orphan drug indications, topical applications for hair growth, local delivery applications for treatment of cardiovascular disease, and use of the technology with stem cells.

Hedgehog Agonist Cardiovascular Disease Program

In November 2003, researchers from the St. Elizabeth's Medical Center in Boston, Massachusetts presented data at the annual Scientific Sessions of the American Heart Association demonstrating that localized activation of the Hedgehog signaling pathway, several hours after heart injury, can significantly improve heart function and reduce overall heart damage in a model of myocardial infarction, or heart attack.

Our scientists and our academics collaborators are currently conducting additional studies to evaluate the therapeutic potential of using locally-delivered Hedgehog agonists that activate the Hedgehog pathway to promote recovery from cardiovascular disease. Wyeth has a first right of negotiation to license our Hedgehog pathway technologies in the field of cardiovascular disease.

Hedgehog Small Molecule Agonist and Antagonist Hair Growth Regulation Program

Several years ago, our scientists and other researchers demonstrated that activation of the Hedgehog pathway can stimulate rapid hair re-growth in models of hair loss, including hair loss as a result of chemotherapy treatment. These latter results were published in the *Journal of the National Cancer Institute* 2001 Dec 19 93(24): 1858-64.

More recently, our scientists have demonstrated that our small molecule Hedgehog agonists can induce hair re-growth in animal models. We are currently evaluating the therapeutic potential of small molecule Hedgehog agonists to promote hair re-growth in preclinical models of hair loss. We are also evaluating the potential of Hedgehog pathway antagonists to block hair growth.

PPY Peptide Obesity License

PYY is a gut peptide that has been shown to suppress appetite and reduce food intake in animals and humans. Several years ago, our scientists working in the field of diabetes filed patent applications on the potential utility of using PYY as a treatment for certain metabolic disorders, including obesity.

In December 2002, we licensed our PYY patent applications to Amylin Pharmaceuticals for in-vivo therapeutic uses in exchange for an up-front fee, milestone payments upon the achievement of specified development objectives, and royalties on potential future product sales. Amylin has extensive development experience with our similar gut peptides.

In December 2003, Amylin filed an investigational new drug application with the FDA on PYY for an obesity indication and has indicated that it expects to initiate clinical testing in the first quarter of 2004. Amylin has responsibility for all expenses related to further development of the PYY compound.

Strategic Alliances And License Agreements

Our strategy for development and commercialization of products depends upon successful strategic alliances with third parties. We use strategic alliances 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 alliances, 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;
- technology and patent rights; and
- scientific and development resources.

Since inception, substantially all of our revenue has been derived from our collaborations and other agreements with third parties.

Our current strategic alliances are described below.

Ortho Biotech, a subsidiary of Johnson & Johnson

In November 2002, we licensed our broad BMP technology portfolio to Ortho Biotech on an exclusive, worldwide royalty-bearing basis, for all non-orthopedic and non-dental therapeutic applications in exchange for a \$3.5 million up-front fee, a series of cash milestones if specified clinical research objectives and regulatory approvals are achieved, including a \$30 million milestone payment upon U.S. regulatory approval of a product for the treatment of kidney disease, and a royalty on potential future product sales. If the program progresses successfully through clinical development, we are entitled to receive additional milestone payments for the kidney disease related product candidate and milestone payments for the first neurology product candidate. Initial target indications include the systemic use of BMP-7 for the prevention of bone and blood vessel complications associated with chronic kidney disease and treatments to promote recovery following stroke and brain injury.

Genentech

In June 2003, we licensed our novel small molecule and antibody inhibitors of the Hedgehog signaling pathway to Genentech on an exclusive worldwide royalty-bearing basis for applications in cancer therapy. Under the terms of the agreement, Genentech paid us an upfront license fee of \$5 million, purchased 1,323,835 shares of our common stock at a price of \$2.644 per share for aggregate proceeds of \$3.5 million, and is also obligated to pay us a total of \$4 million in maintenance fees by July 2005. Genentech is also obligated to make cash payments to us upon the successful achievement of clinical development and drug approval milestones. In addition, Genentech will pay a royalty on potential future net product sales, which increases with increasing sales volume. We have retained the right to co-develop products in the field of basal cell carcinoma, in which event we will share in any profits related to the basal cell carcinoma program in a percentage that is equal to our co-development cost sharing contribution.

Wyeth Pharmaceuticals, a division of Wyeth

In January 2004, we entered into an agreement to license our Hedgehog proteins and novel small molecule Hedgehog pathway agonists to Wyeth on an exclusive worldwide, royalty-bearing basis for the development and commercialization of pharmaceutical products for the therapeutic applications in treatment of neurological disorders, including neurodegenerative diseases and neuropathies. Under the terms of the agreement, Wyeth Pharmaceuticals paid us a license fee of \$1.5 million and purchased 315,524 shares of our common stock at a price of \$4.754 per share for an aggregate purchase price of \$1.5 million. Wyeth will provide research funding for a minimum of two years. In addition, Wyeth is obligated to make cash payments to us upon the successful achievement of clinical development and drug approval milestones and is obligated to pay a royalty on net product sales, if any, that escalates with increasing sales volume. Excluding product royalties, the transaction has a potential value to us of more than \$170 million, assuming at least two products are successfully developed and commercialized.

Amylin Pharmaceuticals

In December 2002, we granted Amylin Pharmaceuticals an exclusive worldwide, royalty-bearing license to our PYY patent applications for use in the research, development and commercialization of products in exchange for an up-front fee, milestone payments upon the achievement of specified development objectives, and royalties on potential future product sales, if any. PYY is a gut peptide that has been shown in animals and humans to suppress appetite and reduce food intake. Amylin has exclusive responsibility for expenses related to further development of the PYY compound.

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 164 issued patents and 121 pending patent applications in the United States expiring on various dates between 2007 and 2021 and have 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 38 issued U.S. patents and 5 allowed U.S. applications expiring on various dates between 2015 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 107 issued U.S. patents and 3 allowed U.S. applications expiring on various dates between 2007 and 2021, 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 limitations on publication of 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 publish discoveries arising from their efforts. Any such publication could 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 opportunities, consistent with our broad interest in regenerative signaling pathways. As of December 31, 2003, our research group consists of 43 employees, consisting of molecular biologists, cell biologists, pharmacologists and other scientific disciplines.

During the years ended December, 2003, 2002 and 2001, we estimate that our total company-sponsored research and development expenses were approximately \$10.8 million, \$8.7 million and \$26.3 million,

respectively, and that our collaborator-sponsored research and development expenses were approximately \$2.6 million, \$5.3 million and \$2.7 million, respectively.

Regulatory Matters

FDA Requirements for New Drug Compounds

The research, testing, manufacture and marketing of drug products are extensively regulated by numerous governmental authorities in the United States and other countries. 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 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 and/or the inability to obtain or maintain required approvals or to market approved drug products.

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, 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, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. 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. The results of preclinical testing are submitted to the FDA as part of an investigational new drug application.

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.

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 clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls.

If FDA evaluations of the new drug application and 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. 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.

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 may 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. Although there are some procedures for unified filings for some European countries with the sponsorship of the country which first granted marketing approval, in general each country has its own procedures and requirements, many of which are time consuming and expensive. Thus, 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 at a centralized, a decentralized or a national level. 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. As of January 1995, a mutual recognition procedure 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 will include many large pharmaceutical and biopharmaceutical companies, as well as specialized biotechnology and medical device firms.

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 which are competitive with our products and technologies.

The technology underlying the development of human therapeutic products is 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 collaborative partners 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 or genes 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 partners 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 partners are conducting multiple product development efforts within each disease area that is the subject of our strategic alliance with them. Our strategic alliance agreements may not restrict the strategic partner 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 partner.

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 partners 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 plan to rely on our corporate partners 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 Professor, 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, Center for Neurobiology and Behavior 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. | Professor of Developmental Biology Investigator, Howard Hughes Medical Institute Stanford University Medical School |
| Martin C. Raff, M.D. | Professor, Department of Biology MRC Laboratory For Molecular and Cell Biology University College London |
| Matthew Scott, Ph.D. | Professor, Department of Developmental Biology & Genetics Investigator, Howard Hughes Medical Institute 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, 2003, we had 64 full-time employees, of whom 38 hold Ph.D. or other advanced degrees. Of these employees, 43 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 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. All of these facilities are leased until April 2007. Except for 17,280 square feet which we have sublet, we currently use our space to conduct our research and development initiatives and to manage the administrative aspects of our business.

ITEM 3. LEGAL PROCEEDINGS

We are currently not 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 | 43 | President and Chief Executive Officer |
| Lee L. Rubin, Ph.D. | 53 | Senior Vice President of Research and Chief Scientific Officer |
| Michael P. Gray | 33 | Vice President of Finance and Chief Financial Officer |
| Mark W. Noel | 45 | Vice President, Technology Management and Business Development |
| Mary Elizabeth Potthoff, Esq. | 50 | Vice President, General Counsel |
| Christopher U. Missling, Ph.D. | 38 | Senior Vice President of Strategic Analysis and Planning |

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 Senior Vice President of Research and Chief Scientific Officer since September 2000 and prior to that served as our Vice President of Research since March 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 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.

Christopher U. Missling, Ph.D. Dr. Missling has served as Senior Vice President of Strategic Analysis and Planning since November 2003 and served as Senior Vice President of Finance, Chief Financial Officer, Treasurer and Secretary August 2002 until November 2003. From November 2001 until August 2002, Dr. Missling was employed by Axaron Bioscience AG, a genomics biotechnology company, where he served as Chief Financial Officer. From January 2000 until October 2001, Dr. Missling was employed by Aventis SA, a leading pharmaceutical company, as Head of Financial Planning, with responsibility for

financial modeling and determining investment valuations. From July 1997 to December 1999, Dr. Missling was employed by Hoechst AG, a pharmaceutical company, most recently as Head of Financial Planning. Dr. Missling received his MBA from the Kellogg Graduate School of Management at WHU and Northwestern University, and his Ph.D., summa cum laude, and M.Sc. from Ludwig-Maximilians-University in Munich.

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:

| | <u>Curis Common Stock</u> | |
|-------------------------------------|-------------------------------|--------|
| <u>Year ended December 31, 2002</u> | | |
| First Quarter | \$5.68 | \$1.96 |
| Second Quarter | \$2.24 | \$1.00 |
| Third Quarter | \$1.37 | \$0.51 |
| Fourth Quarter | \$1.28 | \$0.50 |
| <u>Year ended December 31, 2003</u> | | |
| First Quarter | \$1.25 | \$0.65 |
| Second Quarter | \$5.60 | \$0.76 |
| Third Quarter | \$5.34 | \$2.80 |
| Fourth Quarter | \$5.92 | \$4.34 |

(b) *Holders of Record.* On February 23, 2004, the last reported sale price of our common stock on The Nasdaq National Market was \$4.96 and there were 329 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 growth 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) *Recent Sales of Unregistered Securities.* Effective September 30, 2003, we issued an aggregate of 100,000 shares of our common stock to Johns Hopkins University, University of Washington, Philip A. Beachy and Jeffrey Porter as partial consideration for the amendment of a license agreement. We issued and delivered these securities in reliance upon an exemption from registration under Section 4(2) of the Securities Act of 1933.

Effective September 30, 2003, we issued an aggregate of 100,000 shares of our common stock to the President and Fellows of Harvard College as partial consideration for the amendment of a license agreement. We issued and delivered these securities in reliance upon an exemption from registration under Section 4(2) of the Securities Act of 1933.

ITEM 6. SELECTED FINANCIAL DATA

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

| | Year Ended December 31, | | | | |
|--|---------------------------------------|-------------|-------------|--------------|-------------|
| | 2003 | 2002 | 2001 | 2000 | 1999 |
| | (in thousands, except per share data) | | | | |
| Consolidated Statement of Operations Data: | | | | | |
| Revenues: | | | | | |
| Research and development contracts and government grants | \$ 1,629 | \$ 245 | \$ 968 | \$ 997 | \$ 3,160 |
| License fees and royalties | 9,419 | 18,146 | 119 | 26 | 52 |
| Total revenues | 11,048 | 18,391 | 1,087 | 1,023 | 3,212 |
| Costs and expenses: | | | | | |
| Research and development | 13,399 | 14,058 | 29,072 | 17,424 | 10,435 |
| General and administrative | 5,855 | 8,160 | 10,493 | 9,330 | 5,524 |
| Stock-based compensation (A) | 1,631 | 2,160 | 10,358 | 16,628 | 64 |
| Amortization of and impairment charge related to intangible assets | 75 | 474 | 23,339 | 14,451 | 808 |
| Loss of property and equipment | — | 5,337 | — | 204 | — |
| Impairment of goodwill | — | 64,098 | — | — | — |
| Restructuring expenses | — | 3,490 | — | — | — |
| In-process research and development | — | — | — | 294,800 | — |
| 1999 reorganization and 1998 sale of manufacturing operations | — | — | — | (38) | 256 |
| Total costs and expenses | 20,960 | 97,777 | 73,262 | 352,799 | 17,087 |
| Loss from operations | (9,912) | (79,386) | (72,175) | (351,776) | (13,875) |
| Equity in loss from joint venture | — | (4,311) | (13,453) | — | — |
| Other income (expense) | | | | | |
| Interest and other income (expense) | (1,017) | 2,329 | 4,548 | 1,906 | 1,926 |
| Interest expense | (694) | (947) | (784) | (481) | (161) |
| Total other income (expense) | (1,711) | 1,382 | 3,764 | 1,425 | 1,765 |
| Net loss | (11,623) | (82,315) | (81,864) | (350,351) | (12,110) |
| Accretion and repurchase costs on Series 1998/A Preferred Stock | — | — | — | — | (2,395) |
| Accretion on Series A Redeemable Preferred Stock | (271) | (723) | (326) | — | — |
| Net loss applicable to common stockholders | \$ (11,894) | \$ (83,038) | \$ (82,190) | \$ (350,351) | \$ (14,505) |
| Basic and diluted net loss per common share | \$ (0.33) | \$ (2.57) | \$ (2.58) | \$ (19.80) | \$ (1.36) |
| Weighted average common shares (basic and diluted) | 36,016 | 32,267 | 31,859 | 17,694 | 10,682 |
| (A) The following summarizes the departmental allocation of the stock-based compensation charge: | | | | | |
| Research and development | \$ 1,267 | \$ 1,222 | \$ 6,156 | \$ 8,358 | \$ — |
| General and administrative | 364 | 938 | 4,202 | 8,270 | 64 |
| Total stock-based compensation | \$ 1,631 | \$ 2,160 | \$ 10,358 | \$ 16,628 | \$ 64 |

| | As of December 31, | | | | |
|--|--------------------|-----------|-----------|-----------|-----------|
| | 2003 | 2002 | 2001 | 2000 | 1999 |
| | (in thousands) | | | | |
| Consolidated Balance Sheet Data: | | | | | |
| Cash, cash equivalents and marketable securities | \$ 35,148 | \$ 36,573 | \$ 52,107 | \$ 75,799 | \$ 21,371 |
| Cash and cash equivalents—restricted | 191 | 4,403 | — | — | — |
| Working capital | 34,278 | 36,293 | 42,848 | 67,364 | 17,116 |
| Total assets | 55,736 | 62,442 | 144,756 | 182,682 | 28,892 |
| Debt and lease obligations, net of current portion | — | 3,424 | 4,951 | 4,155 | 1,009 |
| Convertible notes payable | 5,334 | 6,885 | 2,507 | — | — |
| Series A Convertible/Exchangeable Preferred Stock | — | 13,064 | 12,341 | — | — |
| Accumulated deficit | (649,068) | (637,174) | (554,136) | (471,946) | (121,595) |
| Total stockholders’ equity | 38,865 | 19,736 | 101,020 | 168,814 | 23,422 |

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 below under "Factors That May Affect Results" 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 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. We have successfully developed several promising preclinical product candidates in the fields of kidney disease, cancer, neurological disorders, cardiovascular disease and hair growth regulation.

Since our inception, we have funded our operations primarily through license fees, research and development funding from our collaborative partners, 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 \$649,068,000 as of December 31, 2003. 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.

We currently have strategic collaborations with Ortho Biotech, Genentech and Wyeth. Our strategic alliances and collaborations generally provide for our research, development and commercialization programs to be 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. In some cases, we have retained development and commercialization rights in areas where we believe we can attain the greatest potential long-term value through the application of our own internal resources. In the future, we plan to continue to seek corporate partners for the further development and commercialization of some of our technologies. Even though we are seeking partners to help develop some of our technologies, we expect to select at least one program that we will develop further on our own.

Financial Operations Overview

General. Our future operating results will depend largely on the magnitude of payments from our current and potential future corporate partners and the progress of other product candidates currently in our research and development pipeline. The results of our operations will vary significantly from year to year and quarter to quarter and depend on, among other factors, the timing of our entry into new collaborations, the timing of the receipt of payments from collaborators and the cost and outcome of clinical trials. We believe that our existing capital resources should enable us to maintain current and planned operations into the first half of 2006.

Revenue. Other than royalty revenue from Stryker Corporation's sales of OP-1, a bone-inducing protein, we have not generated any revenue from product sales since our inception and do not expect to generate any revenue from the sale of products for several years, if ever. In late 2002, Stryker paid us \$14,000,000 in exchange for the termination of its future royalty obligations on OP-1. Accordingly, we will receive no future royalties on sales by Stryker of OP-1. Other than revenues from our agreements with Stryker, substantially all of our revenue

to date has been derived from license fees and research and development payments that we have received from our corporate collaborators. In the future, we will seek to generate revenue from a combination of up-front fees, research and development funding and milestone payments in connection with strategic collaborations, and royalties resulting from the sale of products which incorporate our intellectual property. We expect that any revenue 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 product candidates. These expenses consist primarily of salaries and related expenses for personnel, outside service costs including medicinal chemistry, consulting and sponsored research collaborations, occupancy and depreciation charges and the legal costs of pursuing patent protection of our intellectual property. We expense research and development costs, including patent-related costs, as incurred.

The following table summarizes our primary research and development programs, including the current development status of each program. In the table below, the term 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, and 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 application, or IND, filing with the FDA seeking to commence a phase I clinical trial to assess safety in humans. We have set forth below under “Results of Operations” the expenses incurred with respect to each product candidate for the fiscal years ended December 31, 2003, 2002 and 2001. We have not provided program costs since inception because prior to 2001 we did not track and accumulate cost information by research program.

| Product Candidate | Primary Indication | Partner/Licensee | Status |
|------------------------------|-------------------------------------|-------------------------|-------------------|
| BMP-7 protein | Kidney disease | Ortho Biotech | Late preclinical |
| Hh small molecule antagonist | Basal cell carcinoma | Genentech | Late preclinical |
| Hh small molecule antagonist | Cancer | Genentech | Mid preclinical |
| Hh antibody antagonist | Cancer | Genentech | Mid preclinical |
| Hh small molecule agonist | Central nervous system disorders | Wyeth | Mid preclinical |
| Hh small molecule agonist | Peripheral nervous system disorders | Wyeth | Mid preclinical |
| Hh small molecule agonist | Hair loss | In-house development | Late preclinical |
| Hh agonist/protein/gene | Cardiovascular disease | In-house development | Mid preclinical |
| Hh small molecule antagonist | Hair growth inhibition | In-house development | Early preclinical |
| PYY peptide | Obesity | Amylin Pharmaceuticals | IND filed |

There is a risk that any drug discovery and development program may not produce products or revenue. Moreover, because of uncertainties inherent in drug discovery and development, including those factors described below under “Risk Factors That May Affect Results,” we and our collaborative partners may not be able to successfully develop and commercialize any of the product candidates included in the table above.

All of our product development initiatives are in various stages of preclinical testing, other than our PYY peptide, which has been licensed to Amylin Pharmaceuticals and which is currently the subject of an investigational new drug application seeking FDA approval to begin human clinical trials. Because all of our product development initiatives are in early stages of development, 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, rate of progress and cost of clinical trials and other research and development activities undertaken by us or our collaborative partners;
- future clinical trials results;

- 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 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 the risks and uncertainties associated with completing our projects on schedule, or at all, and some consequences of failing to do so, are set forth below in “Risk Factors That May Affect Results.”

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 and professional fees for legal and accounting services.

Strategic Alliances and License Agreements. Since inception, substantially all of our revenue has been derived from collaborations and other research and development arrangements with third parties. Our current strategic alliances and key license agreements are as follows:

Ortho Biotech Collaboration. In November 2002, we licensed our broad BMP technology portfolio to Ortho Biotech on an exclusive, worldwide royalty-bearing basis, for all non-orthopedic and non-dental therapeutic applications in exchange for a \$3,500,000 up-front fee, a series of cash milestones if specified clinical research objectives and regulatory approvals are achieved, including a \$30,000,000 milestone payment upon U.S. regulatory approval of a product for the treatment of kidney disease, and a royalty on potential future product sales. If the program progresses successfully through clinical development, we are entitled to receive additional milestone payments for the kidney disease related product candidate and milestone payments for the first neurology product candidate.

Genentech, Inc. Collaboration. In June 2003, we licensed our novel small molecule and antibody inhibitors of the Hedgehog signaling pathway to Genentech on an exclusive worldwide royalty-bearing basis for applications in cancer therapy. Under the terms of the agreement, Genentech paid us an upfront license fee of \$5,000,000, purchased 1,323,835 shares of our common stock at a price of \$2.644 per share for aggregate proceeds of \$3,500,000, and is also obligated to pay us a total of \$4,000,000 in maintenance fees by July 2005. Genentech is also obligated to make cash payments to us upon the successful achievement of clinical development and drug approval milestones. In addition, Genentech will pay a royalty on potential future net product sales, which increases with increasing sales volume. We have retained the right to co-develop products in the field of basal cell carcinoma, in which event we will share in any profits related to the basal cell carcinoma program in a percentage that is equal to our co-development cost sharing contribution.

Wyeth Pharmaceuticals Collaboration. In January 2004, we entered into an agreement to license our Hedgehog proteins and novel small molecule Hedgehog pathway agonists to Wyeth on an exclusive worldwide, royalty-bearing basis for the development and commercialization of pharmaceutical products for the therapeutic applications in treatment of neurological disorders, including neurodegenerative diseases and neuropathies. Under the terms of the agreement, Wyeth Pharmaceuticals paid us a license fee of \$1,500,000 and purchased 315,524 shares of our common stock at a price of \$4.754 per share for an aggregate purchase

price of \$1,500,000. Wyeth will provide research funding for a minimum of two years. In addition, Wyeth is obligated to make cash payments to us upon the successful achievement of clinical development and drug approval milestones and is obligated to pay a royalty on net product sales, if any, that escalates with increasing sales volume.

Amylin Pharmaceuticals Licenses. In December 2002, we granted Amylin Pharmaceuticals an exclusive worldwide, royalty-bearing license to our PYY patent applications for use in the research, development and commercialization of products in exchange for an up-front fee, milestone payments upon the achievement of specified development objectives, and royalties on potential future product sales, if any. PYY is a gut peptide that has been shown in animals and humans to suppress appetite and reduce food intake. Amylin has exclusive responsibility for expenses related to further development of the PYY compound.

Critical Accounting Policies

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:

Long-Lived Assets. Long-lived assets consist of goodwill, long-term receivables, equity securities held in Micromet, ES Cell International and Aegera Therapeutics, capitalized patent costs and long-term deposits. We assess the impairment of identifiable intangibles and long-lived assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. In addition, we perform a goodwill impairment test annually. If it were determined that the carrying value of intangible or long-lived assets might not be recoverable based upon the existence of one or more indicators of impairment, we would measure any impairment based on a projected cash flow method.

As a result of the adoption of SFAS No. 142, effective January 1, 2002, we ceased amortization of goodwill and performed an initial assessment of impairment of our goodwill in the first quarter of 2002. This initial assessment involved comparing our fair value to our net assets. We determined our fair value based on quoted market prices adjusted to provide for a control premium. Our fair value was in excess of our net assets and, therefore, we concluded that our goodwill was not impaired. 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. During the three-month period ended June 30, 2002, we concluded that the decline in our market capitalization indicated that the carrying value of goodwill might be impaired. As a result, we conducted an impairment assessment as required under SFAS No. 142 by comparing our fair value to our net assets, including goodwill, as of June 30, 2002. Because the carrying value of our net assets exceeded our fair value at June 30, 2002, we determined that our goodwill had been impaired. To determine the amount of the impairment charge as a single reporting unit, we calculated our implied goodwill as the difference between our fair value and the fair value of our assets and liabilities. The fair value of our intangible assets, principally consisting of completed and in-process technology, was estimated using a discounted cash flow methodology. Based on this valuation, we determined that our implied goodwill was \$8,982,000, and we recorded a non-cash charge in the quarter ended June 30, 2002, of \$64,098,000 to write-down our existing goodwill.

The goodwill impairment analysis as of June 30, 2002 involved considerable judgment and the use of several estimates including: control premium, discount rates, projected cash flows of OP-1 and projected cash flows of our in-process research and development programs. The control premium used in determining our fair value was based on an analysis of control premiums involved in other biotechnology and medical products acquisitions. Most of our research and development programs will not be completed for several years, if ever, and therefore estimating the costs to complete these programs and the revenue to be derived through collaborations and commercialization of the products involves substantial judgment. The discount rates used to determine the net present value of these cash flows were based on a consideration of the risks associated with

achieving these cash flow projections, including the risk of successfully completing our in-process technology. All of these estimates involve a significant amount of judgment by our management. Although the estimates used reflect management's best estimates based upon all available evidence, the use of different estimates could have yielded different results in our transitional impairment assessment conducted as of January 1, 2002, and in our impairment assessment conducted in the second quarter of 2002. Had we used a significantly lower control premium in determining our fair value, our transitional impairment analysis could have indicated that goodwill was impaired at January 1, 2002. In addition, using different estimated cash flows or discount rates in determining our implied goodwill in the second quarter of 2002 could have resulted in a higher or lower goodwill impairment charge.

We completed our annual goodwill impairment test in December 2003, and determined that as of that date our fair value exceeded the carrying value of our net assets. Accordingly, no goodwill impairment was recognized in 2003.

During the year ended December 31, 2003, we recorded, in other expense, charges of \$1,708,000 related to the write-off of a euro-denominated note receivable that is due in June 2005 from Micromet, a former collaborator, and \$286,000 related to a reduction in the carrying value of Micromet equity securities held by us. We determined that these charges were necessary due to Micromet's recent announcement that it was terminating one-third of its workforce as the result of a contract dispute with a co-development partner. Micromet has stated that this dispute will result in a significant decrease of previously budgeted cash inflows in 2004, which, in our estimate, materially and adversely affects the likelihood of collection of the note receivable.

During the fourth quarter of the year ended December 31, 2002, we recorded an impairment charge of \$271,000 to write-off the carrying value of patents associated with our OP-1 technology, which is licensed to Stryker. The charge was recorded as a result of our transaction with Stryker under which, in exchange for \$14,000,000, we sold our rights to future royalties from Stryker on sales of OP-1. We wrote these patents off because we will not receive any future royalties or other revenue from Stryker and because these patents cannot be utilized for alternative uses in either current or future operations.

During the first quarter of the year ended December 31, 2002, we recorded impairment charges of property and equipment assets related to our business realignment of \$5,337,000. These charges related to impairment on assets at our former manufacturing and development facility located at 21 Erie Street in Cambridge, Massachusetts. Of the total impairment charge, \$4,761,000 relates to the write-off of tenant improvements made to the Erie Street facility, since such were affixed to the facility and therefore could not have been sold separately from the facility. The remaining charge of \$576,000 was to write-down equipment to its estimated salvage value. The amount we received from the sale of these assets was not significantly different from the originally estimated salvage value.

Revenue recognition. Revenue is a key component of our results of operations. We follow the provisions of the Securities and Exchange Commission's Staff Accounting Bulletin No. 104 (SAB No. 104), *Revenue Recognition*, and EITF 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*. In accordance with SAB No. 104, we recognize revenue related to research activities as they are performed, so long as there is persuasive evidence of an arrangement, the fee is fixed or determinable and collection of the related receivable is probable.

Amounts received for license fees are deferred and recognized as services are performed over the performance period of the contract. Amounts received for milestones will be recognized upon achievement of the milestone, as long as the milestone is deemed to be substantive and we have no other performance obligations. In the event that we have remaining performance obligations, the portion of the milestone payment equal to the lesser of the non-refundable cash received or the percentage of the services performed through that date multiplied by the total milestone payment would be recognized as revenue.

We recognized \$728,000 in revenue related to our collaboration with Genentech for the year ended December 31, 2003. This amount primarily consists of revenue recognized under the amortization of a \$5,000,000 up-front license fee received from Genentech in July 2003 and future maintenance fees totaling \$4,000,000 that will be paid over the first two years of the collaboration. The remainder will be recognized proportionately as the remaining services are performed. Revenues for research and development services are recognized as such services are performed.

For the year ended December 31, 2003, we recognized \$1,470,000 of revenues relating to research and development services performed under an agreement with ES Cell International.

Royalty revenue is recognized upon the sale of the related products, provided the royalty amounts are fixed or determinable and collection of the related receivable is reasonably assured. No royalty revenue was recognized during the year ended December 31, 2003.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying balance sheets. Amounts that we expect will not be recognized prior to December 31, 2004 are classified as long-term deferred revenue. As of December 31, 2003, we have recorded short- and long-term deferred revenue of \$1,241,000 and \$7,089,000, respectively, both of which are solely related to the \$5,000,000 up-front payment and the \$4,000,000 in future maintenance fee payments under our collaboration with Genentech.

We follow detailed guidelines in measuring revenue; however, certain judgments affect the application of our revenue policy. For example, in connection with our collaboration agreement with Genentech, 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. The estimate of deferred revenue reflects management's estimate of the period of our involvement with the collaboration. Our period of involvement is largely determined by the time to commercialize clinical candidates that we may co-develop with Genentech. Since the timing of clinical development is difficult to estimate, our estimates may change in the future. Such changes to estimates would result in a change in revenue recognition rates. As of December 31, 2003, \$670,000 has been recognized as revenue related to the amortization of the up-front license fee and future maintenance fees. The remaining \$8,330,000 is recorded as deferred revenue on our balance sheet at December 31, 2003. Under our current operating plan, we plan to recognize this revenue on a straight-line basis through the third quarter of 2010.

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.

Critical Accounting 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 include the collectibility of receivables, the carrying value of property and equipment and intangible assets and the value of certain liabilities. Actual results may differ from such estimates. Our more significant estimates are as follows:

Valuation of investments in privately-held companies. We have investments in Aegera, Micromet and ES Cell International with original cost bases of \$167,000, \$400,000 and \$150,000, respectively. These investments are included in the "Deposits and other assets" category of our consolidated balance sheets. At each balance sheet date, we review these investments to determine whether the fair value of these investments is less than the carrying value and, if so, whether we should write-down the investment. These companies are not publicly-traded and, therefore, determining the fair value of our investments in these companies involves significant judgment. We consider available information in estimating the fair value of these investments and, as of December 31, 2003, believe that the fair value of our investments in Aegera and ES Cell are not less than their carrying value.

However, Micromet recently announced that it terminated one-third of its workforce as the result of a contract dispute with a co-development partner that resulted in a significant decrease of previously budgeted cash inflows in 2004. Accordingly, we concluded that the carrying value of our investment in Micromet common stock had been impaired, and we recorded \$286,000 in other expense to reduce the carrying value to the estimated fair value of \$400,000. If the financial condition or results of Aegea or ES Cell decline significantly or if Micromet's financial condition continues to decline, the fair value of these investments would likely decline and, as a result, we may have to record an impairment charge to the extent such impairment is deemed other than temporary.

Timing of deferred revenue recognition. We have recorded short-term deferred revenue of \$1,241,000 and long-term deferred revenue of \$7,089,000 as of December 31, 2003. Short-term deferred revenue consists of amounts that are expected to be recognized as revenue by December 31, 2004. However, this estimate is based on our current operating plan as of December 31, 2003. If this operating plan should change in the future, we may recognize a different amount of deferred revenue over the twelve-month period from January 1, 2004, through December 31, 2004.

Results of Operations

Years Ended December 31, 2003 and 2002

Revenues

Total revenues are summarized as follows:

| | <u>For the Year Ended December 31,</u> | |
|--|--|---------------------|
| | <u>2003</u> | <u>2002</u> |
| Research and development contracts and government grants | \$ 1,629,000 | \$ 245,000 |
| License fees and royalties | 9,419,000 | 18,146,000 |
| Total revenues | <u>\$11,048,000</u> | <u>\$18,391,000</u> |

The increase in revenue from research and development contracts and government grants for the year ended December 31, 2003, as compared to the year ended December 31, 2002, was primarily due to our recognition of \$1,470,000 in the year ended December 31, 2003, relating to research and development services performed by us under our 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 and will therefore not recognize future revenues related to this collaboration. The research and development contract and government grant revenue for the year ended December 31, 2002, was derived entirely from revenue recognized under our licensing agreement with ES Cell International and our former collaboration with Micromet.

Our license fee revenue for 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. The decrease in license fees and royalty revenue for the year ended December 31, 2003, as compared to the year ended December 31, 2002, was primarily due to the recognition of revenue upon the completion of various transactions in 2002, including \$14,000,000 in revenue we recognized upon Stryker's buy-out of its royalty obligation to us for OP-1 and \$3,500,000 in revenue we recognized from an up-front payment received by us in connection with the licensing of certain of our BMP technologies to Ortho Biotech. In addition, we received \$387,000 in royalty revenue from Stryker on sales of OP-1 for the year ended December 31, 2002. As part of the Stryker transaction, we will receive no future royalties on sales by Stryker of OP-1. The decrease in license fee and royalty revenue from transactions in 2002 was partially offset by the Micromet revenue described above.

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>2003</u> | <u>2002</u> |
| Hh small molecule antagonist | Basal cell carcinoma | \$ 55,000 | \$ 34,000 |
| Hh small molecule antagonist and Hh small molecule antibody antagonist | Cancer | 3,830,000 | 3,536,000 |
| Hh small molecule agonist | Central nervous system disorders | 4,385,000 | 5,778,000 |
| Hh small molecule agonist | Peripheral nervous system disorders | 2,209,000 | 3,511,000 |
| Hh small molecule agonist | Hair loss | 673,000 | — |
| Other programs | | 2,247,000 | 6,462,000 |
| Costs allocated to Curis Newco joint venture | | — | (5,263,000) |
| Total research and development expense | | <u>\$13,399,000</u> | <u>\$14,058,000</u> |

In the foregoing table, “Other programs” includes expenses related to our Hh agonist/protein/gene product candidate for cardiovascular disease, as well as research and development expenses relating to adult stem cell and cell therapy programs. For the years ended December 31, 2003 and 2002, \$1,892,000 and \$5,255,000, respectively, related to our adult stem cell and cell therapy programs. As further described below, we reduced expenses incurred under our adult stem cell and cell therapy programs in connection with our business realignment in 2002. To date, we have not incurred material research and development expenses for our Hh small molecule antagonist product candidate for hair growth inhibition. All expenses relating to the development of our BMP-7 protein product candidate for kidney disease are borne by our partner, Ortho Biotech. Costs allocated to the Curis Newco joint venture relate to research expenses incurred by us and charged to Curis Newco, a joint venture that, until May 16, 2003, was operated by us and affiliates of Elan Corporation. Of this aggregate amount, \$2,984,000 was related to our central nervous system disorders program and \$2,279,000 was related to our peripheral nervous system disorders program.

The decrease in research and development expenses for the year ended December 31, 2003, as compared to the year ended December 31, 2002, was primarily due to a reduction in ongoing operating costs as a result of our business realignment in the first quarter of 2002, including reductions in amounts spent on stem cell and cell therapy programs. As a result of this realignment, our research and development expenses were focused principally on regulatory signaling pathways, particularly the Hedgehog Pathway, for the year ended December 31, 2003, and spending on our stem cell, cell therapy and other programs decreased by an aggregate of \$4,215,000, to \$2,247,000 for the year ended December 31, 2003, as compared to \$6,462,000 for the year ended December 31, 2002. Reductions in spending on our stem cell, cell therapy and other programs were offset by the termination of our collaboration with Elan, which resulted in no research and development expense being charged to Curis Newco in 2003 verse \$5,263,000 in 2002. In 2002, our research and development expenses were presented net of these expenses charged to Curis Newco.

General and administrative expenses are summarized as follows:

| | For the Year Ended December 31, | |
|---|------------------------------------|--------------------|
| | 2003 | 2002 |
| Personnel | \$2,584,000 | \$3,689,000 |
| Occupancy and depreciation | 671,000 | 889,000 |
| Legal and professional services | 706,000 | 1,221,000 |
| Consulting services | 326,000 | 327,000 |
| Reserve against notes receivable | 34,000 | 686,000 |
| Insurance costs | 547,000 | 512,000 |
| Other general and administrative expenses | 987,000 | 836,000 |
| Total general and administrative expenses | <u>\$5,855,000</u> | <u>\$8,160,000</u> |

The decrease in general and administrative expenses for the year ended December 31, 2003, as compared to the year ended December 31, 2002, was primarily due to a reduction in ongoing operating costs as a result of our business realignment in the first quarter of 2002, including reductions in personnel costs and legal and professional services. In addition, the amount charged to reserve for the possible non-collection of notes receivable outstanding to two former officers decreased by \$652,000 to \$34,000 for the year ended December 31, 2003, from \$686,000 for the year ended December 31, 2002.

Stock-based compensation decreased by \$529,000, or 24%, to \$1,631,000 for the year ended December 31, 2003, as compared to \$2,160,000 for the year ended December 31, 2002. The decrease was primarily attributable to a decrease in the amount of stock-based compensation expense related to our issuance on August 18, 2000 of stock options with exercise prices below fair market value. We recorded \$1,100,000 and \$1,893,000 in stock-based compensation related to these options for the years ended December 31, 2003 and 2002, respectively. Because these options were issued with exercise prices below fair market value, we recorded deferred compensation and have been amortizing the deferred compensation over the four-year vesting period of the options. When an option holder's employment with us is terminated, we treat any unvested portion of their options and related deferred compensation as charged to additional paid-in capital rather than stock-based compensation. Accordingly, the departure of four officers and 55 additional employees as a result of the realignment of our business and a subsequent staff reduction in December 2002 has resulted in a decrease in stock-based compensation expense, as the remaining deferred compensation balance associated with each terminated employees' August 18, 2000, stock options was immediately charged to additional paid-in capital.

Amortization of intangible assets decreased by \$399,000, or 84%, to \$75,000 for the year ended December 31, 2003, from \$474,000 for the year ended December 31, 2002. The decrease was primarily due to an impairment charge of approximately \$271,000 that we recorded during the fourth quarter of the year ended December 31, 2002, to reduce the carrying value of patents associated with our OP-1 technology that is licensed to Stryker. The charge was recorded as a result of our transaction with Stryker, under which Stryker bought out its future royalty obligation to us on sales of OP-1 for \$14,000,000. We wrote these patents off because we will not receive any future royalties or other revenue from Stryker and because these patents cannot be utilized for alternative uses in either current or future operations.

Loss on property and equipment for the year ended December 31, 2002, of \$5,337,000 related to impairment on assets at our facility at 21 Erie Street in Cambridge, Massachusetts. The total carrying value of assets at the Erie Street facility before the impairment charge was approximately \$5,652,000. The property and equipment assets at the Erie Street facility were used to support clinical programs that were suspended or terminated as part of the realignment and were deemed to be unlikely to be used in our future operations. Of the impairment charge, \$4,761,000 related to the write-off of tenant improvements made to the Erie Street facility since such improvements were affixed to the facility and therefore could not have been sold separately. The remaining

\$576,000 of impairment charge was to write down furniture and equipment assets to their estimated salvage value. We do not expect to incur additional impairment on property and equipment related to the realignment in future periods. The amount we received from the sale of these assets was not significantly different from the originally estimated salvage value.

Impairment of goodwill for the year ended December 31, 2002 was \$64,098,000. In accordance with SFAS No. 142, we concluded that the decline in our market capitalization during the three-month period ended June 30, 2002 indicated that the carrying value of our goodwill might be impaired. Accordingly, we conducted an impairment review as required under SFAS No. 142 as of June 30, 2002, and determined that goodwill impairment had occurred as of June 30, 2002. Our value, as a single reporting unit, was calculated using quoted market prices adjusted to provide for a control premium. In calculating the impairment charge, the fair value of our intangible assets, principally consisting of completed and in-process technology, was estimated using a discounted cash flow methodology.

Realignment expenses of \$3,490,000 were recorded for the year ended December 31, 2002. These charges relate to \$1,139,000 associated with workforce reductions of 46 people, including 4 officers, \$2,306,000 associated with the closing of clinical programs and decommissioning of a manufacturing and development facility and other costs of \$45,000. As of December 31, 2002, we expended approximately all of the \$3,490,000 in realignment expenses. We do not expect to incur additional expenses related to this realignment in future periods.

Equity in Loss from Joint Venture

We recorded no equity in loss from joint venture during the year ended December 31, 2003, as compared to \$4,311,000 during the year ended December 31, 2002. The equity in loss from joint venture relates to a joint venture, Curis Newco, which we formed in July 2001 with affiliates of Elan Corporation. This joint venture was terminated on May 16, 2003. As a result of the termination, we now own 100% of the outstanding shares of Curis Newco.

Other Income (Expense)

For the year ended December 31, 2003, interest income was \$428,000 as compared to \$1,067,000 for the year ended December 31, 2002, a decrease of \$639,000, or 60%. The decrease in interest income resulted from a lower available investment balance and lower average investment yields for the year ended December 31, 2003, as compared to the year ended December 31, 2002.

For the year ended December 31, 2003, other expense was \$1,445,000 as compared to other income of \$1,262,000 for the year ended December 31, 2002, a decrease of \$2,707,000. This decrease was principally due to an impairment charge of \$1,994,000 for the write-off of a euro-denominated note receivable from Micromet, a former collaborator, during the fourth quarter of the year ended December 31, 2003, as well as a decrease in the gain recognized on currency rate fluctuations on the Micromet note receivable of \$207,000. In addition, the amount of gain recognized on sales of securities decreased by \$504,000 in the year ended December 31, 2003, as compared to the year ended December 31, 2002. We recognized gains on sales of securities of \$97,000 for the year ended December 31, 2003, as compared to \$601,000 for the year ended December 31, 2002.

For the year ended December 31, 2003, interest expense was \$694,000, as compared to \$947,000 for the year ended December 31, 2002, a decrease of \$253,000, or 27%. The decrease in interest expense resulted from the decrease in the amount of interest expense that we paid on capital leases in 2003 compared to 2002.

Accretion on Series A Convertible Exchangeable Preferred Stock

Accretion of preferred stock dividend for the year ended December 31, 2003 was \$271,000, as compared to \$723,000 for the year ended December 31, 2002, a decrease of \$452,000, or 63%. This charge relates to the

accretion of a mandatory 6% dividend on shares of convertible exchangeable preferred stock issued to an affiliate of Elan as part of a joint venture with Elan. The decrease is attributed to the termination of the joint venture on May 16, 2003, in which the convertible exchangeable preferred stock was cancelled as part of the termination. The amounts are included in the net loss applicable to common stockholders for the years ended December 31, 2003 and 2002.

Net Loss Applicable to Common Stockholders

As a result of the foregoing, we incurred a net loss applicable to common stockholders of \$11,895,000 for the year ended December 31, 2003, as compared to \$83,038,000 for the year ended December 31, 2002.

Years Ended December 31, 2002 and 2001

Revenues

Total revenues are summarized as follows:

| | For the Year Ended December 31, | |
|--|--|--------------------|
| | 2002 | 2001 |
| Research and development contracts and government grants | \$ 245,000 | \$ 968,000 |
| License fees and royalties | 18,146,000 | 119,000 |
| Total revenues | <u>\$18,391,000</u> | <u>\$1,087,000</u> |

Revenue from research and development contracts and government grants for the year ended December 31, 2002, was derived entirely from revenue recognized under our licensing agreement with ES Cell International and our former collaboration with Micromet. For the year ended December 31, 2001, this revenue was derived solely from government grants.

The increase in license fees and royalties for the year ended December 31, 2002, as compared to the year ended December 31, 2001, was primarily due to the recognition of revenue upon the completion of various transactions in 2002 including \$14,000,000 in revenue we recognized upon Stryker's buy-out of its royalty obligation to us for OP-1, \$3,500,000 in revenue we recognized from an up-front payment received by us in connection with the licensing of certain of our BMP technology to Ortho Biotech and \$258,000 we recognized under other transactions completed in 2002. In addition, royalty revenue received in 2002 from Stryker on sales of OP-1 increased by \$268,000 to \$387,000 for the year ended December 31, 2002, as compared to \$119,000 for the year ended December 31, 2001. As part of the Stryker transaction, we will receive no future royalties on sales by Stryker of OP-1.

Operating Expenses

Research and development expenses are summarized as follows:

| Research and Development Program | Primary Indication | Year Ended December 31, | |
|--|-------------------------------------|--------------------------------|---------------------|
| | | 2002 | 2001 |
| Hh small molecule antagonist | Basal cell carcinoma | \$ 34,000 | \$ 3,631,000 |
| Hh small molecule antagonist and Hh small molecule antibody antagonist | Cancer | 3,536,000 | 2,940,000 |
| Hh small molecule agonist | Central nervous system disorders | 5,778,000 | 2,219,000 |
| Hh small molecule agonist | Peripheral nervous system disorders | 3,511,000 | 5,037,000 |
| Hh small molecule agonist | Hair loss | — | — |
| Other programs | | 6,462,000 | 17,019,000 |
| Costs allocated to Curis Newco joint venture | | (5,263,000) | (1,774,000) |
| Total research and development expense | | <u>\$14,058,000</u> | <u>\$29,072,000</u> |

In the foregoing table, "Other programs" includes expenses related to our Hh agonist/protein/gene product candidate for cardiovascular disease, as well as research and development expenses relating to adult stem cell and cell therapy programs. For the years ended December 31, 2002 and 2001, \$5,255,000 and \$16,160,000, respectively, related to our adult stem cell and cell therapy programs. As further described below, we reduced expenses incurred under our adult stem cell and cell therapy programs in connection with our business realignment in 2002. To date, we have not incurred material research and development expenses for our Hh small molecule antagonist product candidate for hair growth inhibition. All expenses relating to the development of our BMP-7 protein product candidate for kidney disease are borne by our partner, Ortho Biotech. Costs allocated to the Curis Newco joint venture relate to research expenses incurred by us and charged to Curis Newco. For the year ended December 31, 2002, \$2,984,000 was related to our central nervous system disorders program and \$2,279,000 was related to our peripheral nervous system disorders program. For the year ended December 31, 2001, \$764,000 was related to our central nervous system disorders program and \$1,010,000 was related to our peripheral nervous system disorders program.

The decrease in research and development expenses for the year ended December 31, 2002, as compared to the year ended December 31, 2001, was primarily due to a reduction in ongoing operating costs as a result of our business realignment in the first quarter of 2002, particularly for reductions in amounts spent on our cell therapy programs since all such programs were terminated as a result of this realignment. Spending on our cell therapy programs decreased by \$12,174,000, to \$742,000 for the year ended December 31, 2002, as compared to \$12,916,000 for the year ended December 31, 2001. In addition, our research expenses charged to Curis Newco increased by \$3,489,000, from \$1,774,000 for year ended December 31, 2001, to \$5,263,000 for the year ended December 31, 2002. This resulted in lower research and development expenses in 2002, as compared to 2001, since research and development expenses at our consolidated statement of operations are presented net of expenses charged to Curis Newco.

General and administrative expenses are summarized as follows:

| | For the Year Ended December 31, | |
|---|------------------------------------|---------------------|
| | 2002 | 2001 |
| Personnel | \$3,689,000 | \$ 3,978,000 |
| Occupancy and depreciation | 889,000 | 1,545,000 |
| Legal and professional services | 1,221,000 | 1,842,000 |
| Consulting services | 327,000 | 775,000 |
| Creative officer notes receivable | 686,000 | 508,000 |
| Insurance costs | 512,000 | 352,000 |
| Other general and administrative expenses | 836,000 | 1,493,000 |
| Total general and administrative expenses | <u>\$8,160,000</u> | <u>\$10,493,000</u> |

The decrease in general and administrative expenses in the year ended December 31, 2002, as compared to the year ended December 31, 2001, was primarily due to a reduction in ongoing operating costs as a result of our business realignment in the first quarter of 2002, including reductions in consulting and legal and professional services. We also entered into two agreements in 2002 for the sublease of 17,000 square feet of lab and office space, resulting in decreases to our occupancy costs in 2002.

Stock-based compensation decreased by \$8,198,000, or 79%, to \$2,160,000 for the year ended December 31, 2002, from \$10,358,000 for the year ended December 31, 2001. The decrease was primarily attributable to the stock-based compensation expense related to deferred compensation resulting from our merger in 2000. This stock-based compensation, which was \$6,257,000 for the year ended December 31, 2001, was amortized over the vesting period of the underlying options through August 1, 2001. Because the amortization period ended on August 1, 2001, we recorded no stock-based compensation related to these options for the year ended December 31, 2002. In addition, there was a decrease in the amount of stock-based compensation expense related to our issuance on August 18, 2000, of stock options with exercise prices below fair market value. We recorded

\$1,893,000 and \$3,964,000 in stock-based compensation related to these options for the years ended December 31, 2002 and 2001, respectively. Because these options were issued with exercise prices below fair market value, we recorded deferred compensation and have been amortizing the deferred compensation over the four-year vesting period of the options. When an option holder's employment with us is terminated, we treat any unvested portion of their options and related deferred compensation as charged to additional paid-in capital rather than to stock-based compensation. Accordingly, the departure of four officers and approximately 55 other employees as a result of the realignment of our business and a subsequent staff reduction in December 2002 has resulted in a decrease of stock-based compensation expense, since the remaining deferred compensation balance associated with each terminated employees' August 18, 2000, stock options was immediately charged to additional paid-in capital. The remaining deferred compensation related to the August 12, 2000, options will be amortized in 2004.

Amortization of intangible assets decreased by \$22,864,000, or 98%, to \$475,000 for the year ended December 31, 2002, from \$23,339,000 for the year ended December 31, 2001. The decrease was primarily due to the adoption of SFAS 142, which required companies to stop amortizing goodwill and certain other intangible assets. We currently amortize only capitalized patent and technology costs. Amortization of goodwill totaling \$23,114,000 was recorded for the year ended December 31, 2001.

Loss on property and equipment for the year ended December 31, 2002 of \$5,337,000 related to impairment on assets at our facility at 21 Erie Street in Cambridge, Massachusetts, as described above.

Impairment of goodwill for the year ended December 31, 2002 was \$64,098,000, as described above.

Realignment expenses of \$3,490,000 were recorded for the year ended December 31, 2002. These charges relate to: (i) \$1,139,000 associated with workforce reductions of 46 people, including 4 officers, (ii) \$2,306,000 associated with the closing of clinical programs and decommissioning of a manufacturing and development facility and other costs of \$45,000. As of December 31, 2002, we expended approximately all of the \$3,490,000 in realignment expenses. We do not expect to incur additional expenses in future periods.

Equity in Loss from Joint Venture

Equity in loss from joint venture decreased by \$9,142,000, or 68%, to \$4,311,000 for the year ended December 31, 2002, from \$13,453,000 for the year ended December 31, 2001. The equity in loss from joint venture related to our joint venture with affiliates of Elan. The decrease was primarily caused by our 80.1%, or \$12,015,000, share of a \$15,000,000 write-off of technology recorded by the joint venture in July 2001. This decrease was partially offset by an increase in our 80.1% share of ongoing operating expenses recorded by the joint venture for the year ended December 31, 2002, as compared to the year ended December 31, 2001. The increase in ongoing operating expenses for the year ended December 31, 2002, as compared to the year ended December 31, 2001, was primarily caused by the joint venture operating for twelve months in 2002 versus five months in 2001.

Other Income (Expenses)

For the year ended December 31, 2002, interest income was \$1,067,000 as compared to \$2,854,000 for the year ended December 31, 2001, a decrease of \$1,787,000, or 63%. The decrease in interest income resulted from a lower available investment balance and lower average investment yields for the year ended December 31, 2002, as compared to the year ended December 31, 2001.

For the year ended December 31, 2002, other income was \$1,262,000 as compared to \$1,694,000 for the year ended December 31, 2001, a decrease of \$432,000, or 26%. This decrease was principally due to a decrease in the amount of gain recognized on sales of Exelixis common stock. We recognized gains of \$601,000 and \$1,466,000 for the years ended December 31, 2002 and 2001, respectively, related to sales of Exelixis, Inc. common stock. The decrease in the gain recognized on sales of Exelixis common stock was partially offset by an increase in the gain recognized on currency rate fluctuations on a euro-denominated note receivable issued to us by Micromet in connection with a collaboration. We recognized gains on currency rate fluctuations of \$660,000 and \$145,000, respectively, for the years ended December 31, 2002 and 2001.

For the year ended December 31, 2002, interest expense was \$947,000, as compared to \$784,000 for the year ended December 31, 2001, an increase of \$163,000, or 21%. The increase in interest expense resulted partially from the increase in the amount that we owed to Elan Pharma International, Ltd., an affiliate of Elan, as part of our Curis Newco joint venture. Interest expense associated with the Curis Newco joint venture increased to \$200,000 for the year ended December 31, 2002, from \$1,000 for the year ended December 31, 2001. In addition, we incurred \$193,000 for the year ended December 31, 2002 in non-cash interest expense related to a \$2,000,000 convertible subordinated note payable issued to Becton Dickinson in June 2001. This represented a \$121,000 increase over the \$99,000 incurred for the year ended December 31, 2001. These increases were partially offset by a decrease in interest expense paid on capital leases in 2002 compared to 2001.

Accretion on Series A Convertible Exchangeable Preferred Stock

Accretion on Series A Convertible Exchangeable Preferred Stock increased by \$397,000, or 121%, to \$723,000 for the year ended December 31, 2002, from \$326,000 for the year ended December 31, 2001. This charge relates to the accretion of a mandatory dividend on shares of convertible exchangeable preferred stock issued to an affiliate of Elan. The amounts are included in the net loss applicable to common stockholders for years ended December 31, 2002 and 2001.

Net Loss Applicable to Common Stockholders

As a result of the foregoing, we incurred a net loss applicable to common stockholders of \$83,038,000 for the year ended December 31, 2002, as compared to \$82,190,000 for the year ended December 31, 2001.

Liquidity and Capital Resources

Our liquidity requirements have historically consisted of research and development expenses, capital expenditures, working capital and general corporate expenses. At December 31, 2003, our principal sources of liquidity consisted of cash, cash equivalents, marketable securities and long-term investments of \$37,538,000, excluding restricted cash and cash equivalents of \$191,000. Since inception, we have financed our operations primarily through license fees, research and development funding from our collaborative partners, the private and public placement of our equity securities, debt financing and the amortization of certain royalty rights.

Net cash used in operating activities was \$9,761,000 for the year ended December 31, 2003, as compared to \$6,918,000 for the year ended December 31, 2002. Cash used in operating activities during the year ended December 31, 2003 was primarily to fund our net loss of \$11,623,000, partially offset by \$5,588,000 in non-cash charges including stock-based compensation expense, depreciation and amortization, non-cash interest expense on notes payable, amortization of intangible assets and an impairment of a long-term note receivable and investment in Micronet, a former collaborator of ours. In addition, we used \$3,273,000 of operating cash as a result of changes in certain of our operating assets and liabilities during the year ended December 31, 2003. Net cash used in operating activities during the year ended December 31, 2002, was primarily the result of our net loss for the period of \$82,315,000, partially offset by \$74,384,000 in non-cash charges including impairment charges on our intangible and tangible assets, stock-based compensation, depreciation, amortization and non-cash interest income and expense. Our net loss was further offset by our equity in loss of joint venture and our use of operating cash as a result of changes in certain of our assets and liabilities.

Investing activities generated \$1,645,000 of net cash for the year ended December 31, 2003, as compared to net cash used in investing activities of \$1,066,000 for the year ended December 31, 2002. Net cash generated for the year ended December 31, 2003, was driven by a reduction in restricted cash balances of \$4,213,000, resulting from the full repayment of our loan agreement with the Boston Private Bank & Trust Company. Cash used by investing activities in 2002 was primarily the result of the transfer of \$4,403,000 to a restricted cash account under the terms of a debt agreement with the Boston Private Bank & Trust Company, offset in part by net proceeds from the sale of marketable securities.

Financing activities generated \$8,930,000 of net cash for the year ended December 31, 2003, as compared to net cash used in financing activities of \$3,374,000 for the year ended December 31, 2002. The cash generated by financing activities during 2003 was principally the result of the sale of \$15,401,000 of our common stock, including \$9,805,000 from a private placement of 3,589,700 shares of common stock, and warrants to purchase 1,076,910 shares of common stock, in August 2003, \$3,500,000 from the sale of 1,323,835 shares of common stock to Genentech, and \$1,057,000 in proceeds received upon stock option exercises. These amounts were partially offset by repayments of debt totaling \$6,820,000, including \$4,213,000 in full repayment of our debt with the Boston Private Bank & Trust Company, \$1,500,000 as partial repayment of our convertible promissory note payable to Elan pursuant to our May 16, 2003 termination agreement, and \$1,224,000 in repayments of notes payable and capital leases. The cash used in financing activities for the year ended December 31, 2002 was primarily due to \$2,549,000 in net repayments of obligations under capital lease and debt arrangements. In addition, we used \$869,000 in cash to repurchase shares of our common stock during 2002.

In June, 2003, we licensed our small molecule and antibody antagonists of the Hedgehog signaling pathway to Genentech for applications in cancer therapy pursuant to the terms of a collaborative research, development and license agreement. The collaboration agreement provides for cash payments from Genentech, including an up-front payment of \$5,000,000, maintenance fee payments totaling \$4,000,000 over the first two years of the collaboration, none of which was received in 2003, and milestone payments at various intervals during the regulatory approval process of small molecule and antibody product candidates, assuming specified research objectives are met. Genentech is also obligated to pay us a royalty on potential future product sales. Under the terms of the collaboration agreement, we are required to commit eight employees to the small molecule and/or antibody programs for a period of two years. We are recognizing revenue related to the \$5,000,000 up-front payment and the \$4,000,000 maintenance fee payments receivable over our estimated period of involvement related to the collaboration. Under our current operating plan, we expect to recognize approximately \$1,200,000 in 2004 related to these payments. In addition, as partial consideration for the rights and licenses granted under the collaboration agreement, with respect to certain types of licensed compounds, we sold 1,323,835 shares of our common stock to Genentech at a purchase price of \$2.644 per share for aggregate proceeds of \$3,500,000, pursuant to the terms of a stock purchase agreement. We also entered into a registration rights agreement with Genentech covering the registration of the shares of common stock for resale under specified conditions.

In April 2003, we amended our loan agreement with the Boston Private Bank & Trust Company. Under the terms of the amended loan amendment, we ceased making our quarterly principal payments. Instead, the loan was structured as a revolving credit facility under which up to \$7,000,000 could have been borrowed and remained outstanding until the repayment date of April 1, 2005. We continued to pay interest monthly in arrears at variable interest rates during 2003. This loan was fully collateralized with a money market account maintained at the Boston Private Bank & Trust Company. In December 2003, we paid in full the outstanding loan balance of \$3,996,000 with funds held in our fully collateralized money market account at the Boston Private Bank & Trust Company. We had paid \$217,000 earlier in 2003.

In July 2001, we issued to Elan shares of our Series A convertible/exchangeable preferred stock valued at \$12,015,000 to fund our pro rata share of the initial capitalization of Curis Newco. We 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 of the joint venture program with Elan. As partial consideration for the rights and benefits described in the termination agreement, including the cancellation of the preferred stock, we issued 2,878,782 shares of our common stock to Elan, having a fair value of \$8,377,000 based on the May 16, 2003 closing price of our common stock on The Nasdaq National Market. Upon the termination of the Elan agreement, we 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 our common stock. Lastly, as a result of the termination, all rights granted by both us 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 us, both in our own right and as sole shareholder of Curis Newco. According to provisions in the

termination agreement, we 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.

In June 2001, we received \$2,000,000 from Becton Dickinson under a convertible subordinated note payable in connection with the exercise by Becton Dickinson of an option to negotiate a collaboration agreement. The note payable is repayable at any time up to its maturity date of June 26, 2006, by us, at our discretion, in either cash or issuance to Becton Dickinson of shares of our common stock. The note payable bears interest at 7%. As of December 31, 2003, there was \$2,352,000, including \$352,000 in accrued interest, outstanding under the note payable.

We lease equipment under various capital lease arrangements. Monthly payments on leases outstanding as of December 31, 2003 range from \$1,880 to \$21,170 and maturities range from March 2004 to July 2004. The initial terms of the leases range from 36 months to 60 months and bear interest at rates ranging from 12.5% to 16.3%. As of December 31, 2003, \$323,000 was outstanding under these agreements and we were in compliance with all material covenants under these agreements.

As of December 31, 2003, we had future payments required under contractual obligations and other commitments as follows:

| | (Amounts in \$ 000's) | | | | | Total |
|---|-----------------------|---------------|-----------------|-----------------|------------|-----------------|
| | 2004 | 2005 | 2006 | 2007 | 2008 | |
| Convertible subordinated long-term debt (1) | \$ — | \$— | \$2,805 | \$3,812 | \$— | \$ 6,617 |
| Capital lease obligations | 339 | — | — | — | — | 339 |
| Operating lease obligations | 822 | 822 | 1,433 | 518 | — | 3,595 |
| Outside service obligations | 1,373 | — | — | — | — | 1,373 |
| Licensing obligations | 450 | — | — | — | — | 450 |
| Total future obligations | <u>\$ 2,984</u> | <u>\$ 822</u> | <u>\$ 4,238</u> | <u>\$ 4,330</u> | <u>\$—</u> | <u>\$12,374</u> |

(1) Convertible subordinated debt is convertible into either shares of our common stock or payable in cash at our option.

We anticipate that existing capital resources should enable us to maintain current and planned operations into the first half of 2006. 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 first half of 2006 is dependent upon the success of our collaborations, our ability to maintain or reduce 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, 2003.

Inflation

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

New Accounting Pronouncements

In January 2003, the FASB issued Interpretation No. 46, *Consolidation of Variable Interest Entities* and, in December 2003, issued a revision to that interpretation FIN 46R. FIN 46R replaces FIN 46 and addresses consolidation by business enterprises of variable interest entities that possess certain characteristics. A variable interest entity (“VIE”) is defined as (a) an ownership, contractual or monetary interest in an entity where the ability to influence financial decisions is not proportional to the investment interest, or (b) an entity lacking the invested capital sufficient to fund future activities without the support of a third party. FIN 46R establishes standards for determining under what circumstances VIEs should be consolidated with their primary beneficiary, including those to which the usual condition for consolidation does not apply. Our adoption of FIN 46R is not expected to have any effect on our financial position or results of operations.

In April 2003, the FASB issued SFAS No. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities*. This statement amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts, collectively referred to as derivatives, and for hedging activities under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. SFAS No. 149 is effective for contracts entered into or modified and for hedging relationships designated after June 30, 2003. At December 31, 2003, we had no financial instruments falling within the scope of SFAS No. 149.

In May 2003, the FASB issued SFAS 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*. SFAS 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of those instruments were previously classified as equity. This statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after December 15, 2003. The adoption of SFAS 150 did not have a material effect on our financial statements.

In May 2003, the FASB also issued EITF 01-8, *Determining Whether an Arrangement Contains a Lease*, which requires capital lease treatment for arrangements containing an embedded lease, thereby conveying the right to control the use of property, plant or equipment (collectively, “property”) whether the right to control the use of the property is explicitly or implicitly specified. The right is conveyed if the purchaser (lessee) obtains physical or operational control of the underlying property or takes substantially all of its output. This pronouncement applies prospectively to new or modified arrangements beginning after May 28, 2003. The adoption of EITF 01-8 had no impact on our financial statements.

Effective July 1, 2003, we adopted EITF 00-21, *Accounting For Revenue Arrangements with Multiple Deliverables*, which establishes criteria for whether revenue on a deliverable can be recognized separately from other deliverables in a multiple deliverable arrangement. The criteria considers whether the delivered item has stand-alone value to the customer, whether the fair value of the delivered item can be reliably determined and the customer’s right of return for the delivered item. The adoption of EITF 00-21 did not have a material impact on our financial statements.

On December 17, 2003, the Staff of the Securities and Exchange Commission (SEC or the Staff) issued SAB 104, *Revenue Recognition*, which amends SAB 101, *Revenue Recognition in Financial Statements*. SAB 104’s primary purpose is to rescind accounting guidance contained in SAB 101 related to multiple element revenue arrangements, superseded as a result of the issuance of EITF 00-21. Additionally, SAB 104 rescinds the SEC’s *Revenue Recognition in Financial Statements Frequently Asked Questions and Answers* (the FAQ) issued with SAB 101 that had been codified in SEC Topic 13, *Revenue Recognition*. Selected portions of the FAQ have been incorporated into SAB 104. While the wording of SAB 104 has changed to reflect the issuance of EITF 00-21, the revenue recognition principles of SAB 101 remain largely unchanged by the issuance of SAB 104. The adoption of SAB 104 did not have a material impact on our financial statements.

Factors That May Affect Results

Risks Relating To Our Financial Results And Need For Financing

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, 2003, we had an accumulated deficit of approximately \$649.1 million. It is uncertain when, if ever, we will develop significant sources of ongoing revenue or achieve profitability, even if we are able to develop and commercialize products.

Even if our collaboration agreements provide funding for a portion of our research and development expenses for some of our programs, we expect to spend significant capital to fund our internal research and development programs for the foreseeable future. As a result, we will need to generate significant revenues in order to achieve profitability. We cannot be certain whether or when this will occur because of the significant uncertainties that affect our business. 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 are likely to require additional financing, which may be difficult to obtain and may dilute your ownership interest in us.

We will require substantial funds to continue our research and development programs. We believe that our existing cash and working capital should be sufficient to fund our operations until the first half of 2006. However, our future capital requirements may vary from what we expect and will depend on numerous factors, many of which are outside our control, including the following:

- continued progress in our research and development programs, as well as the magnitude of these programs;
- the cost of additional facilities requirements, if any;
- our ability to establish and maintain collaborative arrangements;
- the timing, receipt and amount of research funding and milestone, license, royalty and other payments, if any, from collaborative partners;
- 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 to us, if any, from our product candidates in the market;
- the cost of manufacturing and commercialization activities, if any; 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 collaborative arrangements with strategic partners and may seek additional funding through public or private financings. However, the biotechnology market in general, and the market for our common stock, in particular, is highly volatile. Due to 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, development, commercialization, manufacturing and marketing 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 collaborative partners 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. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. There can be no assurance, however, that our estimates, or the assumptions underlying them, will be correct. Our actual financial results may vary significantly from the estimates contained in our financial statements.

Risks Relating To Our Collaborations

We are dependent on collaborative partners for the development and commercialization of many of our product candidates. If we lose any of these partners, 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, Ortho Biotech Products, and Wyeth. We expect to enter into additional collaborations in the future. Our existing and any future alliances may not be scientifically or commercially successful.

The risks that we face in connection with these alliances 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 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 alliance agreements are for fixed terms and are subject to termination under various circumstances, including in some cases, on short notice without cause. If any collaborative partner were to terminate an agreement, we may be required to 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 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 alliance with us.
- Our collaborators may change the focus of their development and commercialization efforts. Pharmaceutical and biotechnology companies historically have re-evaluated their priorities following mergers and consolidations, which have been common in recent years in these industries. The ability of certain of our product candidates to reach their potential 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 alliances, which could adversely affect our ability to develop and commercialize products and services.

As an integral part of our ongoing research and development efforts, we periodically review opportunities to establish new collaborations, joint ventures and strategic alliances 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 alliances or other alternative arrangements. Even if we are successful in our efforts to establish an alliance or agreement, the terms that we establish may not be favorable to us. Finally, such strategic alliances or other arrangements may not result in successful products and associated revenue.

Risks Related To Our Business, Industry, Strategy And Operations

Other than OP-1, which we and Stryker commercialized under our former collaboration, we have not commercialized any products to date, either alone or with a collaborator. If we are not able to commercialize any products, we will not be profitable.

Most of our product opportunities are in various stages of preclinical development. Because our product opportunities have several years of development prior to reaching commercialization, there is a substantial risk that none of our current product opportunities will ever be commercialized. If none of our product opportunities are commercialized, we will not be profitable.

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 with existing and new 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 in cancer, with Genentech and renal disease, with Ortho Biotech, 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 in advance of us. 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 collaboration partner. For those programs that we have selected for further 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 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.

Since our technologies have many potential applications and we have limited resources, our election to focus on a particular application may result in our failure to capitalize on other potentially profitable applications of our technologies.

We have limited financial and managerial resources. These limitations require us to focus on a select group of product candidates in specific therapeutic areas and to forego the exploration of other product opportunities. While our 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. Our decisions as to resource allocation may not lead to the development of viable commercial products and may divert resources away from other market opportunities which ultimately prove to be more profitable.

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

If any of our product opportunities ever receive regulatory approval, the commercial success of these products will depend upon their acceptance by patients, the medical community and third-party payors. 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 our products. If we are not able to obtain a positive reception for our products, our expected revenues from sales of these products would be adversely affected.

We could be exposed to significant risk from liability claims if we are unable to obtain insurance at acceptable costs or otherwise protect ourselves against potential product liability claims.

We may be subjected to product liability claims arising from the testing, manufacturing, marketing and sale of human health care products. 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.

Our growth could be limited if we are unable to attract and retain key personnel and consultants.

Our success depends on the ability to attract, train and retain qualified scientific and technical personnel to further our research and development efforts. The loss of services of one or more of our key employees or consultants could have a negative impact on our business and operating results. Locating candidates with the appropriate qualifications can be difficult. Although we expect to be able to attract and retain sufficient numbers of highly skilled employees for the foreseeable future, we may not be able to do so.

Any growth and expansion into areas and activities that may require additional human resources or expertise, such as regulatory affairs and compliance, would require us to either hire new key personnel or obtain such services via an outsourcing arrangement. The pool of personnel with the skills that we require is limited. We may not be able to hire or contract such additional personnel.

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. If these clinical trials are not successful, or if we or our collaborators are not able to obtain the necessary 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 contract research organizations and collaborative partners 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, 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, obtain unfavorable results in a development program, or fail to obtain regulatory approval for the commercialization of a product. Furthermore, the timing and completion of clinical trials, if any, of our product candidates depend on, among other factors, the numbers of patients required for approval and the rate at which those patients are enrolled. Any increase in the required number of patients or decrease in recruitment rates may result in increased costs, program delays or both. 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. 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 are able to advance an internal program through the clinic, we will be required to obtain regulatory approval for any product we develop in such program. In instances where our product candidates are being developed by our collaborators, our partners will be required to obtain regulatory approval for marketing and selling efforts.

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. 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 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 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, 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 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, our stock price could decline.

Even if marketing approval is obtained, internally developed or licensed products will be subject to ongoing regulatory oversight which may affect the successful commercialization of our 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 are subject to governmental regulations other than those imposed by the FDA. We may not be able to comply with these regulations, which could subject us to penalties and otherwise result in the limitation of our operations.

In addition to regulations imposed by the FDA, we 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 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 commercial quantities, in compliance with regulatory requirements, at acceptable costs and in a timely manner. The manufacture of our product candidates may be complex, difficult to accomplish and difficult to scale-up when large-scale production is required. Manufacture may be subject to delays, inefficiencies and poor or low yields of quality products. The cost of manufacturing some of our products may make them prohibitively expensive. If supplies of any of our product candidates or related materials become unavailable 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, there will be a dependency upon these third parties to perform their obligations in a timely and effective manner and in accordance with government regulations. 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, Ortho Biotech and Wyeth, 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 Relating To Intellectual Property

If we breach any of the agreements under which we license or have acquired intellectual property from others, we could lose intellectual property rights that are important to our business.

We are a party to intellectual property licenses and agreements that are important to our business and expect to enter into similar licenses and agreements in the future. These licenses and agreements impose various research, development, commercialization, sublicensing, royalty, indemnification, insurance and other obligations on us. If we or our collaborators fail to perform under these agreements or otherwise breach obligations thereunder, we could lose intellectual property rights that are important to our business.

We may not be able to obtain patent protection for our discoveries and our technologies may be found to infringe patent rights of third parties.

The patent positions of pharmaceutical and biotechnology companies, including ours, are generally uncertain and involve complex legal, scientific and factual questions.

The long-term success of our enterprise depends in significant part on our ability to:

- obtain patents to protect our 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 allowed claims 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.

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

We also rely significantly upon proprietary technology, information, processes and know-how that is 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 may be breached, and we may not have adequate remedies for such breach. In addition, our trade secrets may otherwise become known or be independently developed by competitors.

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

There has 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 or proposed services 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, likely would 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.

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 licensees or assignees of our intellectual property rights breach any of the agreements under which we have licensed or assigned our intellectual property to them, 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.

Risks Related To Our Common Stock

We expect that our stock price will fluctuate significantly and the market price of our common stock could drop below the price you 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 \$5.92 and as low as \$0.65 per share in the year ended December 31, 2003. The stock market, particularly in recent years, has experienced significant volatility with respect to biopharmaceutical- and biotechnology-based company stocks. The volatility of biopharmaceutical- and biotechnology-based company stocks often does not relate to the operating performance of the companies represented by the stock. Prices for our stock will be determined in the market place 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;
- deviations in our operating results from the estimates of securities analysts;
- adverse results or delays in clinical trials;
- 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.

Our common stock may be delisted from The Nasdaq National Market, which could reduce the liquidity of our common stock and adversely affect our ability to raise additional necessary capital.

In order to continue trading on The Nasdaq National Market, we must comply with The Nasdaq National Market's continued listing requirements, which require that we either maintain a minimum stockholders' equity of \$10.0 million and a minimum closing bid price of \$1.00 per share or, if we fall below the minimum stockholders' equity requirement, maintain a minimum closing bid price of \$3.00 per share.

We currently are in compliance with The Nasdaq National Market's continued listing requirements. However, if in the future we fail to satisfy The Nasdaq National Market's continued listing requirements, our common stock may be delisted from The Nasdaq National Market. The delisting of our common stock may result in the trading of the stock on the Nasdaq SmallCap Market or the OTC Bulletin Board. Consequently, a delisting of our common stock from The Nasdaq National Market may reduce the liquidity of our common stock and adversely affect our ability to raise capital.

Substantially all of our total outstanding shares may be sold into the market at any time. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

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 shares, could reduce the market price of our common stock. As of December 31, 2003, we had outstanding approximately 40.6 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. The exercise of these options 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 regulates corporate acquisitions. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our class A common stock. These provisions may also prevent changes in our management.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We invest 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 expect to hold our investments to maturity. 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

Report of Independent Public Auditors

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

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations and comprehensive loss, of stockholders' equity and of cash flows present fairly, in all material respects, the financial position of Curis, Inc. and its subsidiaries at December 31, 2003 and 2002, and the results of their operations and their cash flows for the years then ended, 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 auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit 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.

The consolidated financial statements of Curis, Inc. and its subsidiaries as of December 31, 2001, and for the year then ended were audited by other independent accountants who have ceased operations. Those independent accountants expressed an unqualified opinion on those financial statements in their report dated February 14, 2002.

As discussed in Note 3(j) to the consolidated financial statements, the Company changed its method of accounting for goodwill in 2002.

/s/ PRICEWATERHOUSECOOPERS LLP

Boston, Massachusetts
February 4, 2004

Report of Independent Public Accountants

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

We have audited the accompanying consolidated balance sheets of Curis, Inc. (f.k.a. Creative BioMolecules, Inc.) and its subsidiaries as of December 31, 2001 and 2000, and the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for the years then ended. These financial statements are the responsibility of Curis, Inc.'s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the 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 includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Curis, Inc. and its subsidiaries as of December 31, 2001 and 2000 and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States.

ARTHUR ANDERSEN LLP

Boston, Massachusetts
February 14, 2002

NOTE: THIS IS A COPY OF THE AUDIT REPORT PREVIOUSLY ISSUED BY ARTHUR ANDERSEN LLP IN CONNECTION WITH CURIS, INC.'S FORM 10-K FILING FOR THE FISCAL YEAR ENDED DECEMBER 31, 2001. THE INCLUSION OF THIS PREVIOUSLY ISSUED ARTHUR ANDERSEN LLP REPORT IS PURSUANT TO THE "TEMPORARY FINAL RULE AND FINAL RULE REQUIREMENTS FOR ARTHUR ANDERSEN LLP AUDITING CLIENTS," ISSUED BY THE SECURITIES AND EXCHANGE COMMISSION IN MARCH 2002. NOTE THAT THE PREVIOUSLY ISSUED ARTHUR ANDERSEN LLP REPORT INCLUDES REFERENCES TO CERTAIN FISCAL YEARS WHICH ARE NOT REQUIRED TO BE PRESENTED IN THE ACCOMPANYING CONSOLIDATED FINANCIAL STATEMENTS AS OF AND FOR THE YEAR ENDED DECEMBER 31, 2003. THIS AUDIT REPORT HAS NOT BEEN REISSUED BY ARTHUR ANDERSEN LLP IN CONNECTION WITH THIS FILING ON FORM 10-K.

CURIS, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

| | December 31, | |
|--|---------------|---------------|
| | 2003 | 2002 |
| ASSETS | | |
| Current Assets: | | |
| Cash and cash equivalents | \$ 27,734,548 | \$ 26,920,605 |
| Cash and cash equivalents—restricted | 190,661 | 4,403,188 |
| Marketable securities | 7,413,703 | 9,652,671 |
| Accounts receivable | 2,184,973 | 446,853 |
| Prepaid expenses and other current assets | 1,202,993 | 939,964 |
| Due from joint venture | — | 1,299,289 |
| Total current assets | 38,726,878 | 43,662,570 |
| Property and Equipment, net | 2,500,703 | 3,775,269 |
| Long-term investments | 2,389,742 | — |
| Goodwill, net | 8,982,000 | 8,982,000 |
| Other intangible assets, net | 177,193 | 252,273 |
| Long-term notes receivable | 2,000,000 | 4,662,553 |
| Deposits and other assets | 959,974 | 1,107,028 |
| | \$ 55,736,490 | \$ 62,441,693 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current Liabilities: | | |
| Debt and lease obligations, current portion | \$ 322,884 | \$ 2,105,049 |
| Accounts payable | 456,860 | 726,092 |
| Accrued liabilities | 2,427,783 | 3,257,230 |
| Deferred revenue, current portion | 1,241,379 | 191,782 |
| Due to joint venture | — | 1,089,083 |
| Total current liabilities | 4,448,906 | 7,369,236 |
| Debt and Lease Obligations, net of current portion | — | 3,424,422 |
| Convertible Notes Payable | 5,333,733 | 6,885,486 |
| Deferred Revenue, net of current portion | 7,088,638 | 11,962,224 |
| Total liabilities | 16,871,277 | 29,641,368 |
| Preferred stock, \$0.01 par value, 5,000,000 shares authorized Series A Convertible Exchangeable Preferred Stock—1,426 shares authorized; 1,000 shares issued and outstanding at December 31, 2002 and none at December 31, 2003 | — | 13,064,283 |
| Commitments (Notes 10 and 11) | | |
| Stockholders' Equity: | | |
| Common stock, \$0.01 par value—125,000,000 shares authorized; 41,608,698 and 40,560,991 shares issued and outstanding, respectively, at December 31, 2003 and 32,768,545 and 31,746,338 shares issued and outstanding, respectively, at December 31, 2002 | 416,088 | 327,685 |
| Additional paid-in capital | 689,489,382 | 659,512,957 |
| Notes receivable | (110,368) | (143,898) |
| Treasury stock (at cost, 1,047,707 and 1,022,207 shares at December 31, 2003 and 2002, respectively) | (891,274) | (869,384) |
| Deferred compensation | (963,931) | (2,037,230) |
| Accumulated deficit | (649,068,435) | (637,174,017) |
| Accumulated other comprehensive (expense) income | (6,249) | 119,929 |
| Total stockholders' equity | 38,865,213 | 19,736,042 |
| | \$ 55,736,490 | \$ 62,441,693 |

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

CURIS, INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Loss

| | Year Ended December 31, | | |
|--|-------------------------|----------------|----------------|
| | 2003 | 2002 | 2001 |
| Revenues: | | | |
| Research and development contracts and government grants | \$ 1,628,724 | \$ 244,954 | \$ 967,928 |
| License fees and royalties | 9,419,509 | 18,145,584 | 118,575 |
| Total revenues | 11,048,233 | 18,390,538 | 1,086,503 |
| Costs and Expenses: | | | |
| Research and development | 13,399,492 | 14,057,715 | 29,072,068 |
| General and administrative | 5,854,569 | 8,160,012 | 10,492,525 |
| Stock-based compensation (a) | 1,631,098 | 2,159,594 | 10,358,302 |
| Amortization and impairment charge related to intangible assets | 75,079 | 474,509 | 23,338,539 |
| Loss on property and equipment | — | 5,336,786 | — |
| Impairment of goodwill | — | 64,098,344 | — |
| Restructuring expenses | — | 3,490,000 | — |
| Total costs and expenses | 20,960,238 | 97,776,960 | 73,261,434 |
| Loss from operations | (9,912,005) | (79,386,422) | (72,174,931) |
| Equity in Loss from Joint Venture (Note 5) | — | (4,310,912) | (13,453,140) |
| Other Income (Expense): | | | |
| Interest income | 427,912 | 1,066,881 | 2,854,027 |
| Other income (expense) | (1,445,055) | 1,261,885 | 1,694,193 |
| Interest expense | (694,104) | (946,867) | (783,799) |
| Total other income (expense) | (1,711,247) | 1,381,899 | 3,764,421 |
| Net loss | (11,623,252) | (82,315,435) | (81,863,650) |
| Accretion on Series A Redeemable Preferred Stock | (271,306) | (722,903) | (326,381) |
| Net loss applicable to common stockholders | \$(11,894,558) | \$(83,038,338) | \$(82,190,031) |
| Net Loss per Common Share (Basic and Diluted) | \$ (0.33) | \$ (2.57) | \$ (2.58) |
| Weighted Average Common Shares (Basic and Diluted) | 36,015,610 | 32,267,106 | 31,858,923 |
| Net Loss | \$(11,623,252) | \$(82,315,435) | \$(81,863,650) |
| Unrealized (Loss) Gain on Marketable Securities | (126,178) | 119,929 | 116,398 |
| Comprehensive loss | \$(11,749,430) | \$(82,195,506) | \$(81,747,252) |
| (a) The following summarizes the departmental allocation of the stock-based compensation charge: | | | |
| Research and development | \$ 1,266,902 | \$ 1,221,563 | \$ 6,156,323 |
| General and administrative | 364,196 | 938,031 | 4,201,979 |
| Total stock-based compensation | \$ 1,631,098 | \$ 2,159,594 | \$ 10,358,302 |

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

CURIS, INC. AND SUBSIDIARIES

Consolidated Statements of Stockholders' Equity

| | <u>Common Stock</u> | | <u>Additional Paid-in Capital</u> | <u>Notes Receivable</u> | <u>Treasury Stock</u> | <u>Deferred Compensation</u> | <u>Accumulated Deficit</u> | <u>Accumulated Other Comprehensive Income (Loss)</u> | <u>Total Stockholders' Equity</u> |
|---|---------------------|---------------|---|-----------------------------|---------------------------|----------------------------------|--------------------------------|--|---|
| | <u>Shares</u> | <u>Amount</u> | | | | | | | |
| Balance, January 1, 2001 | 31,383,585 | \$313,836 | \$662,339,492 | \$(1,204,596) | \$ — | \$(22,893,619) | \$(471,945,648) | \$2,204,301 | \$168,813,766 |
| Issuance of common stock, net of issuance costs of approximately \$147,000 | 546,448 | 5,464 | 3,847,268 | — | — | — | — | — | 3,852,732 |
| Other issuances of common stock | 328,528 | 3,285 | 947,474 | — | — | — | — | — | 950,759 |
| Issuance of common stock for license fee | 10,667 | 107 | 97,896 | — | — | — | — | — | 98,003 |
| Issuance of common stock as repayment of note payable | 60,000 | 600 | 309,600 | — | — | — | — | — | 310,200 |
| Interest on notes receivable | — | — | — | (87,336) | — | — | — | — | (87,336) |
| Stock-based compensation from modification of option agreement and options granted at below market value | — | — | 138,050 | — | — | — | — | — | 138,050 |
| Amortization of deferred compensation | — | — | — | — | — | 10,220,252 | — | — | 10,220,252 |
| Reversal of deferred compensation related to forfeited options | — | — | (2,260,433) | — | — | 2,260,433 | — | — | — |
| Reversal of deferred compensation related to options granted to non-employees | — | — | (796,139) | — | — | 796,139 | — | — | — |
| Realized gain on sale of Exelixis common stock | — | — | — | — | — | — | — | (1,469,517) | (1,469,517) |
| Unrealized gain on marketable securities | — | — | — | — | — | — | — | 116,398 | 116,398 |
| Discount on subordinated debt | — | — | 266,370 | — | — | — | — | — | 266,370 |
| Accretion of Series A redeemable preferred stock dividend | — | — | — | — | — | — | (326,381) | — | (326,381) |
| Net loss | — | — | — | — | — | — | (81,863,650) | — | (81,863,650) |
| Balance, December 31, 2001 | 32,329,228 | 323,292 | 664,889,578 | (1,291,932) | — | (9,616,795) | (554,135,679) | 851,182 | 101,019,646 |
| Issuance of restricted common stock for services | 396,231 | 3,962 | 272,550 | — | — | — | — | — | 276,512 |
| Other issuances of common stock | 43,086 | 431 | 39,824 | — | — | — | — | — | 40,255 |
| Issuance of stock options with exercise prices below fair market value | — | — | 131,500 | — | — | (131,500) | — | — | — |
| Interest on notes receivable | — | — | — | (45,629) | — | — | — | — | (45,629) |
| Amortization of deferred compensation | — | — | (26,590) | — | — | 1,917,160 | — | — | 1,890,570 |
| Reversal of deferred compensation related to forfeited options | — | — | (5,793,905) | — | — | 5,793,905 | — | — | — |
| Reclassification of reserve on officer note receivable | — | — | — | 1,193,663 | — | — | — | — | 1,193,663 |
| Purchase of treasury stock | — | — | — | — | (869,384) | — | — | — | (869,384) |
| Realized gain on sale of Exelixis common stock | — | — | — | — | — | — | — | (601,292) | (601,292) |
| Unrealized loss on marketable securities | — | — | — | — | — | — | — | (129,961) | (129,961) |
| Accretion of Series A Convertible Exchangeable preferred stock dividend | — | — | — | — | — | — | (722,903) | — | (722,903) |
| Net loss | — | — | — | — | — | — | (82,315,435) | — | (82,315,435) |
| Balance, December 31, 2002 | 32,768,545 | \$327,685 | \$659,512,957 | \$(143,898) | \$(869,384) | \$(2,037,230) | \$(637,174,017) | \$119,929 | \$19,736,042 |

CURIS, INC. AND SUBSIDIARIES
Consolidated Statements of Stockholders' Equity—(Continued)

| | <u>Common Stock</u> | | <u>Additional Paid-in Capital</u> | <u>Notes Receivable</u> | <u>Treasury Stock</u> | <u>Deferred Compensation</u> | <u>Accumulated Deficit</u> | <u>Accumulated Other Comprehensive Income (Loss)</u> | <u>Total Stockholders' Equity</u> |
|--|---------------------|------------------|---|-----------------------------|---------------------------|----------------------------------|--------------------------------|--|---|
| | <u>Shares</u> | <u>Amount</u> | | | | | | | |
| Balance, December 31, 2002 | 32,768,545 | \$327,685 | \$659,512,957 | \$(143,898) | \$(869,384) | \$(2,037,230) | \$(637,174,017) | \$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 | 3,486,981 | — | — | — | — | — | 3,500,220 |
| 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 | — | — | (269,693) | — | — | 341,125 |
| Amortization of deferred compensation | — | — | — | — | — | 1,190,864 | — | — | 1,190,864 |
| 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 | — | — | — | — | — | — | (11,623,252) | — | (11,623,252) |
| Balance, December 31, 2003 | <u>41,608,698</u> | <u>\$416,088</u> | <u>\$689,489,382</u> | <u>\$(110,368)</u> | <u>\$(891,274)</u> | <u>\$ (963,931)</u> | <u>\$(649,068,435)</u> | <u>\$ (6,249)</u> | <u>\$38,865,213</u> |

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

CURIS, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows

| | Year Ended December 31, | | |
|---|-------------------------|----------------------|----------------------|
| | 2003 | 2002 | 2001 |
| Cash Flows from Operating Activities: | | | |
| Net loss | \$(11,623,252) | \$(82,315,435) | \$(81,863,650) |
| Adjustments to reconcile net loss to net cash used in operating activities— | | | |
| Depreciation and amortization | 1,425,842 | 1,954,856 | 3,288,575 |
| Stock-based compensation expense | 1,631,096 | 2,159,594 | 10,358,302 |
| Amortization of intangible assets | 75,079 | 474,509 | 23,338,539 |
| Equity in loss of joint venture | — | 4,310,912 | 13,453,140 |
| Issuance of common stock in lieu of cash for license fee | — | — | 98,003 |
| Noncash interest expense on notes payable | 461,377 | 405,467 | 83,487 |
| Noncash interest income on notes receivable | — | (45,629) | (215,189) |
| Loss on impairment of property and equipment | 281 | 5,336,786 | — |
| Impairment of goodwill | — | 64,098,344 | — |
| Impairment of long-term receivable and investment | 1,994,782 | — | — |
| Foreign currency exchange gain | (452,857) | — | — |
| Increase (decrease) in operating assets and liabilities— | | | |
| Accounts receivable | (1,738,120) | (72,253) | (16,212) |
| Prepaid expenses and other current assets | (263,029) | (158,945) | 147,352 |
| Accounts payable and accrued liabilities | (1,065,149) | (2,732,786) | (591,183) |
| Due from joint venture | 210,207 | (341,491) | (957,798) |
| Deferred contract revenue | (417,013) | 8,473 | 8,000,000 |
| Total adjustments | 1,862,496 | 75,397,837 | 56,987,016 |
| Net cash used in operating activities | (9,760,756) | (6,917,598) | (24,876,634) |
| Cash Flows from Investing Activities: | | | |
| Purchase of marketable securities | (21,063,891) | (16,237,437) | (24,387,748) |
| Sale of marketable securities | 23,176,683 | 19,022,779 | 33,249,661 |
| Decrease (increase) in restricted cash | 4,212,527 | (4,403,188) | — |
| Purchase of long-term investments | (2,389,742) | — | — |
| Expenditures for property and equipment | (152,057) | (411,691) | (1,745,949) |
| Proceeds from sale of assets | — | 405,491 | — |
| Notes receivable from related parties | — | 700,000 | (500,000) |
| Increase in other long-term assets | (2,138,794) | (141,692) | (187,366) |
| Net cash provided by (used in) investing activities | 1,644,726 | (1,065,738) | 6,428,598 |
| Cash Flows from Financing Activities: | | | |
| Proceeds from issuance of common stock, net of issuance costs | 9,805,388 | — | 3,852,732 |
| Proceeds from other issuances of common stock | 5,966,052 | 44,217 | 950,759 |
| Issuance of notes payable | — | 4,696,804 | 2,000,000 |
| Repayment of note payable to Genetics Institute | — | — | (83,800) |
| Repayment of convertible notes payable | (1,601,563) | — | — |
| Purchases of treasury stock | (21,890) | (869,384) | — |
| Repayments of notes payable and capital leases | (5,218,014) | (7,245,505) | (1,603,273) |
| Net cash provided by (used in) financing activities | 8,929,973 | (3,373,868) | 5,116,418 |
| Effect of Exchange Rates on Cash and Cash Equivalents | — | (660,253) | (144,632) |
| Net Increase (Decrease) in Cash and Cash Equivalents | 813,943 | (12,017,457) | (13,476,250) |
| Cash and Cash Equivalents, beginning of period | 26,920,605 | 38,938,062 | 52,414,312 |
| Cash and Cash Equivalents, end of period | <u>\$ 27,734,548</u> | <u>\$ 26,920,605</u> | <u>\$ 38,938,062</u> |

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

CURIS, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows

| | Year Ended December 31, | | |
|---|-------------------------|-------------|--------------|
| | 2003 | 2002 | 2001 |
| Supplemental Disclosure of Noncash Investing and Financing Activities: | | | |
| Property and equipment purchased under financing or capital lease obligations | \$ — | \$ — | \$ 3,905,542 |
| Repayment of notes payable by issuance of 60,000 shares of common stock | \$ — | \$ — | \$ 310,200 |
| 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 | \$ — | \$ — |
| Issuance of notes receivable and receipt of common stock in Micromet | \$ — | \$ — | \$ 4,145,533 |
| Issuance of convertible note payable to Elan Pharma International, Limited to fund the Company's 80.1% interest in joint venture | \$ — | \$3,986,442 | \$ 673,929 |
| Issuance of Series A redeemable preferred stock to purchase initial 80.1% interest in joint venture | \$ — | \$ — | \$12,015,000 |

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

CURIS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

(1) OPERATIONS

The Company 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 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. The Company has successfully developed several preclinical product candidates in the fields of kidney disease, cancer, neurological disorders, cardiovascular disease and hair growth regulation.

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 partners 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) FINANCIAL STATEMENT RECLASSIFICATIONS

The Company has reclassified \$1,194,000 reserve on notes receivable to former officers of Creative BioMolecules (see Note 12) from "Accrued liabilities" to "Notes receivable" in the Company's Stockholders' Equity section of its Consolidated Balance Sheets. The underlying notes total \$1,338,000 and are presented net of the underlying reserve. As of December 31, 2003 and 2002, the Company recorded reserves on these notes of \$1,228,000 and \$1,194,000, respectively. Accordingly, as of December 31, 2003 and 2002, the Notes receivable balances, presented net of the underlying reserve at the Company's Stockholders' Equity section of its Consolidated Balance Sheets, were \$110,000 and \$144,000, respectively.

(3) 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 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.

(c) REVENUE RECOGNITION

The Company's research and development contract revenue is primarily derived from contracts with biotechnology and pharmaceutical companies. These contracts may include payments for research-

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

related activities, license fees, research and development milestones and royalties. The Company follows the provisions of the Securities and Exchange Commission's Staff Accounting Bulletin (SAB) No. 104 (SAB No. 104), *Revenue Recognition* and EITF 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*. In accordance with SAB No. 104 and EITF 00-21, the Company recognizes revenue related to research activities as they are performed, so long as there is persuasive evidence of an arrangement, the fee is fixed or determinable and collection of the related receivable is probable.

Amounts received for license fees are deferred and recognized as services are performed over the performance period of the contract. Amounts received for milestones will be recognized upon achievement of the milestone as long as the milestone is deemed to be substantive and the Company has no other performance obligations. In the event the Company has remaining performance obligations, the portion of the milestone payment equal to the lesser of the non-refundable cash received or the percentage of the services performed through that date multiplied by the total milestone payment would be recognized as revenue. The percentage of services performed is based on the ratio of the number of labor hours performed to-date to total labor hours the Company is obligated to perform under the related contract, as determined on a full-time equivalent basis. The remainder, if any, will be recognized proportionately as the remaining services are performed. Royalty revenue is recognized upon the sale of the related products, provided the royalty amounts are fixed or determinable and collection of the related receivable is reasonably assured.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying balance sheets. Amounts not expected to be recognized during the year ended December 31, 2004, are classified as long-term deferred revenue. As of December 31, 2003, the Company has short- and long-term deferred revenue of \$1,241,000 and \$7,089,000, respectively, related to its collaboration with Genentech, Inc. (see Note 4(a)).

Government grant revenues consist of grant awards from the Department of Health and Human Services and the National Institute of Standards and Technology (NIST). Revenue is recognized under government grants as the services are provided and when payment is reasonably assured under the terms of the grant. The Company will not receive additional revenue under these government grants.

During the years ended December 31, 2003, 2002 and 2001, total revenues from major customers as a percent of total revenues of the Company were as follows:

| | Year Ended December 31, | | |
|----------------------------------|----------------------------|------|------|
| | 2003 | 2002 | 2001 |
| Micromet AG | 77% | 1% | — % |
| ES Cell International | 13% | — % | — % |
| Genentech, Inc. | 7% | — % | — % |
| Stryker Corporation | — % | 78% | 9% |
| Ortho Biotech Products | — % | 19% | — % |
| NIST | — % | — % | 88% |

(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 government grants, and the expenses related to these activities are included

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

in research and development costs. Research and development costs include personnel costs, lab and animal supplies, outside services including sponsored research agreements, an allocation of facility costs and fringe benefits, and legal costs associated with the Company's patent portfolio.

For the years ended December 31, 2002 and 2001, research and development costs are presented net of costs incurred by the Company on behalf of Curis Newco, Ltd. (Curis Newco), a joint venture established by the Company and affiliates of Elan Corporation, or Elan. Curis Newco was originally formed in July 2001 and became a wholly-owned subsidiary of the Company as part of a termination agreement between the Company and Elan entered into on May 16, 2003. Curis Newco did not incur any research expenses for the year ended December 31, 2003. Research expenses of \$5,263,000 were recognized for the year ended December 31, 2002. However, 80.1% of these costs, the Company's share of the joint venture's costs, are included as part of Equity in loss from joint venture in the 2002 Consolidated Statement of Operations and Comprehensive Loss.

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

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

The amortized cost, unrealized gains (losses) and fair value of marketable securities available-for-sale as of December 31, 2003, with maturity dates ranging between one and 12 months and with a weighted average maturity of 3.4 months are as follows:

| | Amortized Cost | Unrealized Loss | Fair Value |
|---------------------------------------|-------------------|--------------------|-------------|
| U.S. government obligations | \$ 250,000 | \$ — | \$ 250,000 |
| Corporate bonds and notes | 7,168,000 | (4,000) | 7,164,000 |
| Total marketable securities | \$7,418,000 | \$(4,000) | \$7,414,000 |

The amortized cost, unrealized gains and fair value of marketable securities available-for-sale as of December 31, 2002, with maturity dates ranging between one and 11 months and with a weighted average maturity of 2.5 months are as follows:

| | Amortized Cost | Unrealized Gain | Fair Value |
|---------------------------------------|-------------------|--------------------|-------------|
| Insurance annuity contracts | \$9,533,000 | \$120,000 | \$9,653,000 |

As of December 31, 2003, the Company recorded long-term investments of \$2,390,000 on its Consolidated Balance Sheet. This amount is comprised of corporate debt securities with maturities in excess of 12 months and with amortized cost totaling \$2,392,000, less unrealized losses of \$2,000.

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

(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 lease 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.

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 effected values since the last such investment by other outside investors. The Company periodically reevaluates the book valuation of its investments in privately-held companies to determine if its carrying value should be changed. As of December 31, 2003 and 2002, the value of the Company's investments in privately-held companies was \$717,000 and \$853,000, respectively, and these amounts are included in "Deposits and other assets" in the Consolidated Balance Sheets.

The convertible notes payable and lease obligations have fixed rates of interest and will be subject to fluctuations in fair value during their terms. As of December 31, 2003, the Company estimates that the fair values of these instruments approximate their carrying amounts.

(g) **PLANT 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 straight-line method over the estimated useful lives of the related assets or the remaining terms of the leases, as follows:

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

As a result of a realignment of the Company's operations during the first quarter of 2002, the Company recorded an impairment charge of property and equipment assets of \$5,337,000. This charge related to impairment on assets at the Company's Erie Street facility (see Note 6).

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

(h) OTHER INTANGIBLE ASSETS

The Company has filed applications for United States and foreign patents covering aspects of its technology. Certain costs related to patent applications for which patents have issued and certain costs related to pending patent applications from which the Company is currently deriving economic benefit, were capitalized and are being amortized over the estimated useful life of the patent, generally 16 to 20 years, using the straight-line method. The Company evaluates all patent costs annually and, to the extent there is uncertainty as to the realizability of such costs, they are expensed.

(i) 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 current strategic alliance partners, capitalized patent costs and long-term deposits. The aggregate balances for these long-lived assets were \$5,527,000 and \$6,022,000 as of December 31, 2003 and 2002, respectively. The Company adopted SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, which superseded SFAS No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of*, effective January 1, 2002. SFAS No. 144 further refines the requirements of SFAS No. 121, requiring that companies (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. The Company adopted SFAS No. 144 on January 1, 2002.

During the fourth quarter of the year ended December 31, 2003, the Company recorded an impairment charge of \$1,708,000 for the write-off of a euro-denominated note receivable from Micromet AG, a former collaborator of the Company (see Note 5(b)). During the fourth quarter of the year ended December 31, 2002, the Company recorded an impairment charge of \$271,000 to reduce the carrying value of patents associated with the Company's OP-1 technology which is licensed to Stryker (see Note 7).

(j) GOODWILL

Effective January 1, 2002, the Company applied the provisions of SFAS No. 142, *Goodwill and Other Intangible Assets*. In accordance with SFAS No. 142, on January 1, 2002, the Company reclassified assembled workforce as goodwill and ceased amortization of goodwill. During 2003, the Company completed its goodwill impairment test in December 2003, and determined that as of that date the fair value of the Company exceeded the carrying value of its net assets. Accordingly, no goodwill impairment was recognized.

In 2002, goodwill was subject to both a transitional goodwill impairment test as of January 1, 2002 and an annual assessment for impairment based on fair value. The Company determined that it consists of a single reporting unit. In conjunction with the adoption of SFAS No. 142, the Company completed the transitional goodwill impairment test in the first quarter of 2002 by comparing the Company's fair value to its net assets, including goodwill. If the carrying value of the Company's net assets exceeded the Company's fair value, then goodwill would have been impaired. In performing its analysis, the Company determined its fair value based on quoted market prices adjusted to provide for a control premium. The transitional goodwill impairment test indicated that no impairment of goodwill had occurred as of January 1, 2002.

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Notes to Consolidated Financial Statements—Continued

In addition to requiring transitional and annual assessments of goodwill impairment, SFAS No. 142 requires that a goodwill impairment review be performed whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Because key employees were terminated and certain development programs were suspended or terminated as part of a realignment of our operations in the first quarter of 2002, the Company determined that an impairment indicator had arisen during the three-month period ending March 31, 2002 that required the Company to reevaluate the carrying value of goodwill. The Company performed this reevaluation and concluded that no goodwill impairment had occurred as of March 31, 2002.

After the March 31, 2002, goodwill impairment test was completed, the Company experienced a decrease in its market value during the three-month period ended June 30, 2002. The Company concluded that the decline in market value served as an indication that the carrying value of its goodwill asset may be impaired. Accordingly, the Company conducted an impairment review as required under SFAS No. 142 as of June 30, 2002, and concluded that goodwill impairment had occurred as of June 30, 2002. To determine the amount of the impairment charge, the Company calculated its implied goodwill as the difference between the fair value of the Company as a whole and the fair value of the Company's assets and liabilities. In calculating the impairment charge, the fair value of the Company's intangible assets, principally consisting of completed and in-process technology, was estimated using a discounted cash flow methodology. The Company determined that its implied goodwill was \$8,982,000 and recorded a non-cash charge of \$64,098,000 to write-down its existing goodwill. This charge is included in operating costs and expenses within the Company's Consolidated Statements of Operations and Comprehensive Loss for the year ended December 31, 2002.

The Company recorded expense related to the amortization of goodwill of \$23,114,000 during the year ended December 31, 2001. The Company recorded expense related to the amortization of assembled workforce of \$100,000 during the year ended December 31, 2001. Due to the adoption of SFAS No. 142, the Company recorded no amortization of either goodwill or assembled workforce during the years ended December 31, 2003 or 2002. As of December 31, 2002, the Company determined that all of its intangible assets, other than goodwill and assembled workforce, have finite lives and, therefore, the Company will continue to amortize these intangible assets in future periods. This assessment is only made upon adoption of SFAS 142.

The following table presents the impact SFAS 142 would have had on the Company's net loss and net loss per share had the standard been in effect for the year ended December 31, 2001:

| | The Year Ended December 31, 2001 | | |
|-------------------------------------|---|---|------------------------|
| | As Reported | Goodwill Amortization Adjustment | As Adjusted |
| Net Loss | \$(81,863,000) | \$(23,114,000) | \$(58,749,000) |
| Net Loss per Common Share | \$ (2.58) | \$ (0.73) | \$ (1.85) |

(k) **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

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

Company with treasury shares for general corporate purposes, such as stock to be issued under employee stock option and stock purchase plans. Under this repurchase program, the Company repurchased 25,500 shares during the year ended December 31, 2003, at a cost of \$22,000. 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.

(l) **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, 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 5(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 consist of stock options, warrants, convertible debt and Series A Convertible Exchangeable Preferred Stock, that were not included in diluted net loss per common share were 11,070,422, 12,812,883 and 9,608,562 as of December 31, 2003, 2002 and 2001, respectively.

(m) **STOCK-BASED COMPENSATION**

Stock options issued to employees under the Company's stock option and employee stock purchase plans are accounted for under APB Opinion No. 25, *Accounting for Stock Issued to Employees* and related interpretations, including FASB Interpretation No. 44 (see Note 15). 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*, and Emerging Issues Task Force (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, 2003, the Company has two stock-based compensation plans, which are described more fully in Note 15. The Company accounts 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 the Company's 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 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:

| | Year Ended December 31, | | |
|--|----------------------------|--------|--------|
| | 2003 | 2002 | 2001 |
| Risk-free interest rate | 3.1% | 2.1% | 5.0% |
| Expected dividend yield | — | — | — |
| Expected lives | 7.0 | 7.0 | 7.0 |
| Expected volatility | 121% | 116% | 111% |
| Weighted average grant date fair value | \$2.44 | \$1.22 | \$3.20 |

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

Forfeitures for grants to executives are recognized as they occur. If the computed fair values of the 2003, 2002 and 2001 awards 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, | | |
|---|-------------------------|-----------------------|-----------------------|
| | 2003 | 2002 | 2001 |
| Net loss applicable to common stockholders as reported | \$(11,895,000) | \$(83,038,000) | \$(82,190,000) |
| Add back: Stock-based compensation, included in net loss, as reported | 1,124,000 | 2,160,000 | 10,358,000 |
| Deduct: Stock-based compensation expense determined under fair value based method for all award | (7,838,000) | (7,406,000) | (23,131,000) |
| Total | \$(18,609,000) | \$(88,284,000) | \$(94,963,000) |
| Net loss per common share (basic and diluted)— | | | |
| As reported | \$ (0.33) | \$ (2.57) | \$ (2.57) |
| Pro forma | (0.52) | (2.80) | (2.98) |

(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, 2003, 2002 and 2001, the Company did not have any derivative instruments.

(o) NEW ACCOUNTING PRONOUNCEMENTS

In January 2003, the FASB issued Interpretation (“FIN”) No. 46, *Consolidation of Variable Interest Entities* (“FIN 46”) and, in December 2003, issued a revision to that interpretation (“FIN 46R”). FIN 46R replaces FIN 46 and addresses consolidation by business enterprises of variable interest entities that possess certain characteristics. A variable interest entity (“VIE”) is defined as (a) an ownership, contractual or monetary interest in an entity where the ability to influence financial decisions is not proportional to the investment interest, or (b) an entity lacking the invested capital sufficient to fund future activities without the support of a third party. FIN 46R establishes standards for determining under what circumstances VIEs should be consolidated with their primary beneficiary, including those to which the usual condition for consolidation does not apply. The Company’s adoption of FIN 46R did not have a material effect on its financial position or results of operations.

In April 2003, the FASB issued SFAS No. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities*. This Statement amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts (collectively referred to as derivatives) and for hedging activities under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. SFAS No. 149 is effective for contracts entered into or modified and for hedging relationships designated after June 30, 2003. At December 31, 2003, the Company had no financial instruments falling within the scope of SFAS No. 149.

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Notes to Consolidated Financial Statements—Continued

In May 2003, the FASB issued SFAS 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*. SFAS 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of those instruments were previously classified as equity. This Statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of SFAS 150 did not have a material effect on the Company's financial statements.

In May 2003, the FASB also issued EITF 01-8, *Determining Whether an Arrangement Contains a Lease*, which requires capital lease treatment for arrangements containing an embedded lease, thereby conveying the right to control the use of property, plant or equipment (collectively, "property") whether the right to control the use of the property is explicitly or implicitly specified. The right is conveyed if the purchaser (lessee) obtains physical or operational control of the underlying property or takes substantially all of its output. This pronouncement applies prospectively to new or modified arrangements beginning after May 28, 2003. The adoption of EITF 01-8 had no impact on the Company's financial statements.

Effective July 1, 2003, the Company adopted EITF 00-21, *Accounting For Revenue Arrangements with Multiple Deliverables*, which establishes criteria for whether revenue on a deliverable can be recognized separately from other deliverables in a multiple deliverable arrangement. The criteria considers whether the delivered item has stand-alone value to the customer, whether the fair value of the delivered item can be reliably determined and the customer's right of return for the delivered item. The adoption of EITF 00-21 did not have a material impact on the Company's financial statements.

On December 17, 2003, the Staff of the Securities and Exchange Commission (SEC or the Staff) issued SAB 104, *Revenue Recognition*, which amends SAB 101, *Revenue Recognition in Financial Statements*. SAB 104's primary purpose is to rescind accounting guidance contained in SAB 101 related to multiple element revenue arrangements, superseded as a result of the issuance of EITF 00-21. Additionally, SAB 104 rescinds the SEC's *Revenue Recognition in Financial Statements Frequently Asked Questions and Answers* (the FAQ) issued with SAB 101 that had been codified in SEC Topic 13, *Revenue Recognition*. Selected portions of the FAQ have been incorporated into SAB 104. While the wording of SAB 104 has changed to reflect the issuance of EITF 00-21, the revenue recognition principles of SAB 101 remain largely unchanged by the issuance of SAB 104. The adoption of SAB 104 did not have a material impact on the Company's financial statements.

(4) RESEARCH AND DEVELOPMENT AND SIGNIFICANT COLLABORATIONS

(a) GENENTECH, INC.

On June 11, 2003, the Company licensed its small molecule and antibody antagonists of the Hedgehog signaling pathway to Genentech for applications in cancer therapy pursuant to the terms of a Collaborative Research, Development and License Agreement. The Collaboration Agreement provides for cash payments from Genentech, including an up-front payment of \$5,000,000, maintenance fee payments totaling \$4,000,000 over the first two years of the collaboration, and milestone payments at various intervals during the regulatory approval process of small molecule and antibody product candidates, assuming specified development objectives are met. Genentech is also obligated to pay the Company a royalty on any future product sales.

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

Under the terms of the Collaboration Agreement, the Company is required to commit eight employees to the small molecule and/or antibody programs for a period of two years. In addition, the Company will participate on a joint steering committee to oversee the preclinical development of product candidates. Per the Collaboration Agreement, product candidates identified by the joint steering committee for further (i.e., clinical) development are classified as either “Lead Products” or “Co-Development Products.”

- *Lead Products:* Lead Products include all small molecule and antibody antagonists of the Hedgehog signaling pathway, except for those in either the basal cell carcinoma, a form of skin cancer, or the hair growth prevention fields. Genentech bears sole decision making authority and development costs for all Lead Products, including clinical trial development and management, regulatory, clinical and commercial manufacturing, product formulation, and, if FDA approval is received, sales and marketing.
- *Co-Development Products:* Co-Development Products include only those product candidates identified by the joint steering committee for further development in either the basal cell carcinoma or the hair growth prevention fields. For product candidates in the basal cell carcinoma field, Genentech will create a co-development plan and budget and the Company will have the option to share in the development costs. For product candidates in the hair growth prevention field, the Company will create a co-development plan and budget and Genentech will have the option to share in the development costs. In both co-development scenarios, a co-development committee will be formed, consisting of an equal number of members from Genentech and the Company, to oversee the co-development efforts.

The Company has recorded the \$5,000,000 up-front payment and the \$4,000,000 in maintenance fee payments due from Genentech as deferred revenue and has been recognizing these amounts as revenue on a straight-line basis over the development period. For the year ended December 31, 2003, the Company recorded license revenue related to this collaboration of \$670,000. This revenue is included in “License fees and royalties” in the Consolidated Statement of Operations and Comprehensive Loss. In addition, the Company has performed certain services or incurred costs that were requested by Genentech but which are outside of the scope of the original contract. The Company has been reimbursed for such costs. For the year ended December 31, 2003, the Company has recorded \$58,000 in revenue related to such cost reimbursement. This revenue is included in “Research and development contracts and government grants” in the Consolidated Statement of Operations and Comprehensive Loss.

In addition, as partial consideration for the rights and licenses granted to Genentech under the Collaboration Agreement, the Company sold to Genentech 1,323,835 shares of its common stock at a purchase price of \$2.644 per share for aggregate proceeds of \$3,500,000, pursuant to the terms of a stock purchase agreement. The Company also entered into a registration rights agreement with Genentech pursuant to which the Company shall use its reasonable best efforts to register the shares of common stock for resale in the future under specified conditions.

(b) ORTHO BIOTECH PRODUCTS, L.P.

In November of 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’s research affiliates, Johnson & Johnson Pharmaceutical Research & Development, L.L.C. and Centocor Research & Development, also members of the Johnson & Johnson

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

family of companies, will have joint responsibility for further research and development of the Company's licensed BMP technology portfolio.

The transaction covers 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 (renal osteodystrophy and vascular calcification) 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 cash payments from Ortho Biotech to the Company, including an up-front payment of \$3,500,000, which was paid in December 2002, and milestone payments at various intervals during the U.S. and European regulatory approval process for the first two therapeutic indications developed. These milestones include a \$30,000,000 payment for 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. The Company recognized the upfront payment of \$3,500,000 as revenue in the fourth quarter of 2002 because the Company has no continuing performance obligations under the contract.

(c) AMYLIN PHARMACEUTICALS, INC.

In December 2002, the Company licensed its PYY patent applications to Amylin Pharmaceuticals, Inc. in exchange for an up-front fee, milestone payments and a royalty on product sales, if any are ever realized. Amylin has sole responsibility for all further development of the PYY compound. Since the Company has no continuing obligation under the terms of this transaction, 100% of the up-front payment was recognized as revenue during 2002.

(d) 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 years ended December 31, 2003 and 2002, the Company recognized \$1,470,000 and \$62,000, respectively, 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.

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. As of December 31, 2002, the Company had recorded \$192,000 in deferred revenue relating to this transaction. Since the Company's obligation was completed during 2003, this amount was recognized as revenue during the year ended December 31, 2003, and the Company will not recognize additional revenue related to this collaboration.

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

The Company maintains an equity position in ES Cell International. As of December 31, 2003 and 2002, 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.

(5) FORMER COLLABORATIONS AND GOVERNMENT GRANTS

(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 has become a wholly-owned subsidiary of the Company and Curis Newco is consolidated into the Company’s consolidated financial statements.

Curis Newco did not incur any research expenses during the twelve-month period ended December 31, 2003. In accordance with the development agreement between the Company and Elan that governed Curis Newco’s operations prior to the termination agreement, the Company and Elan were required to agree upon a Curis Newco development plan in order for any expenses to be incurred by Curis Newco. The Company and Elan did not reach agreement on a development plan prior to termination of the joint venture on May 16, 2003, and, therefore, no research expenses were recorded at Curis Newco in 2003. As of the termination date, the Company had recorded a payable to Curis Newco of \$1,089,000, which represented the Company’s 80.1% share of Curis Newco’s loss for the three-month period ended December 31, 2002. In addition, the Company had recorded a receivable from Curis Newco of \$1,299,000 which represented charges for services performed by the Company on behalf of Curis Newco for the three-month period ended December 31, 2002. Both of these amounts were paid as part of the termination and there are no remaining balances related to these amounts as of December 31, 2003.

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 interest rate was reduced from 8% to 6% and the conversion rate was increased to \$10.00 from \$8.63. As of December 31, 2003, there was \$3,115,000, including \$115,000 in accrued interest, outstanding under the amended and restated convertible note payable.

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

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

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 July 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 bears interest at 7% and is 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 has 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, but not the obligation, to jointly fund research to develop antibodies on up to four potential targets through the proof of principle stage. The Company had the right, but not the obligation, to 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 to satisfy the Company's performance obligation 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. Amounts that had not been recognized as revenue were recorded on the Company's Consolidated Balance Sheet as short- and long-term deferred revenue based on the Company's best estimate of when such revenue would be recognized. As of December 31, 2002, the Micromet note receivable was recorded at \$4,663,000.

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 no longer has any performance or contractual obligations with Micromet. Accordingly, the Company immediately recognized as revenue \$8,555,000 of previously deferred revenue related to its agreements with Micromet.

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

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 upon payment of the note receivable. During the fourth quarter of the year ended December 31, 2003, however, the Company determined that the note receivable was impaired and recorded an impairment charge of \$1,708,000 to write-off of this note receivable. Prior to the impairment charge, the Company had reported this note as a long-term note receivable asset of \$5,115,000, reflecting the note's then-current carrying value after giving effect to interest income and foreign currency gains. The impairment charge reflects the net effect of the write-off of the \$5,115,000 note receivable and the elimination of \$3,407,000 in related deferred revenue. 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 co-development partner. Micromet has stated that this dispute will result in a significant decrease in previously budgeted cash inflows in 2004.

(c) STRYKER CORPORATION

Creative BioMolecules, Inc., one of the companies that merged to form Curis in 2000, had an agreement with Stryker to identify and develop OP-1, a bone-inducing protein, as orthopaedic reconstruction and dental therapy products. In exchange for research funding, future royalties and revenue from commercial manufacturing, Creative developed OP-1 as a therapy for orthopedic reconstruction and cartilage regeneration and supplied Stryker material for use in clinical trials. Creative restructured its agreements with Stryker in November 1998 to provide Stryker with the exclusive rights to manufacture OP-1 products in these fields. At that time, Stryker acquired Creative's commercial manufacturing operations. As a result, Stryker had the exclusive right to develop, market, manufacture and sell products based on OP-1 proteins for use in orthopedic reconstruction and dental therapies and was required to pay the Company royalties on such commercial sales. Stryker paid the Company royalties of \$387,000 and \$97,000 for the years ended December 31, 2002 and 2001, respectively.

On October 1, 2002, the Company completed a transaction with Stryker, under the terms of which Stryker paid the Company \$14,000,000 in cash in exchange for the termination of any future BMP-7 (OP-1) royalty obligations. This transaction also allows the Company to reduce future BMP-7 royalties that it would owe to Stryker for products sold in therapeutic indications other than orthopedics and dental, if any such sales are ever achieved. The Company recorded the \$14,000,000 received as revenue during the fourth quarter of 2002 because the Company has no continuing performance obligations under the contract. As a result of this transaction, the Company will receive no future royalties or payments of any other kind from Stryker.

(d) AEGERA THERAPEUTICS

The Company entered into a license and collaboration agreement, effective January 5, 2001, with Aegera Therapeutics, Inc. granting the Company an exclusive worldwide license of Aegera's skin-derived, adult stem cell technologies. In consideration for the technology license, the Company paid \$100,000 up-front license fee, paid \$250,000 for equity securities in privately-held Aegera, and issued to Aegera 10,667 shares of the Company's common stock with an approximate value of \$100,000. In addition, under the terms of the agreement, the Company made one additional license payment of \$100,000 which was expensed in 2002.

The agreement also provided for a three-year research collaboration under which the Company was obligated to fund six full-time equivalent researchers per year at Aegera dedicated to the agreement at

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

an aggregate cost to the Company of \$600,000. Effective October 24, 2002, the Company terminated the research collaboration component of its relationship. Effective April 30, 2003, the Company terminated the remaining components of this license and collaboration agreement.

(e) GOVERNMENT GRANTS

Effective September 20, 1998, Reprogenesis received a grant award for its vesicoureteral reflux product under the Orphan Drug Program of the Department of Health and Human Services. This grant award provides for cost reimbursement funding over a three-year period of approximately \$323,000 for certain patient costs associated with a vesicoureteral reflux Phase III clinical trial to the extent the Company complies with all of the requirements governing the grant. The Company recognized \$101,000 under this grant for the year ended December 31, 2003. The Company has received all reimbursement that it is entitled to under this grant and, as such, will not recognize future revenue related to this grant.

Effective November 1, 1999, Reprogenesis, one of the companies that merged to form Curis in 2000, received a grant award for its cardiovascular project from the advanced technology program of the National Institute of Standards and Technology (NIST) to support the development of the Company's cardiovascular products, Vascugel and Vasucject. The Company has assumed this award in conjunction with the Merger. Under the terms of the grant award, the Company will receive \$2,000,000 in cost reimbursement funding to be paid at a rate of approximately \$666,000 annually over a three-year period. Funding under the NIST grant is contingent on the Company meeting minimum cost-sharing and other requirements, as defined in the financial assistance award and annual government appropriations for the award. The Company terminated its work on its cardiovascular products as part of the Realignment. As a result, on April 15, 2002, this award was terminated.

On October 5, 2000, the Company announced the receipt of a second \$2,000,000 grant from NIST to support the development of a new class of biomaterials designed to enable surgical procedures that augment, repair or regenerate lost structural tissue or physiological function. The grant period is from January 1, 2001 to December 31, 2003. Under the terms of the grant award, the Company will receive \$2,000,000 in cost reimbursement funding to be paid at a rate of approximately \$666,000 annually over a three-year period. Funding under the NIST grant is contingent on the Company meeting minimum cost-sharing and other requirements, as defined in the financial assistance award and annual government appropriations for the award. The Company terminated its work on biomaterials research as part of the Realignment. As a result, on April 15, 2002, this award was terminated.

The Company recognized \$101,000 of government grant revenue for the year ended December 31, 2003. No government grant revenue was recorded for the year ended December 31, 2002 and approximately \$968,000 of government grant revenue under was recognized for the year ended December 31, 2001.

(6) REALIGNMENT

The Company announced a realignment of its research and development programs in the first quarter of 2002. Realignment expenses of \$3,490,000 were recorded in the three-month period ended March 31, 2002. These charges related to: (i) \$1,139,000 associated with workforce reductions of 46 people, including 4 officers, (ii) \$2,306,000 associated with the closing of clinical programs and decommissioning of a manufacturing and development facility and (iii) other costs of \$45,000. As of

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

December 31, 2002, the Company had paid all of these costs and does not expect to incur additional costs related to this realignment in the future.

In connection with this realignment, the Company recorded impairment charges of property and equipment assets of \$5,337,000. This charge related to impairment of assets at the Company's manufacturing and development facility located at its facility located at 21 Erie Street, Cambridge, MA. \$4,761,000 of the total impairment charge related to the write-off of tenant improvements made to the Erie Street facility since such improvements were affixed to the facility and therefore could not have been sold separately from the facility. The remaining \$576,000 of impairment charge represented the write-down of the furniture and equipment assets held at the Erie Street facility to their estimated salvage value. The amount the Company received from the sale of these assets was not significantly different from the originally estimated fair value.

(7) GOODWILL AND INTANGIBLE ASSETS

As of December 31, 2003 and 2002, the Company had recorded goodwill of \$8,982,000. During 2003, the Company completed its goodwill impairment test in December 2003, and determined that as of that date, the fair value of the Company exceeded the carrying value of its net assets. Accordingly, no goodwill impairment was recognized.

Intangible assets consist of the following:

| | December 31, | |
|---|--------------|------------|
| | 2003 | 2002 |
| Patents | \$ 612,000 | \$ 612,000 |
| Less—Accumulated amortization | (435,000) | (360,000) |
| | \$ 177,000 | \$ 252,000 |

The changes in the carrying amounts of goodwill for the year ended December 31, 2002, are as follows:

| | |
|---|---------------|
| Balance as of January 1, 2002 | \$ 73,080,000 |
| Impairment loss | (64,098,000) |
| Balance as of December 31, 2002 | \$ 8,982,000 |

During the fourth quarter of the year ended December 31, 2002, the Company recorded an impairment charge of \$271,000 to reduce the carrying value of patents associated with the Company's OP-1 technology which is licensed to Stryker. The charge was recorded as a result of the Company's transaction with Stryker, under which the Company sold its rights to future royalties from Stryker on sales of OP-1 in exchange for \$14,000,000. The Company wrote these patents off because the Company will not receive any future royalties or other revenue from Stryker and because these patents cannot be utilized for alternative uses in either current or future operations and have no alternative future use to the Company.

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

(8) PROPERTY AND EQUIPMENT

Property and equipment consist of the following:

| | December 31, | |
|--|--------------|--------------|
| | 2003 | 2002 |
| Laboratory equipment and computers | \$ 5,701,000 | \$ 4,515,000 |
| Equipment and furniture under capital leases | 1,610,000 | 2,701,000 |
| Leasehold improvements | 3,857,000 | 4,316,000 |
| Leasehold improvements under capital leases | 703,000 | 703,000 |
| Office furniture and equipment | 553,000 | 523,000 |
| | 12,424,000 | 12,758,000 |
| Less—Accumulated depreciation and amortization | (9,923,000) | (8,983,000) |
| Total | \$ 2,501,000 | \$ 3,775,000 |

The Company recorded depreciation and amortization expense of \$1,426,000, \$1,955,000 and \$3,289,000 for the years ended December 31, 2003, 2002 and 2001, respectively.

During the year ended December 31, 2002, the Company recorded property and equipment impairment charges of \$5,337,000 related to a realignment of its research and development programs. This charge relates to an impairment of assets at the Company’s manufacturing and development facility located at 21 Erie Street in Cambridge, Massachusetts. \$4,761,000 of the total impairment charge related to the write-off of tenant improvements made to the Erie Street facility since such improvements were affixed to the facility and, therefore, could not be sold separately from the facility. The remaining \$576,000 of impairment charge represented the loss on disposition of the furniture and equipment assets held at the Erie Street facility.

(9) ACCRUED LIABILITIES

Accrued liabilities consist of the following:

| | December 31, | |
|--|--------------|-------------|
| | 2003 | 2002 |
| Collaboration and clinical costs | \$ 481,000 | \$ 856,000 |
| Professional fees | 740,000 | 936,000 |
| Accrued compensation | 320,000 | 702,000 |
| Other | 887,000 | 763,000 |
| Total | \$2,428,000 | \$3,257,000 |

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

(10) LONG-TERM DEBT AND CAPITAL LEASE OBLIGATIONS

Long-term debt and capital lease obligations consist of the following at December 31, 2003 and 2002:

| | December 31, | |
|--|--------------|--------------|
| | 2003 | 2002 |
| Notes payable to financing agencies for capital purchases | \$ — | \$ 4,239,000 |
| Obligations under capital leases, net of approximately \$12,000 and \$31,000 discount at December 31, 2003 and 2002, respectively | 323,000 | 1,291,000 |
| Convertible promissory note agreement with Elan Pharma International, Limited including approximately \$115,000 and \$200,000 of accrued interest at December 31, 2003 and 2002, respectively | 3,115,000 | 4,860,000 |
| Convertible subordinated note payable to Becton Dickinson, net of \$133,000 and \$187,000 discount and including \$352,000 and \$212,000 of accrued interest at December 31, 2003 and 2002, respectively | 2,219,000 | 2,025,000 |
| | 5,657,000 | 12,415,000 |
| Less—current portion | (323,000) | (2,105,000) |
| Total long-term debt and capital lease obligations | \$5,334,000 | \$10,310,000 |

On June 14, 2002, the Company entered into a loan agreement with the Boston Private Bank & Trust Company under which the Company borrowed \$4,695,000. The Company used the proceeds of the loan agreement to pay off its existing credit facility with Fleet National Bank. Under the terms of the loan agreement, the Company was required to (i) pay interest monthly in arrears at a variable interest rate and (ii) repay principal in equal quarterly installments of \$235,000 over a five-year term, beginning September 1, 2002. The outstanding balance on the loan agreement was fully collateralized with a money market account maintained by the Company at the Boston Private Bank & Trust Company. Effective April 2, 2003, the Company amended this loan agreement with the Boston Private Bank & Trust Company. Under the terms of the amended loan amendment, the Company ceased its quarterly principal payments. The loan was structured as a revolving credit facility under which up to \$7,000,000 could have been borrowed and remained outstanding until the repayment date of April 1, 2005. Curis continued to pay interest monthly in arrears at a variable interest rate during 2003. This loan was fully collateralized with a money market account of Curis maintained at the Boston Private Bank & Trust Company. On December 1, 2003, the Company paid in full to the Boston Private Bank & Trust Company its outstanding loan balance of \$3,996,000, comprised of \$3,991,000 in principal and \$5,000 in accrued interest. The Company had paid \$217,000 earlier in 2003. The Company paid this loan with funds held in its fully collateralized money market account at the Boston Private Bank & Trust Company.

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 5. 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 is July 18, 2007. However, EPIL has the option to convert all or any portion of the outstanding principal amount into the

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

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. As of December 31, 2003, there was \$3,115,000, including \$115,000 in accrued interest, outstanding under the amended and restated convertible note.

The Company leases equipment under various capital lease arrangements. Monthly payments on leases outstanding as of December 31, 2003 range from \$1,880 to \$21,170 and maturities range from March 2004 to July 2004. The initial terms of the leases range from 36 months to 60 months and bear interest at rates ranging from 12.5% to 16.3%. As of December 31, 2003, \$323,000 was outstanding under these agreements and the Company was in compliance with all covenants under these agreements.

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 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, 2003, \$2,352,000, including \$352,000 of accrued interest, was outstanding under the note payable.

Maturities of long-term debt and future capital lease obligations are as follows:

| <u>Year Ending December 31,</u> | | |
|---------------------------------|-----------------------------------|-------------|
| 2004 | | \$ 339,000 |
| 2005 | | — |
| 2006 | | 2,219,000 |
| 2007 | | 3,115,000 |
| Thereafter | | — |
| | Total minimum payments | 5,673,000 |
| | Less—Amount representing interest | (16,000) |
| | Principal obligation | 5,657,000 |
| | Less—Current portion | (323,000) |
| | | \$5,334,000 |

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

(11) 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> | |
|---------------------------------|--------------------|
| 2004 | \$ 822,000 |
| 2005 | 822,000 |
| 2006 | 1,433,000 |
| 2007 | 518,000 |
| Thereafter | <u>—</u> |
| Total minimum payments | <u>\$3,595,000</u> |

Rent expense for all operating leases was \$339,000, \$1,227,000 and \$2,017,000 for the years ended December 31, 2003, 2002 and 2001, respectively, net of facility sublease income of \$583,000, \$607,000 and \$405,000 in 2003, 2002 and 2001, respectively. The Company's lease obligations expire on April 30, 2007. The Company has an option to extend its lease to April 2012.

Effective August 15, 2002, the Company sublet approximately 12,000 square feet, or 67%, of the rentable square footage of its facility at 61 Moulton Street, Cambridge, MA, at a rate of \$29.48 per square foot. The Company's cost of the sublet space is \$26.50 per square foot. The initial term of the sublease is two years with an option, at the subtenant's discretion, to extend the sublease for an additional term of two years and eight months. During the twelve months ending December 31, 2003 and 2002, the Company received sublease payments of \$370,000 and \$132,000, respectively. In addition to the sublease payments, the subtenant is required to pay its pro rata share (approximately 67%) of all building operating costs. The Company's lease obligation ends on April 30, 2007.

As a result of a realignment of its research and development programs, effective June 30, 2002, the Company terminated its lease for a 50,000 square foot facility at 21 Erie Street, Cambridge, MA. Under the terms of the agreement, the Company made no payments upon lease termination and has no further financial or other obligations after June 30, 2002.

Effective March 1, 2002, the Company subleased 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. The term of the sublease is two years and six months. During the twelve months ending December 31, 2003 and 2002, the Company received sublease payments of \$213,000 and \$163,000, respectively. In addition to the sublease payments, the subtenant is required to pay its pro rata share (approximately 15%) of all building operating costs. The Company's lease obligation ends on April 30, 2007.

During 2000, the Company entered into a sublease for its Boston, Massachusetts, facility previously occupied by Creative BioMolecules commencing on July 1, 2000. The sublease terminated on July 31, 2002, also the termination date of the Company's original lease on this facility. For the years ended December 31, 2002 and 2001, the Company received sublease payments of \$312,000 and \$332,000, respectively.

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

(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 product sales, if any, resulting from the underlying licensed technology. 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 over their respective service periods 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 \$1,264,000, \$364,000 and \$691,000 for the years ended December 31, 2003, 2002 and 2001, respectively. During the twelve months ending December 31, 2003, the Company incurred \$74,000 in expenses associated with development milestone payments or royalties on licensed technology. The Company did not incur any such expenses for the years ended December 31, 2002 and 2001.

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 milestones 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 is currently 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.

In connection with the termination of a collaboration, for which the Company retained its rights to the underlying technology, the Company is required to make milestone payments of \$3,500,000 contingent upon regulatory approval and commercialization of the reflux and incontinence products. The Company terminated its reflux and incontinence programs as part of the realignment. No milestone payments have been made on this agreement through December 31, 2003.

(12) NOTES RECEIVABLE—FORMER OFFICERS

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 are full recourse loans that each bear 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

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

funds. As of December 31, 2003, the notes have not been repaid. The book value of the notes is \$1,338,000 as of December 31, 2003 and 2002, respectively, and is included as “Notes receivable” in the Company’s Stockholders’ Equity section of its Consolidated Balance Sheets. The book value of the notes is presented net of a reserve for the estimated uncollectible portion of the notes. During 2002 and the first quarter of 2003, this reserve was equal to the total amount outstanding under the Creative Notes less the underlying value of the Curis common stock that collateralize the notes. Beginning in the second quarter of 2003, the value of the underlying Curis common stock began appreciating. The Company elected not to decrease the reserve based on increases in Curis’ common stock value and will not reverse the reserve until the Company believes collection of an amount in excess of the carrying value is reasonably assured. The Company has recorded charges of \$34,000 during 2003 and \$686,000 for the year ended December 31, 2002, to write-down the carrying value of the notes. The reserve on the notes was \$1,229,000 and \$1,194,000 as of December 31, 2003 and 2002, respectively, and is included in “Notes receivable” at the Company’s Stockholders’ Equity section of its Consolidated Balance Sheets .

(13) 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 fair value of the Series A preferred shares was determined based on an arm’s length negotiation between the Company and Elan. The Company recorded charges to accumulated deficit for the accretion of a mandatory 6% dividend on the preferred stock of \$271,000, \$723,000 and \$326,000 for the years ended December 31, 2003, 2002 and 2001, respectively. Such amounts are included in the net loss applicable to common stockholders for the year 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.

(14) WARRANTS

The Company has a total of 1,135,884 warrants to purchase its common stock outstanding as of December 31, 2003. These warrants are summarized as follows:

- (a) 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, 2003, none of these warrant have been exercised.
- (b) 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, 2003, the warrant has not been exercised.
- (c) At December 31, 2003, other warrants to purchase 8,974 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 November 2004 until December 2009.

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

(15) 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. As of December 31, 2003, the number of shares of common stock subject to issuance under the 2000 Plan is 13,000,000. At December 31, 2003, 2,893,549 shares are available for grant under the 2000 Plan.

The 2000 Plan permits the granting of incentive and nonqualified stock options to employees, officers, directors, and consultants of the Company and its subsidiaries at prices determined by the Compensation Committee of 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 Compensation Committee. Options become exercisable as determined by the Compensation Committee 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, 2003, the number of shares of common stock subject to issuance under the 2000 Director Plan is 500,000. As of December 31, 2003, 210,000 shares are available for grant under the 2000 Director Plan.

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

| | Number of Shares | Weighted Average Exercise Price per Share |
|--|-----------------------------|--|
| Outstanding, January 1, 2001 (2,384,703 exercisable at weighted average price of \$10.16 per share) | 6,883,684 | 12.00 |
| Granted | 3,512,399 | 3.43 |
| Exercised | (274,640) | 2.67 |
| Canceled | (1,914,044) | 13.19 |
| Outstanding, December 31, 2001 (2,484,998 exercisable at weighted average price of \$9.40 per share) | 8,207,399 | 8.37 |
| Granted | 4,761,800 | 1.44 |
| Exercised | (1,822) | 1.18 |
| Canceled | (4,262,485) | 8.92 |
| 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 |
| Canceled | (2,141,969) | 4.06 |
| Outstanding, December 31, 2003 (4,186,437 exercisable at weighted average price of \$5.37 per share) | 9,117,249 | \$ 4.01 |

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

The table below summarizes options outstanding and exercisable at December 31, 2003:

| Exercise Price Range | Options Outstanding | | | Options Exercisable | |
|-------------------------|---------------------|--|---|---------------------|---|
| | Number of Shares | Weighted Average Remaining Contractual Life (in years) | Weighted Average Exercise Price per Share | Number of Shares | Weighted Average Exercise Price per Share |
| \$ 0.56 - \$ 1.32 | 1,255,823 | 8.64 | \$ 0.92 | 508,841 | \$ 0.90 |
| 1.50 - 1.95 | 1,866,742 | 8.03 | 1.52 | 1,225,802 | 1.53 |
| 2.32 - 3.90 | 4,169,023 | 8.50 | 2.91 | 1,103,022 | 3.49 |
| 4.38 - 5.89 | 646,871 | 6.83 | 5.01 | 379,058 | 5.06 |
| 6.30 - 8.75 | 32,800 | 6.19 | 7.00 | 25,425 | 7.11 |
| 10.00 - 17.94 | 1,059,927 | 6.57 | 13.69 | 860,999 | 13.71 |
| 20.00 - 31.15 | 86,063 | 3.49 | 28.53 | 83,290 | 28.72 |
| | <u>9,117,249</u> | <u>8.02</u> | <u>\$ 4.01</u> | <u>4,186,437</u> | <u>\$ 5.37</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 Plan). The Company has reserved 1,000,000 of its shares of common stock for issuance under the ESPP Plan. Eligible employees may purchase shares at 85% of the lower closing market price at the beginning or ending date of the ESPP Plan period, as defined. During the years ended December 31, 2003, 2002 and 2001, 50,717, 41,264, and 53,888 shares, respectively, were issued under the ESPP Plan. As of December 31, 2003, 837,000 shares are available for future purchase under the ESPP Plan.

(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.

In June 2002, the Company issued from the 2000 Plan 352,752 shares of restricted common stock to its Board of Directors. These shares were awarded in lieu of cash compensation for director and committee services for the period beginning October 2001 through June 12, 2003. In addition, the Company issued 43,478 shares of restricted common stock to an executive officer in exchange for a \$50,000 reduction in cash compensation for the period of June 13, 2002 through June 12, 2003. All of the restricted shares were fully vested on October 21, 2002. Each Director and the executive officer paid consideration equal to the par value for each share awarded (\$0.01). The total value of the restricted stock, less the cash consideration paid, was \$431,000.

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 is being recognized as an expense on a straight-line basis over the vesting period, generally four years, of the underlying stock options for

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

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. The Company recorded compensation expense related to these options for the years ended December 31, 2003, 2002 and 2001, per the following table:

| | For the Year ended December 31, | | |
|---------------------|---------------------------------|-------------|-------------|
| | 2003 | 2002 | 2001 |
| Employees | \$1,076,000 | \$1,914,000 | \$3,934,000 |
| Non-employees | 24,000 | (21,000) | 30,000 |
| Total | \$1,100,000 | \$1,893,000 | \$3,964,000 |

During the years ended December 31, 2003 and 2002, the Company reversed \$152,000 and \$5,794,000, respectively, of unamortized deferred compensation related to options which were forfeited by terminated employees. The deferred compensation balance at December 31, 2003, relating to stock options held by existing employees was \$651,000.

As a result of the merger in July 2000, the Company recorded \$19,146,000 of deferred compensation as a component of stockholders' equity related to the value of unvested stock options held by employees and consultants primarily of Ontogeny, which were exchanged for options to acquire the Company's common stock. The Company amortized this amount over the one-year vesting period of the stock options ending on August 1, 2001. During the year ended December 31, 2001, compensation expense related to these options totaled \$6,257,000. During the year ended December 31, 2001, the Company also reversed approximately \$421,000 of unamortized deferred compensation related to options which were forfeited by terminated employees.

(16) INCOME TAXES

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 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, | |
|--|---------------------------------|---------|
| | 2003 | 2002 |
| Statutory federal income tax rate | 34.0% | 34.0% |
| State income taxes, net of federal benefit | 8.2% | 1.2% |
| Equity in loss from foreign joint venture | —% | (1.8%) |
| Impairment of non-deductible goodwill | —% | (26.5%) |
| Research and development tax credits | 4.3% | 0.8% |
| Deferred compensation | (4.5%) | (—%) |
| Other | (1.2%) | (1.1%) |
| Valuation allowance | (40.8%) | (6.6%) |
| Effective income tax rate | —% | —% |

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

The principle components of the Company's deferred tax assets and liabilities at December 31, 2003 and 2002, respectively are as follows:

| | <u>December 31, 2003</u> | <u>December 31, 2002</u> |
|---|--------------------------|--------------------------|
| Deferred Tax Assets: | | |
| Net operating loss carryforwards | \$ 63,720,000 | \$ 61,094,000 |
| Research and development tax credit carryforwards | 7,574,000 | 7,109,000 |
| Depreciation and amortization | 1,335,000 | 815,000 |
| Capitalized research and development expenditures | 19,893,000 | 17,952,000 |
| Deferred revenue | 3,354,000 | 4,894,000 |
| Impairment of investments | 473,000 | — |
| Accrued expenses and other | 1,826,000 | 1,111,000 |
| Total Gross Deferred Tax Asset | <u>98,175,000</u> | <u>92,975,000</u> |
| Valuation Allowance | <u>(98,175,000)</u> | <u>(92,975,000)</u> |
| Net Deferred Tax Asset | <u>\$ —</u> | <u>\$ —</u> |

As of December 31, 2003, the Company had federal net operating loss and research and experimentation credit carryforwards of approximately \$182,143,000 and \$6,474,000, respectively, which may be available to offset future federal income tax liabilities which expire at various dates starting in 2004 and going through 2023. The Company has recorded a deferred tax asset of approximately \$98,175,000. 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. 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 loss and research and experimentation credit carryforwards. 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 \$98,175,000 has been established at December 31, 2003.

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

(17) 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 Compensation Committee of the Board of Directors. For the year ended December 31, 2003, the Compensation Committee authorized matching contributions up to 6% of participants' salaries for a total of \$184,000. The Compensation Committee authorized matching contributions of \$213,000 for the year ended December 31, 2001. The Compensation Committee did not authorize matching contributions for 2002.

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

(18) SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

The following are selected quarterly financial data for the years ended December 31, 2003 and 2002:

| | Quarter Ended | | | |
|--|-------------------|------------------|-----------------------|----------------------|
| | March 31, 2003 | June 30, 2003 | September 30, 2003 | December 31, 2003 |
| Revenues | \$ 435,358 | \$ 548,942 | \$ 9,308,838 | \$ 755,095 |
| Income (loss) from operations | (4,295,352) | (5,210,056) | 4,525,326 | (4,931,923) |
| Net income (loss) applicable to common stockholders | (4,470,029) | (5,038,873) | 4,549,916 | (6,935,572) |
| Basic net income (loss) per share | \$ (0.14) | \$ (0.15) | \$ 0.12 | \$ (0.17) |
| Diluted net income (loss) per share | \$ (0.14) | \$ (0.15) | \$ 0.11 | \$ (0.17) |
| Shares used in computing basic net loss per share | 31,731,009 | 33,501,511 | 38,282,799 | 40,426,650 |
| Shares used in computing diluted net loss per share | 31,731,009 | 33,501,511 | 42,031,957 | 40,426,650 |

| | Quarter Ended | | | |
|--|-------------------|------------------|-----------------------|----------------------|
| | March 31, 2002 | June 30, 2002 | September 30, 2002 | December 31, 2002 |
| Revenues | \$ 158,632 | \$ 189,603 | \$ 222,351 | \$17,819,952 |
| Income (loss) from operations | (17,315,950) | (70,443,999) | (4,737,026) | 13,110,553 |
| Net income (loss) applicable to common stockholders | (18,002,269) | (71,173,411) | (5,932,911) | 12,070,253 |
| Basic net income (loss) per share | \$ (0.56) | \$ (2.20) | \$ (0.18) | \$ 0.38 |
| Diluted net income (loss) per share | \$ (0.56) | \$ (2.20) | \$ (0.18) | \$ 0.35 |
| Shares used in computing basic net loss per share | 32,329,228 | 32,334,965 | 32,578,225 | 31,843,548 |
| Shares used in computing diluted net loss per share | 32,329,228 | 32,334,965 | 32,578,225 | 35,528,208 |

The net loss amounts presented above for the quarter ending December 31, 2003 included the following expenses:

- *Issuance of common stock under amendment to technology license agreement:* 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 agreements is currently in preclinical development and is not currently commercializable.
- *Write-off of Note Receivable from former collaboration partner:* During the fourth quarter of the year ended December 31, 2003, the Company recorded an impairment charge of \$1,708,000 for the write-off of a euro-denominated note receivable from Micromet AG, a former collaborator of the Company. 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 co-development partner. Micromet stated that this dispute would result in a significant decrease in previously budgeted cash inflows in 2004.

CURIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements—Continued

(19) SUBSEQUENT EVENTS

(a) COLLABORATION WITH WYETH PHARMACEUTICALS

On January 12, 2004, the Company licensed its Hedgehog proteins and novel small molecule Hedgehog pathway agonists to Wyeth for therapeutic applications in the treatment of neurological and other disorders. Under the terms of the agreement, Wyeth paid the Company \$3,000,000, of which of \$1,500,000 was applied to the purchase of 315,524 shares of the Company's common stock. Wyeth is also obligated to provide financial support of the Company's research under the collaboration for a minimum of two years as well as to make additional cash payments if the licensed programs successfully achieve clinical development and drug approval milestones. Wyeth is also obligated to pay the Company a royalty on net product sales, if any, 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 those applications that qualify as orphan drug indications, topical applications for hair growth, local delivery applications for treatment of cardiovascular disease and use of the technology with stem cells. Wyeth has a right of first negotiation to obtain an exclusive license to the orphan drug indications and the cardiovascular applications.

(b) BOSTON PRIVATE BANK & TRUST COMPANY DEBT FINANCING

Effective January 20, 2004, the Company entered into a loan agreement with the Boston Private Bank & Trust Company to finance up to \$1,250,000 in purchases of equipment and facility leasehold improvements from December 1, 2003, until January 20, 2005. Under the terms of the loan agreement, the Company will request periodic financings for qualifying purchases of equipment and leaseholds through January 20, 2005. Until January 20, 2005, the Company will pay interest on any borrowings on a monthly basis in arrears. On January 20, 2005, the Company will convert the then outstanding balance into a 36-month term note that bears interest at either a variable rate (currently 5.00%) or a fixed rate (currently 6.04%) for the repayment period. The note will be secured by any equipment and leaseholds financed. The Company has not drawn any amounts under the loan agreement.

REPORT OF INDEPENDENT PUBLIC AUDITORS

To the Board of Directors and Stockholders of
Curis Newco, Ltd.:

In our opinion, the accompanying balance sheet as of December 31, 2002 and the related statements of operations and comprehensive loss, of stockholders' equity and of cash flows present fairly, in all material respects, the financial position of Curis Newco, Ltd. (a development stage enterprise) at December 31, 2002, and the results of operations and cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America. We did not audit the cumulative totals of the Company for the period from July 16, 2001 (date of inception) to December 31, 2001, which totals reflect a deficit of \$16,795,490 accumulated during the development stage. These cumulative totals were audited by other independent accountants who have ceased operations and whose report dated January 25, 2002 expressed an unqualified opinion on the cumulative amounts. 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 audit. We conducted our audit of these statements in accordance with auditing standards generally accepted in the United States of America which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit 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 audit provides a reasonable basis for our opinion. The financial statements of Curis Newco, Ltd. for the year ended December 31, 2001 were audited by other independent accountants who have ceased operations. Those independent accountants expressed an unqualified opinion on those financial statements in their report dated January 25, 2002.

/s/ PRICEWATERHOUSECOOPERS LLP

Boston, Massachusetts
February 4, 2003

REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To the Stockholders and Board of Directors of
Curis Newco, Ltd.:

We have audited the accompanying balance sheet of Curis Newco, Ltd. (a Bermuda corporation in the development stage) as of December 31, 2001, and the related statements of operations, stockholders' deficit and cash flows for the period from inception (July 16, 2001) to December 31, 2001. 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 audit.

We conducted our audit in accordance with auditing standards generally accepted in the 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 includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Curis Newco, Ltd. as of December 31, 2001 and the results of its operations and its cash flows for the period from inception (July 16, 2001) to December 31, 2001, in conformity with accounting principles generally accepted in the United States.

ARTHUR ANDERSEN LLP

Hamilton, Bermuda
January 25, 2002

NOTE: THIS IS A COPY OF THE AUDIT REPORT PREVIOUSLY ISSUED BY ARTHUR ANDERSEN LLP IN CONNECTION WITH CURIS, INC.'S FORM 10-K FILING FOR THE FISCAL YEAR ENDED DECEMBER 31, 2001. THE INCLUSION OF THIS PREVIOUSLY ISSUED ARTHUR ANDERSEN LLP REPORT IS PURSUANT TO THE "TEMPORARY FINAL RULE AND FINAL RULE REQUIREMENTS FOR ARTHUR ANDERSEN LLP AUDITING CLIENTS," ISSUED BY THE SECURITIES AND EXCHANGE COMMISSION IN MARCH 2002. THIS AUDIT REPORT HAS NOT BEEN REISSUED BY ARTHUR ANDERSEN LLP IN CONNECTION WITH THIS FILING ON FORM 10-K.

CURIS NEWCO, LTD.
(A DEVELOPMENT STAGE COMPANY)
BALANCE SHEET

| | December 31, 2003 | December 31, 2002 |
|---|------------------------------|------------------------------|
| | (Unaudited) | (Audited) |
| ASSETS | | |
| Current Assets: | | |
| Cash | \$ 140 | \$ 1,143 |
| Total assets | \$ 140 | \$ 1,143 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current Liabilities: | | |
| Due to Curis (Note 5) | — | 1,299,289 |
| Due to Elan (Note 5) | — | 61,067 |
| Total current liabilities | — | 1,360,356 |
| Stockholders' Deficit: | | |
| Non-redeemable convertible preferred stock, \$1.00 par value— | | |
| Authorized, issued and outstanding—6,000 shares as of December 31, 2003 and 2002 | 6,000 | 6,000 |
| Common stock, \$1.00 par value— | | |
| Authorized, issued and outstanding—6,000 shares as of December 31, 2003 and 2002 | 6,000 | 6,000 |
| Additional paid-in capital | | |
| Capital in excess of par value of stock | — | 14,988,000 |
| Additional capital | 22,178,006 | 7,177,843 |
| Due from stockholders | — | (1,359,653) |
| Deficit accumulated during the development stage | (22,189,866) | (22,177,403) |
| Total stockholders' equity (deficit) | 140 | (1,359,213) |
| | \$ 140 | \$ 1,143 |

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

CURIS NEWCO, LTD.
(A DEVELOPMENT STAGE COMPANY)
STATEMENT OF OPERATIONS

| | For the Year Ended December 31, 2003 | For the Year Ended December 31, 2002 | For the Period from Inception (July 16, 2001) through December 31, 2001 | For the Period Beginning July 16, 2001 through December 31, 2003 |
|---|---|---|--|---|
| | (Unaudited) | (Audited) | (Audited) | (Unaudited) |
| Costs and Expenses: | | | | |
| Research and development | \$ — | \$ 5,360,748 | \$ 16,782,156 | \$ 22,142,904 |
| General and administrative | 12,463 | 21,165 | 13,334 | 46,962 |
| Net loss applicable to common stockholders .. | <u>\$(12,463)</u> | <u>\$(5,381,913)</u> | <u>\$(16,795,490)</u> | <u>\$(22,189,866)</u> |
| Basic and Diluted Net Loss per Common Share | <u>\$ (2.08)</u> | <u>\$ (896.99)</u> | <u>\$ (2,799.25)</u> | <u>\$ (3,698.31)</u> |
| Basic and Diluted Weighted Average Shares | | | | |
| Outstanding | <u>6,000</u> | <u>6,000</u> | <u>6,000</u> | <u>6,000</u> |

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

CURIS NEWCO, LTD.
(A DEVELOPMENT STAGE COMPANY)
STATEMENTS OF STOCKHOLDERS' DEFICIT

| | Non-redeemable convertible preferred stock | | Common Stock | | Additional Paid-in Capital | Due from Stockholders | Deficit Accumulated During the Development Stage | Total Stockholder's Equity |
|--|--|------------------|------------------|------------------|----------------------------|-----------------------|--|----------------------------|
| | Number of Shares | \$1.00 Par Value | Number of Shares | \$1.00 Par Value | | | | |
| Incorporation of the Company: | | | | | | | | |
| Issuance of non-redeemable convertible preferred stock | 6,000 | \$6,000 | — | \$ — | \$ 7,494,000 | \$ — | \$ — | \$ 7,500,000 |
| Issuance of common stock | — | — | 6,000 | \$6,000 | 7,494,000 | — | — | 7,500,000 |
| Capital contribution | — | — | — | — | 1,805,275 | — | — | 1,805,275 |
| Due from stockholders | — | — | — | — | — | (963,916) | — | (963,916) |
| Net loss | — | — | — | — | — | — | (16,795,490) | (16,795,490) |
| Balance, December 31, 2001 | <u>6,000</u> | <u>\$6,000</u> | <u>6,000</u> | <u>\$6,000</u> | <u>\$16,793,275</u> | <u>\$ (963,916)</u> | <u>\$(16,795,490)</u> | <u>\$ (954,131)</u> |
| Capital contribution | — | — | — | — | 5,372,568 | — | — | 5,372,568 |
| Capital contributions received in cash | — | — | — | — | — | 4,976,831 | — | 4,976,831 |
| Total capital contributions | — | — | — | — | — | (5,372,568) | — | (5,372,568) |
| Net loss | — | — | — | — | — | — | (5,381,913) | (5,381,913) |
| Balance, December 31, 2002 | <u>6,000</u> | <u>\$6,000</u> | <u>6,000</u> | <u>\$6,000</u> | <u>\$22,165,843</u> | <u>\$(1,359,653)</u> | <u>\$(22,177,403)</u> | <u>\$(1,359,213)</u> |
| Capital contribution (unaudited) | — | — | — | — | 12,163 | — | — | 12,163 |
| Payments from stockholders (unaudited) | — | — | — | — | — | 1,359,653 | — | 1,359,653 |
| Net loss (unaudited) | — | — | — | — | — | — | (12,463) | (12,463) |
| Balance, December 31, 2003 (unaudited) | <u>6,000</u> | <u>\$6,000</u> | <u>6,000</u> | <u>\$6,000</u> | <u>\$22,178,006</u> | <u>\$ —</u> | <u>\$(22,189,866)</u> | <u>\$ 140</u> |

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

CURIS NEWCO, LTD.
(A DEVELOPMENT STAGE COMPANY)
STATEMENT OF CASH FLOWS

| | For the Year Ended December 31, 2003 | For the Year Ended December 31, 2002 | For the Period from Inception (July 16, 2001) through December 31, 2001 | For the Period Beginning July 16, 2001 through December 31, 2003 |
|---|---|---|--|--|
| | (Unaudited) | (Audited) | (Audited) | (Unaudited) |
| Cash Flows from Operating Activities: | | | | |
| Net loss | \$ (12,463) | \$(5,381,913) | \$(16,795,490) | \$(22,189,866) |
| Adjustments to reconcile net loss to net cash used in operating activities— | | | | |
| Write-off of acquired technology | — | — | 15,000,000 | 15,000,000 |
| Non-cash increase in capital contributions | (1,360,356) | 400,595 | 963,916 | 4,155 |
| Changes in operating assets and liabilities— | | | | |
| Due from stockholders | 1,359,653 | (400,595) | (963,916) | (4,858) |
| Due to Curis | — | 341,491 | 957,798 | 1,299,289 |
| Due to Elan | — | 54,949 | 6,118 | 61,067 |
| Net cash used in operating activities | <u>(13,166)</u> | <u>(4,985,473)</u> | <u>(831,574)</u> | <u>(5,830,213)</u> |
| Cash Flows from Financing Activities: | | | | |
| Capital contributions received | 12,163 | 4,976,831 | 841,359 | 5,830,353 |
| Net cash provided by financing activities | <u>12,163</u> | <u>4,976,831</u> | <u>841,359</u> | <u>5,830,353</u> |
| Net change in cash | (1,003) | (8,642) | 9785 | 140 |
| Cash, beginning of period | 1,143 | 9,785 | — | — |
| Cash, end of period | <u>\$ 140</u> | <u>\$ 1,143</u> | <u>\$ 9,785</u> | <u>\$ 140</u> |
| Supplemental Disclosure of Noncash Financing Activities: | | | | |
| Issuance of non-redeemable preferred stock and common stock for technology license . . | <u>\$ —</u> | <u>\$ —</u> | <u>\$ 15,000,000</u> | <u>\$ 15,000,000</u> |

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

CURIS NEWCO, LTD.

(A DEVELOPMENT STAGE COMPANY) NOTE TO FINANCIAL STATEMENTS

All information as of and for the year ended December 31, 2003 is unaudited.

(1) OPERATIONS

Curis Newco, Ltd. (Curis Newco) was incorporated on July 16, 2001, as a Bermuda company. Curis Newco is a wholly-owned subsidiary of Curis, Inc. (Curis). From July 16, 2001 until May 16, 2003, Curis Newco was owned by Curis and Elan International Services Ltd. (EIS), holding 80.1% and 19.9% (non-voting shares) interests, respectively. Curis Newco was committed to the research and development of molecules that stimulate the hedgehog (Hh) signaling pathway as defined in the Subscription, Joint Development and Operating Agreement dated July 18, 2001, between EIS and Curis. This pathway has been previously shown to play a role in the development of the central and peripheral nervous systems.

On May 16, 2003, Curis and affiliates of Elan Corporation, plc entered into a termination agreement (Termination Agreement) to conclude the joint venture. As a result of the termination, Elan transferred its 19.9% share of Curis Newco to Curis, such that Curis Newco has become a wholly-owned subsidiary of Curis and Curis Newco is consolidated into Curis' consolidated financial statements.

On July 18, 2001, EIS was issued 1,000 shares of Curis' Series A convertible exchangeable preferred stock (Series A Preferred Stock) valued at \$12,015,000. The Series A Preferred Stock was convertible, at EIS's option, into newly issued, fully paid, non-assessable shares of Curis' common stock or into the preferred stock originally issued to Curis representing 30.1% of the aggregate outstanding shares of Curis Newco on a fully diluted basis. Such exchange would have increased EIS's ownership in Curis Newco to 50% on a fully diluted basis. Curis used the value of the Series A Preferred Stock to acquire its 80.1% interest in Curis Newco on a fully diluted basis. Curis Newco used this investment along with the 19.9% investment from EIS to acquire a license from Neuralab, Ltd., an affiliate of EIS, valued at \$15,000,000, giving Curis Newco rights to use specific Elan drug technologies. Immediately upon completing this transaction, the cost of the license was expensed as a research and development cost as the technology acquired had not yet reached technological feasibility and there was no future alternative use for the technology. The Series A Preferred Stock was cancelled as part of the Termination Agreement. As partial consideration for the rights and benefits set forth in the Termination Agreement, including the cancellation of the Series A Preferred Stock, Curis 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 common stock on the Nasdaq National Market.

Within the period commencing on July 18, 2001 and ending upon termination on May 16, 2003, Curis and EIS had agreed to provide Curis Newco up to an aggregate amount of \$10,000,000 (Development Funding). Such Development Funding was to be provided by Curis and EIS on a pro rata basis based on their respective ownership interests (see Note 4). In order to ensure Curis had funds available for its share of the Development Funding, Curis entered into an \$8,010,000 convertible promissory note agreement (the Note Agreement) with Elan Pharma International Ltd. (EPIL). The borrowings under the Note Agreement were subject to Elan's consent and were restricted for Curis' funding of its pro rata share of Curis Newco expenses. As of December 31, 2002, borrowings of \$4,860,000, including capitalized interest of \$200,000 were outstanding under the Note Agreement. As part of the termination, of the \$4,900,000 outstanding under the Note Agreement, Curis repaid \$1,500,000 in cash and EPIL forgave \$400,000. Curis then entered into an amended and restated convertible note payable with EPIL for the remaining principal amount of \$3,000,000. The terms of the amended and restated convertible note payable were substantially the same as those under the original note payable except that the interest rate was reduced from 8% to 6% and the conversion rate was increased to \$10.00 from \$8.63. As of December 31, 2003, there was \$3,115,000, including \$115,000 in accrued interest, outstanding under the amended and restated convertible note payable.

CURIS NEWCO, LTD.

(A DEVELOPMENT STAGE COMPANY)

NOTE TO FINANCIAL STATEMENTS—CONTINUED

Curis Newco incurred minimal expenses during the twelve-month period ended December 31, 2003. In accordance with the development agreement between Curis and Elan that governed Curis Newco's operations prior to the effectiveness of the Termination Agreement, Curis and Elan were required to agree upon a Curis Newco development plan in order for any research expenses to be incurred by Curis Newco. Curis and Elan did not reach agreement on a development plan prior to the termination of the joint venture on May 16, 2003, and, therefore, no research expenses were recorded at Curis Newco in 2003. Curis Newco, however, incurred minimal administrative expenses, including an annual fee to Bermuda to maintain its legal status. As of the termination date, Curis had recorded a payable to Curis Newco of \$1,089,000, which represented the Company's 80.1% share of Curis Newco's loss for the three-month period ended December 31, 2002 (see Note 5). In addition, the Company had recorded a receivable from Curis Newco of \$1,299,000 that represented charges for services performed by Curis on behalf of Curis Newco for the three-month period ended December 31, 2002. Both of these amounts were paid as part of the termination and there are no remaining balances related to these amounts as of December 31, 2003.

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The accompanying financial statements reflect the application of certain accounting policies described below and elsewhere in the notes to the financial statements.

(a) FAIR VALUE OF FINANCIAL INSTRUMENTS

The carrying amounts of Curis Newco's financial instruments, which include cash, amounts due from stockholders and the amounts due to Curis and EIS approximate their fair value.

(b) CONCENTRATIONS OF SUPPLIERS

Certain materials used in Curis Newco's development process are procured from a single source. The failure of a supplier, including a subcontractor, to deliver on schedule could delay or interrupt the development process and thereby adversely affect Curis Newco's operating results.

(c) USE OF ESTIMATES

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

(d) RESEARCH AND DEVELOPMENT EXPENSES

Curis Newco charges research and development expenses to operations as incurred.

(e) NET LOSS PER SHARE

Basic and diluted net loss per common share is calculated by dividing the net loss applicable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted net loss per common share is the same as basic net loss per common share, since the effects of potentially dilutive securities are antidilutive for all periods presented. Antidilutive securities, which consist of non-redeemable convertible preferred stock, aggregated to 6,000 shares as of December 31, 2003, 2002 and 2001.

CURIS NEWCO, LTD.
(A DEVELOPMENT STAGE COMPANY)
NOTE TO FINANCIAL STATEMENTS—CONTINUED

(f) **COMPREHENSIVE LOSS**

Comprehensive loss is defined as the change in stockholders' deficit during a period from transactions and other events and circumstances from non-owner sources. Curis Newco's net loss is equal to its comprehensive loss for the period presented.

(g) **ORGANIZATION COSTS**

All organization costs have been expensed as incurred.

(h) **DISCLOSURES ABOUT SEGMENTS OF AN ENTERPRISE**

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision making group, in making decisions regarding resource allocation and assessing performance. To date, Curis Newco has viewed its operations and manages its business as principally one operating segment.

(3) INCOME TAXES

Under current Bermuda law, Curis Newco is not required to pay any taxes in Bermuda on either income or capital gains. Curis Newco has received an undertaking from the Minister of Finance in Bermuda that, in the event of such taxes being imposed, Curis Newco will be exempted from taxation until the year 2016.

(4) STOCKHOLDERS' EQUITY (DEFICIT)

(a) **AUTHORIZED STOCK**

Curis Newco has authorized capital stock of 12,000 shares, of which 6,000 are \$1.00 par value common stock and 6,000 are \$1.00 par value non-voting non-redeemable convertible preferred stock.

(b) **COMMON STOCK**

In July 2001, Curis Newco issued 6,000 shares of common stock at \$1,250 per share at a value of \$7,500,000.

(c) **NON-REDEEMABLE CONVERTIBLE PREFERRED STOCK**

In July 2001, Curis Newco issued 6,000 shares of non-redeemable convertible preferred stock (Preferred Stock) at \$1,250 per share at a value of \$7,500,000. As part of the Termination Agreement entered into between Curis and Elan, the preferred stock, which had a carrying value of \$13,336,000, was cancelled on May 16, 2003. The rights, preferences and privileges of the Preferred Stock were as follows:

Voting Rights

Preferred stockholders do not have voting rights.

Dividends

Preferred stockholders are entitled to dividends as and when declared by the board of directors. Preferred stockholders are entitled to participate equally on a pro rata basis in any dividend declared for the holders of common stock.

CURIS NEWCO, LTD.
(A DEVELOPMENT STAGE COMPANY)
NOTE TO FINANCIAL STATEMENTS—CONTINUED

Liquidation Preference

In the event of liquidation, dissolution or winding-up of Curis Newco and before any distribution to common stockholders and any prior series of preferred stock, the holders of Preferred Stock are entitled to receive \$1,250 per share, respectively, plus all declared but unpaid dividends.

Conversion

Each share of Preferred Stock was convertible, at the option of the holder, into one share of common stock, subject to adjustments for dilutive issuances of stock at any time after July 18, 2003.

(5) RELATED PARTY TRANSACTIONS

Curis Newco's research and development and general and administrative costs were paid for directly by the Curis Newco stockholders. These transactions are incurred in the normal course of operations and amounts payable to these stockholders are summarized as follows:

The following table summarizes Curis Newco's related party transactions:

| | <u>December 31, 2003</u> | <u>December 31, 2002</u> |
|--------------------|------------------------------|------------------------------|
| | (Unaudited) | (Audited) |
| Due to Curis | \$— | \$1,299,289 |
| Due to Elan | — | 61,067 |
| Total | <u>\$—</u> | <u>\$1,360,356</u> |

These balances were unsecured and interest free with no set terms of repayment. They are classified as current liabilities as Curis Newco will reimburse Curis and Elan upon its funding by its stockholders.

Due from stockholders represents the amounts required to be funded into Curis Newco as contributed capital by its stockholders. As of December 31, 2003 and 2002, Curis and ESI are obligated to contribute the following to Curis Newco:

| | <u>December 31, 2003</u> | <u>December 31, 2002</u> |
|----------------------|------------------------------|------------------------------|
| | (Unaudited) | (Audited) |
| Due from Curis | \$— | \$1,089,082 |
| Due from Elan | — | 270,571 |
| Total | <u>\$—</u> | <u>\$1,359,653</u> |

As of May 16, 2003, the date of termination of Curis Newco joint venture, Curis had recorded a payable to Curis Newco of \$1,089,000, which represented the Company's 80.1% share of the Curis Newco's loss for the three-month period ended December 31, 2002. In addition, the Company had recorded a receivable from Curis Newco of \$1,299,000 which represented charges for services performed by Curis on behalf of Curis Newco for the three-month period ended December 31, 2002. Both of these amounts were paid as part of the termination and there are no remaining balances related to these amounts as of December 31, 2003.

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

On April 26, 2002, we dismissed Arthur Andersen LLP as its independent public accountants. The decision to dismiss Arthur Andersen LLP was approved by our Audit Committee. None of the reports of Arthur Andersen LLP on our financial statements for either of the two fiscal years prior to Arthur Andersen LLP's dismissal contained an adverse opinion or a disclaimer of opinion, or was qualified or modified as to uncertainty, audit scope or accounting principles. During our two most recently completed fiscal years and any subsequent interim period preceding the date of the dismissal of Arthur Andersen LLP, we had no disagreements with Arthur Andersen LLP on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreement(s), if not resolved to the satisfaction of Arthur Andersen LLP, would have caused Arthur Andersen LLP to make reference to the subject matter of the disagreement in connection with its reports on our financial statements. None of the reportable events listed in Item 304(a)(1)(v) of Regulation S-K under the Securities Exchange Act of 1934 occurred with respect to either of our two most recently completed fiscal years or any subsequent interim period preceding the date of the dismissal of Arthur Andersen LLP.

During our two most recent fiscal years and the subsequent interim period prior to engaging PricewaterhouseCoopers LLP on April 26, 2002, except as indicated below, neither we nor anyone acting on our behalf consulted with PricewaterhouseCoopers LLP regarding either (i) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on our financial statements, and neither a written report nor oral advice was provided to us by PricewaterhouseCoopers LLP that was an important factor considered by us in reaching a decision as to any accounting, auditing or financial reporting issue; or (ii) any matter that was either the subject of a disagreement, as that term is defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions to Item 304 of Regulation S-K, or a reportable event, as that term is defined in Item 304(a)(1)(v) of Regulation S-K. PricewaterhouseCoopers LLP served as independent public accountants of Ontogeny, Inc. until July 31, 2000, the date it was merged, together with Creative Biomolecules, Inc., with and into Curis.

ITEM 9A. DISCLOSURE CONTROLS AND PROCEDURES

- (a) *Evaluation of disclosure controls and 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 defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2003. Based on this evaluation, our chief executive officer and chief financial officer concluded that, as of December 31, 2003, our disclosure controls and procedures were (1) designed to ensure that material information relating to us, including our consolidated subsidiaries, is made known to our chief executive officer and chief financial officer by others within those entities, particularly during the period in which this report was being prepared and (2) effective, in that they provide reasonable assurance 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.
- (b) *Changes in internal controls.* No change in our internal control over financial reporting (as defined in the Securities Exchange Act of 1934, Rules 13a-15(f) and 15d-15(f)) occurred during the fiscal quarter ended December 31, 2003 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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 2004 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 2004 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 2004 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 2004 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 2004 annual meeting of stockholders under the heading “Independent Auditor’s Fees,” which information is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

(a)(1) *Financial Statements.*

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| Consolidated Statements of Cash Flows for the Years Ended December 31, 2003, 2002 and 2001 | 53 |
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| Statement of Stockholders' Deficit for the Years Ended December 31, 2003, 2002 and 2001 | 87 |
| Statement of Cash Flows for the Years Ended December 31, 2003, 2002, for the period from inception (July 16, 2001) through December 31, 2001 and for the period beginning July 16, 2001 through December 31, 2003 | 88 |
| Notes to Financial Statements | 89 |

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

All schedules are omitted because they are not applicable or the required information 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 this reference.

(b) *Reports on Form 8-K.*

(b)(1) On December 30, 2003, we filed a Current Report on Form 8-K to report under Item 5 (Other Events) that we had filed a universal shelf registration statement with the Securities Exchange Commission to sell up to \$40,000,000 of various securities in one or more future offerings.

(b)(2) On November 6, 2003, we furnished a Current Report on Form 8-K to report under Item 12 (Results of Operations and Financial Condition) that we had issued a press release announcing our financial results for the third quarter ended September 30, 2003.

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 | | | | X |
| <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 August 1, 2002, between Curis and Christopher U. Missling | 10-Q | 11/12/02 | 10.4 | |
| #10.3 | Amendment to the Employment Agreement, effective as of January 1, 2004, between Curis and Christopher U. Missling | | | | X |
| #10.4 | Employment Agreement, effective as of November 27, 2003, between Curis and Michael P. Gray | | | | X |
| #10.5 | Employment Agreement, effective as of September 1, 2002, between Curis and Mary Elizabeth Potthoff | | | | X |
| #10.6 | Board of Director and Scientific Advisory Board Services Agreement, effective as of August 11, 2000, between Curis and Douglas A. Melton | | | | X |
| #10.7 | Curis 2000 Stock Incentive Plan | S-4/A (333-32446) | 05/31/00 | 10.71 | |
| #10.8 | Curis 2000 Director Stock Option Plan | S-4/A (333-32446) | 05/31/00 | 10.72 | |
| #10.9 | Curis 2000 Employee Stock Purchase Plan | S-4/A (333-32446) | 05/31/00 | 10.73 | |
| <i>Material contracts—Leases</i> | | | | | |
| 10.10 | 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 | |
| 10.11 | 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 | |
| 10.12 | 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 | |
| <i>Material contracts—Financing Agreements</i> | | | | | |
| 10.13 | Line of Credit Agreement for the Acquisition of Equipment and Leasehold Improvements, dated January 20, 2004, between Curis and Boston Private Bank & Trust Company | | | | X |
| 10.14 | Security Agreement (Specific Equipment), dated January 20, 2004, between Curis and Boston Private Bank & Trust Company | | | | X |
| 10.15 | Secured Non-Revolver Time Note, dated January 20, 2004, made by Curis in favor of Boston Private Bank & Trust Company | | | | X |

| Exhibit No. | Description | Incorporated by Reference | | | |
|--|---|---------------------------|-----------------|----------------|----------------------|
| | | Form | SEC Filing Date | Exhibit Number | Filed with this 10-K |
| <i>Material contracts—License and Collaboration Agreements</i> | | | | | |
| ††10.16 | Master Restructuring Agreement, dated as of October 15, 1998, between Creative and Stryker Corporation | 10-K | 03/30/99 | 10.10 | |
| 10.17 | Second Amendment to Master Restructuring Agreement, dated October 1, 2002, between Curis and Stryker Corporation | 10-Q | 11/12/02 | 10.5 | |
| 10.18 | Irrevocable License Agreement, dated November 20, 1998, between Creative and Stryker Corporation | 10-K | 03/13/00 | 10.7 | |
| 10.19 | Stryker Irrevocable License Agreement, dated November 20, 1998, between Creative and Stryker Corporation | 10-K | 03/13/00 | 10.8 | |
| ††10.20 | 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 | |
| ††10.21 | 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 | |
| ††10.22 | 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 | |
| †10.23 | Amended and Restated License Agreement, dated June 1, 2003, between Curis, The Johns Hopkins University and University of Washington School of Medicine | | | | X |
| †10.24 | Amended and Restated License Agreement (2000), dated June 10, 2003, between Curis and the President and Fellows of Harvard University | | | | X |
| †10.25 | Amended and Restated License Agreement (1995), dated June 10, 2003, between Curis and the President and Fellows of Harvard University | | | | X |
| †10.26 | Agreement, dated as of November 27, 2002, by and between Curis and Ortho Biotech Products, L.P. | 8-K | 12/09/02 | 10.1 | |
| †10.27 | License Agreement, dated December 4, 2002, between Curis and Amylin Pharmaceuticals | | | | X |
| †10.28 | Collaborative Research, Development and License Agreement, dated June 11, 2003, between Curis and Genentech, Inc. | 8-K | 07/10/03 | 10.1 | |
| †10.29 | Collaboration, Research and License Agreement, dated January 12, 2004, between Curis and Wyeth | | | | X |
| <i>Material contracts—Miscellaneous</i> | | | | | |
| †10.30 | 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 | |
| 10.31 | Registration Rights Agreement, dated as of July 18, 2001, among Elan International Services, LTD, Elan Pharma International Limited and Curis, Inc. | 10-Q | 08/14/01 | 4.1 | |
| 10.32 | Registration Rights Agreement, dated June 13, 2003, between the Curis and Genentech, Inc. | 8-K | 07/10/03 | 10.3 | |

| Exhibit No. | Description | Incorporated by Reference | | | |
|-------------|---|---------------------------|-----------------|----------------|----------------------|
| | | Form | SEC Filing Date | Exhibit Number | Filed with this 10-K |
| 10.33 | Common Stock Purchase Agreement, dated June 11, 2003, between the Curis and Genentech | 8-K | 07/10/03 | 10.2 | |
| 10.34 | Common Stock Purchase and Registration Rights Agreement, dated January 9, 2004, between Curis and Wyeth | | | | X |
| 10.35 | 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 | |
| 10.36 | Convertible Note, dated September 11, 2001, made by Micromet AG in favor of Curis | | | | X |
| | <i>Code of Conduct</i> | | | | |
| 14 | Code of Business Conduct and Ethics | | | | X |
| | <i>Additional Exhibits</i> | | | | |
| 21 | Subsidiaries of Curis | | | | X |
| 23.1 | Consent of PricewaterhouseCoopers LLP | | | | X |
| 23.2 | Notice Regarding Consent of Arthur Andersen LLP | | | | X |
| 31.1 | Certification of the Chief Executive Officer pursuant to Rule 13a-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 | | | | X |
| 32.1 | Certification of the Chief Executive Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350 | | | | Furnished |
| 32.2 | Certification of the Chief Financial Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350 | | | | Furnished |

Indicates management contract or compensatory plan or arrangement.

† Confidential treatment has been requested as to certain portions of this exhibit.

†† Confidential treatment has been granted as to certain portions of this exhibit.

RESTORING HUMAN HEALTH