



*2001*

***ANNUAL REPORT***

## SHAREHOLDER INFORMATION

### Curis, Inc. and Subsidiaries

#### MANAGEMENT

Daniel R. Passeri  
*President and Chief Executive Officer*

George A. Eldridge  
*Vice President, Chief Financial Officer,  
and Secretary*

Henry W. McCusker  
*Vice President, Strategic Planning and  
Communications*

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

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

James S. Sigler  
*Vice President, Manufacturing &  
Development*

#### MARKET INFORMATION

Our Common Stock was first traded on the NASDAQ National Market on August 1, 2000. Our trading symbol is "CRIS." There were 285 shareholders of record as of March 20, 2002. 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 2001	High	Low
1st Quarter	\$13.00	\$3.25
2nd Quarter	\$6.90	\$3.00
3rd Quarter	\$7.00	\$3.01
4th Quarter	\$5.75	\$3.25
FY 2000	High	Low
3rd Quarter	\$27.25	\$13.88
(from August 1, 2000)		
4th Quarter	\$19.94	\$6.88

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.

#### 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;  
Former Commissioner of the International  
Commission between the United States and  
Canada; Director, Corvis International,  
Inc., Cubist Pharmaceuticals, Inc. and  
Emmis Communications, Inc.*

Martyn D. Greenacre  
*Director, Cephalon, Inc., Acusphere, Inc.  
and GENSET, S.A.*

Ruth B. Kunath  
*Biotechnology Portfolio Manager, Vulcan  
Ventures Inc.; Director, Vaxgen, Inc. and  
Dendreon Corporation*

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

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; Holds appointment as  
biologist at the Massachusetts General  
Hospital*

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  
www.pwcglobal.com

#### 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 12, 2002 at the offices of Hale and Dorr LLP, 60 State Street, Boston, Massachusetts.

#### CORPORATE HEADQUARTERS

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

#### SEC FORM 10-K

A copy of the Company's annual report to the Securities and Exchange Commission on Form 10-K, without exhibits, is available without charge upon written request to: Investor Relations Curis, Inc. 61 Moulton Street Cambridge, MA 02138

#### FORWARD-LOOKING INFORMATION

This Annual Report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. For this purpose, any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words "believes," "anticipates," "plans," "expects," and similar expressions are intended to identify forward-looking statements. Also, certain statements including, for example, statements as to future financial performance, clinical programs, joint ventures and other corporate or strategic collaborations may be intended as forward-looking statements. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including but not limited to the risk factors and reasons described in our Annual Report on Form 10-K for the year ended December 31, 2001 as filed with the Securities and Exchange Commission on March 28, 2002.

## CURIS, Inc.

### Annual Report 2001—Shareholders Letter

Dear Shareholders:

The past year has been one of transformation for Curis. We have broadened our research capabilities, enhanced our intellectual property portfolio, and have refocused our scientific and business development resources. We believe that the partnerships we have established and the scientific progress we have made are evidence that the signaling pathways controlling cell proliferation and differentiation are key to the future of drug development. What was once hypothetical medicine is now becoming reality, and in the past year we have been working to position Curis at the forefront of what we expect to be the next wave of drug discovery and development.

When I became President and CEO in September 2001, Curis had built a broad portfolio of complementary assets, developed several product candidates and strengthened its scientific position. However, I became convinced that in order to build greater shareholder value, we needed to focus on the value of our assets and our approach to financial performance by placing greater emphasis on development milestones and revenue generation.

As a result, on February 14, 2002, we announced a strategic realignment that we believe is necessary to ensure Curis' position as a future leader in drug development. Our primary focus will be our signaling pathway programs because we believe this is where we have scientific leadership, where the greatest market opportunities exist, and where we can create the most value for our shareholders. We have made some difficult decisions including discontinuing certain clinical programs and reducing staff. We have decided to terminate Chondrogel™, our clinical program for vesicoureteral reflux. We have also decided to suspend our clinical programs for coronary artery disease and basal cell carcinoma, but we hope to partner these product candidates to re-enter clinical development in the future. These programs were terminated and suspended in order to streamline the signaling pathways-based therapeutics programs and focus on those with greater up-side potential. While Curis continues to believe that cell therapy and diagnostics hold long-term promise in the medical field, we will leverage our interest in this research by partnering such programs in order to remain clearly focused on our core efforts in signaling pathways. We believe that these decisions will allow us to deploy our financial resources in a highly focused manner on our core strengths and expedite product development of our most promising assets.

In addition to the difficult choices made this year, we have enjoyed many successes in 2001. Among our most notable success was the approval of Stryker Corporation's OP-1 Implant™ for bone repair and regeneration in four major commercial markets. OP-1, a signaling protein discovered by Curis in the BMP pathway, is the first product from our pipeline to be commercialized. We believe this validates our scientific approach to creating more effective therapeutics based on the body's own repair mechanisms. OP-1 is significantly effecting drug development and the practice of modern medicine by focusing on reactivation of the body's own ability to repair and regenerate. Stryker Corporation, our development and marketing partner, has been granted approval to sell OP-1 Implant™ for non-union bone fractures in Europe, Australia, Canada and the United States (under Human Device Exemption status). Curis began to realize royalty revenue in the 2001 calendar year and we expect that these revenues will increase significantly in 2002.

In addition to our regulatory successes, Curis has worked hard during 2001 to forge strategic collaborations that will build on our scientific development and expertise and strengthen our market leadership position. Each collaboration agreement has broadened our scientific understanding and added specific expertise or intellectual property.

In January 2001, Curis entered into an agreement with Aegera Therapeutics Inc., giving us worldwide exclusive rights to Aegera's skin-derived adult stem cell technologies. In August 2001, this collaboration

announced that adult skin is a source of multipotent stem cells that can be directed toward neuronal or mesodermal development. The results, which have important implications for human therapeutics, were published in *Nature Cell Biology*. This discovery not only provides promise for innovative cell-based therapies, but also provides invaluable insights into the biology of repair and regeneration.

In July 2001, Curis partnered with Elan Corporation, plc, forming a joint venture dedicated to developing Hedgehog therapeutics for the treatment of neurological disorders. Our research demonstrates that the Hedgehog signaling pathway plays a key role in the development, maintenance, and repair of the central and peripheral nervous systems. The joint venture will focus on developing therapeutics that target neurological disorders including Parkinson's Disease, Alzheimer's Disease and Multiple Sclerosis.

Also in July 2001, Curis entered into an extensive strategic alliance with Micromet AG, a German biotechnology company, designed to leverage both companies' complementary expertise, technologies, and product platforms in developmental biology and small molecule discovery. Curis transferred its single chain antibody technology and patent portfolio to Micromet and gained exclusive rights to Micromet's single cell genomics technology. This agreement significantly enhances our capabilities in both stem cell and genomics research. Curis and Micromet will co-develop selected therapeutic antibodies; however, Curis retains all rights to small molecule targets. The alliance also has revenue generating potential from third party usage.

Looking forward, the effects of our realignment, regulatory approval of OP-1 Implant™ and corporate collaborations have made us financially stronger. We ended fiscal year 2001 with \$51.2 million in cash and marketable securities. The strategic realignment measures we have taken will lower Curis' annual net burn rate from approximately \$40 million in 2001 to approximately \$26 million for 2002, excluding costs associated with our realignment. Together with planned future strategic partnerships, we are confident that Curis will be able to continue its mission of transforming the future of therapeutic medical treatment and creating value for its shareholders, into the fourth quarter of 2003 without the need to access capital markets for additional funding.

I would like to thank several members of the senior management team who will be leaving the company in 2002. Andrew Uprichard, M.D., Chief Operating Officer, and George Eldridge, Chief Financial Officer and Vice President Finance, have made significant contributions to Curis' strategic growth. We are also deeply indebted to Doros Platika, Chairman of the Board and Curis' founder, who will be stepping down in May 2002. Doros' vision has been a driving force within Curis, and we are grateful that he will continue to serve as an advisory resource to the Curis management team.

As we progress through this transformation, I want to acknowledge the support of our strategic partners, our employees, our senior management, our Board of Directors and our scientific advisors, in helping us reach our goal. We anticipate that Curis will emerge a leader in drug development based on modulation of signaling pathways, with clear competitive advantages and a rational business strategy that creates value for all its shareholders.

Respectfully,

Daniel R. Passeri  
President and Chief  
Executive Officer

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 10-K**

FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO  
SECTIONS 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

(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, 2001

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, Including 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.

As of March 20, 2002, the aggregate market value of the Common Stock held by non-affiliates of the Registrant was approximately \$79,425,536 based on the closing sale price of \$2.51 of the Registrant's Common Stock on the Nasdaq National Market on such date.

As of March 20, 2002, 32,329,228 shares of the Registrant's Common Stock were outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

The Registrant's definitive proxy statement to be issued in conjunction with the Annual Meeting of Stockholders to be held on June 12, 2002 has been incorporated by reference, in whole or in part, into Part III of this Annual Report on Form 10-K.

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**CURIS, INC.**  
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**FORWARD-LOOKING INFORMATION**

This Annual Report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the

Securities Act of 1933, as amended. For this purpose, any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words "believes," "anticipates," "plans," "expects," and similar expressions are intended to identify forward-looking statements. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including the factors set forth under the caption "Risk Factors" Item 7. All forward-looking statements and reasons why our results may differ included in this Annual Report are made as of the date hereof, and we assume no obligation to update these forward-looking statements or reasons why actual results might differ.

As used in this Annual Report, the terms "we," "us," "our," the "Company" and "Curis" shall mean Curis, Inc.

Curis, Chondrogel and Vascugel are our trademarks. All other trademarks or trade names referred to in this Annual Report are the property of their respective owners.

## **PART I**

### **ITEM 1. BUSINESS**

#### **GENERAL**

We are engaged in the discovery of drug targets and the development of therapeutics based upon the pathways used by the body which control proliferation and differentiation and, therefore, tissue formation, maintenance and repair. We have identified key regulators responsible for turning on the mechanisms for tissue repair in response to trauma, injury or disease. We believe this approach has been validated with the approval of OP-1 Implant for bone repair in four major markets (United States Humanitarian Device Exemption, Europe, Australia and Canada). Independently and in strategic alliances, we are focusing our research efforts on identifying and elucidating key regulators of tissue repair having application for diseases such as kidney disease, cancer and neurological disorders, which we believe represent large market opportunities that are underserved by current therapeutic alternatives.

In the first quarter of 2002, we announced a realignment of our research and development programs and a re-focusing of our resources on our proprietary signaling pathways and stem cell technologies, including the Bone Morphogenic Protein (BMP) and the Hedgehog (Hh) family of product candidates. As part of the realignment, we suspended clinical development efforts for Vascugel in coronary artery disease based on the cost of further clinical development for cell-based therapies, and we will seek a partner before continuing further development of this product opportunity. We also terminated clinical development efforts for Chondrogel in vesicoureteral reflux due to the recent approval and pricing of a competitive non-cell-based product. Further development of Chondrogel for other indications will require the implementation of partnering initiatives that are currently being evaluated. In addition, we suspended our clinical IND program in oncology for basal cell carcinoma in favor of developing an improved topical formulation and seeking a partnership for re-entering clinical development.

As a result of the realignment, we have reduced our staff by 35 people and lowered our annual net burn rate from approximately \$40 million for 2001 to approximately \$26 million for 2002. In addition, we will spend approximately \$3.5 million in 2002 to effect the realignment and are in the process of determining the additional non-cash charges in the first quarter of 2002 against our tangible and intangible assets. See Notes 3(n) and 19 to Notes to Consolidated Financial Statements and the Overview section of "Management's Discussion and Analysis of Financial Condition and Results of Operations."

#### **THE CURIS PARADIGM**

We are working to develop therapies based on key signaling pathways for conditions for which we believe there are no effective treatments currently on the market and which represent major therapeutic markets. Our resources and expertise in developmental biology, genomics and stem cells position us to take advantage of the recent convergence of these disciplines to focus on key signaling pathways. These pathways, which include BMPs and the Hedgehog families of proteins, are important regulators of prenatal tissue development and adult tissue growth and repair. We believe that we will be able to develop product opportunities based on these pathways.

To further enhance product opportunities for our product pipeline, we use stem cell research to identify and validate key signaling pathways that control cell proliferation and differentiation. We believe that this approach will accelerate the discovery of validated drug targets and ultimately drive down the cost of developing new drugs.

#### **THE BMP/OP-1 SIGNALING PATHWAY**

The BMP family of master regulators orchestrates the development and repair of bone and kidneys, and appears to play a role in the repair mechanisms of the brain. OP-1 (osteogenic protein-1, also known as BMP-7), marketed by Stryker Corporation and approved in four major markets for the repair of nonunion long bone fractures, is a member of the BMP family of signaling proteins.

Stryker's approval of the OP-1 product validates our paradigm of developing therapeutics that repair tissue from injury, degeneration and/or illness by reactivating or enhancing the body's natural signaling and repair pathways. The product is a formulation of BMP-7, which is applied at the site of a damaged bone to accelerate the healing process. As individuals age, signaling proteins such as OP-1 are diminished making healing more difficult. The OP-1 product promotes more rapid and complete healing of bone in adults and may also be used to fuse bone, such as is the case with spinal fusion. Stryker, pursuant to its partnering arrangement with us in the orthopaedic market, is currently testing OP-1 for additional orthopaedic indications, including spinal fusion.

Data from Stryker's human clinical trials has proven BMP-7 to be safe for orthopaedic and dental indications. Therefore, the remaining hurdles to approval of BMP-7 for additional indications outside of orthopaedics may be lower than for molecules that have not been shown to be safe in human clinical trials.

We are currently pursuing the development of product candidates based upon BMP-7's potential for repair of damaged kidney tissue. In January 2002, a study, conducted by our researchers and published in the journal *Kidney International*, found that BMP-7 plays a significant role in the maintenance of a healthy kidney in rodents. In this study, our scientists demonstrated that BMP-7 appears to inhibit kidney inflammation and also appears to stimulate the production of other molecules that promote normal blood flow to the kidney. Previously published research has shown that in animal models of acute and chronic kidney disease, treatment with BMP-7 appears to result in decreased inflammation, improved function, and, most importantly, increased survival.

Based on preclinical data and the level of interest shown by potential partners to jointly develop BMP-7, we hope to enter into a collaboration in 2002 for the development of BMP-7 for renal disease. Renal diseases affect a very large population. The number of patients with life-threatening, end-stage renal diseases has increased sharply in the past 30 years. It is estimated that more than 400,000 people suffer from end-stage renal disease in the United States. Each year, nearly 60,000 people in the United States die from causes related to kidney failure. A product that is capable of treating acute and chronic kidney failure would, therefore, have significant commercial potential.

## **THE HEDGEHOG FAMILY: SONIC, DESERT AND INDIAN**

Our scientists and other researchers have shown that the Hedgehog (Hh) family of proteins are key to the formation, maintenance and repair of a number of tissues, including the nervous system and cartilage, as well as in the control of blood vessel formation. Specifically, Sonic Hh (SHh) has been shown to regulate blood vessel, central nervous system and hair development; Desert Hh has been shown to affect peripheral nervous system development and function; and Indian Hh has been shown to control the formation and growth of cartilage. We are developing both protein and small molecule product candidates that effectively activate these pathways.

In a February 2002 study published in *Experimental Neurology*, our scientists and collaborators reported that SHh has been shown to reduce behavioral impairment and dopaminergic nerve loss in preclinical models of Parkinson's Disease. In addition, using rodent models of diabetic neuropathy (in which the animal loses peripheral sensory and motor ability), scientists in the United Kingdom have shown that SHh restores normal nerve function as measured by nerve conduction velocity. This demonstrated improvement in function was dose-dependent and improved both sensory and motor ability.

To our knowledge, this is the first time that there has been complete restoration of both motor and sensory nerve function in an animal model of diabetic neuropathy. We believe there are currently no effective treatments for diabetic neuropathy.

We have identified small molecule compounds that appear to mimic the effects of SHh. These compounds potentially represent drug candidates for Parkinson's Disease and diabetic neuropathy that could be administered orally. In July 2001, we entered into a partnership with Elan Corporation, plc, a publicly held company headquartered in Dublin, Ireland ("Elan"), to develop Hh agonists for the treatment of neurological disorders.



In addition to defraying costs, we believe that the partnership with Elan will enhance and accelerate our ability to bring treatments into clinical development. Based on our preclinical data, the initial therapeutic focus of our alliance with Elan will be in the fields of Parkinson’s Disease and diabetic neuropathy, two indications representing large potential markets.

**ONCOLOGY**

Our scientists have discovered that the inappropriate upregulation of certain signaling pathways, such as Hh, can lead to the growth of cancer in two distinct ways. In the first way, the pathway is inappropriately activated within a cell, which is similar to having a switch “stuck” in the “on” position. Cancers caused by this mechanism result in cell dysregulation and abnormal proliferation. Our scientists have generated small molecule inhibitors that “unstick” or inhibit the “run away” pathway. Upon inhibition, our scientists have observed that this class of cancer undergoes specific programmed cell death or apoptosis. The cancers belonging to this class include basal cell carcinoma, medulloblastoma, and bladder cancer.

In the second way, cancers inappropriately activate signaling pathways that control the cell growth in surrounding tissue. This cell growth ultimately provides essential nutrients required for tumor growth. In a study published in 2001, in Nature Medicine, Hh was demonstrated to be an important regulator of new blood vessel growth. Most tumors, regardless of the mechanism by which they form, need new blood vessels for food and oxygen if they are to grow and spread (metastasize) throughout the body. Preclinical work performed by our scientists suggests that switching off this pathway impedes tumor growth and metastasization by depriving the cancer of critical growth factors, nutrients and blood vessels.

In September of 2001, we received FDA approval to begin human clinical testing of our first Hh antagonist in basal cell carcinoma, the most common form of skin cancer. As a part of our realignment, we have suspended clinical testing of the Hh agonist, which was formulated for administration by intramuscular injection. We intend to reformulate the Hh antagonist as a topical medication and will seek to identify a partner with expertise in dermatology to help accelerate the development process and defray development costs.

Based on the current level of interest expressed by potential partners and the data we hope to generate in 2002, we believe that we may be able to enter into a corporate partnership during the next twelve to eighteen months.

**OP-1 OPPORTUNITIES WITH STRYKER CORPORATION**

Several therapeutic products based upon OP-1 are currently in development by Stryker as part of our commercial collaboration. The following table sets forth the product development programs relating to OP-1:

<u>Potential Application</u>	<u>Development Status(1)</u>
Orthopaedic Reconstruction and Dental Applications Nonunion Fractures . . . . .	Approved in Australia, Europe, U.S. under HDE, and Canada
Fresh Fractures . . . . .	Completed Phase III Trial
Spinal Fusion . . . . .	Phase III Pivotal Clinical Trial initiated in the U.S.
Periodontal Disease . . . . .	Pilot Study Completed

(1) “Pivotal Clinical Trials” are investigations conducted under an Investigational Device Exemption (IDE) intended to be used as the primary supporting documentation for regulatory approval of a new medical device.

### *Orthopaedic Reconstruction and Dental Applications*

Stryker has developed and commercialized orthopaedic reconstruction and dental therapy products using the OP-1 Implant, a powder mixture of OP-1 and a highly purified Type I collagen matrix which is formed into a paste. Pursuant to our commercial collaboration, Stryker has exclusive rights to develop, manufacture and commercialize OP-1 products in the fields of orthopaedic reconstruction and dental applications. Upon commercialization by Stryker of OP-1 products in these fields, we will receive royalties based on Stryker's commercial sales. We have retained our rights to OP-1 for all uses other than orthopaedic reconstruction and dental applications. See “—Collaborative Alliances and License Agreements—Agreements Relating to OP-1 — Stryker Corporation.”

In June 1999, Stryker filed, and had accepted by the FDA, a Pre-Market Approval (PMA) application for the OP-1 Implant. The following month, in July 1999, Stryker filed a Marketing Authorization Application (MAA) with the European Medicines Evaluation Agency (EMEA) for certain OP-1 uses, which was accepted for filing at that time. Stryker received a “Not Approvable” letter from the FDA on January 29, 2001 that cited the failure of the pivotal clinical trial to meet the study endpoint of non-inferiority of the OP-1 Implant compared to the autograft control on a combined clinical and radiographic basis. In the second quarter of 2001, Stryker received marketing approval for its OP-1 Implant product in Australia and the European Union. The approved indication in Australia is for the treatment of nonunion of long bone fractures secondary to trauma for the purposes of initiating repair by new bone formation. The approved indication in Europe is for tibial nonunions of nine-month duration, secondary to trauma, in skeletally mature patients, in cases where previous treatment with autograft has failed or use of autograft is unfeasible. In 2001, Stryker filed an application for a Humanitarian Device Exemption (HDE) with the FDA which, in the fourth quarter of 2001, resulted in Stryker being granted HDE status for OP-1 Implant by the FDA. The approved indication in the U.S. is for use as an alternative to autograft in recalcitrant long bone nonunions where use of autograft is unfeasible and alternative treatments have failed. Under the HDE, OP-1 Implant will be made available as a humanitarian device, defined by the FDA as one intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals per year in the U.S. The first commercial sales of OP-1 in Australia began in mid-May 2001 and the commercial launch of OP-1 in select markets of the European Union began in August 2001. The first sales of OP-1 in the U.S. under the HDE began in November 2001. In February 2002, Stryker received approval to market OP-1 Implant in Canada for the clinical indication of long bone nonunions.

Stryker is also developing the use of OP-1 for other surgical indications in addition to the approved limited trauma indications in certain markets. For example, in 1999, Stryker began to enroll patients in a pilot investigational device exemption (IDE) study for OP-1 in a spine indication. Enrollment in the pilot study was completed in the first quarter of 2001. Stryker obtained conditional approval for a pivotal trial in the U.S. and Canada for the same indication in 2001. Enrollment in this pivotal trial commenced in December 2001. Stryker also has completed enrollment in a single-site clinical feasibility study for a similar indication in Japan and is in the process of submitting an application for a multicenter trial.

### **COLLABORATIVE ALLIANCES AND LICENSE AGREEMENTS**

Our strategy for development and commercialization of products depends upon the formation of collaborations and strategic alliances. These alliances are designed 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:

- 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.

There can be no assurance that we will be able to establish the new strategic alliances necessary to develop and commercialize our products, that any future arrangements will be on terms favorable to us or that current or future strategic alliances will be successful.

*Agreements Relating to OP-1*

*Stryker.* We have an agreement with Stryker for bone-inducing proteins (OP-1) in the field of Orthopaedics. OP-1 was first isolated and characterized by scientists at Creative BioMolecules, Inc., a predecessor of ours, as a part of a collaboration with Stryker. In exchange for research funding, future royalties and revenue from commercial manufacturing from Stryker, Creative developed OP-1 as a therapy for orthopaedic reconstruction and cartilage regeneration, and supplied Stryker material for use in clinical trials. In November 1998, Creative restructured its collaboration agreement to provide Stryker with the exclusive rights to manufacture OP-1 products in orthopaedic reconstruction and cartilage regeneration. At the same time, Stryker acquired Creative's commercial manufacturing operations. As a result, Stryker has the exclusive right to develop, market, manufacture and sell products based on OP-1 proteins for use in orthopaedic reconstruction and dental therapies.

We have agreed not to undertake any BMP-related research, development or commercialization of any products in the fields of orthopaedic reconstruction and dental therapeutics, on our own behalf or for third parties, for the term of certain patents to the extent that such activities utilize technology, patents or certain personnel acquired from Creative in the merger. We have the exclusive and irrevocable right to develop, market and sell products incorporating morphogenic proteins developed under the research program, including OP-1, for all uses and applications other than orthopaedic and dental reconstruction. These applications include neurological diseases, osteoporosis, renal disease and others. Subject to certain exceptions in connection with the acquisition or merger of Stryker, Stryker has agreed not to undertake any research, development or commercialization of any products in our field (applications other than orthopaedic reconstruction and dental therapies), on its own behalf or for third parties, for the term of those patents. Each company has the right to grant licenses to third parties in their respective fields, and each is obligated to pay royalties to the other on its sales of such products and to share royalties received from licensees.

We maintain an exclusive license in our field under certain patents and claims that were assigned to Stryker in November 1998 as part of the sale of Creative's commercial manufacturing rights and assets.

*Genetics Institute.* We have a cross-license agreement with Stryker and Genetics Institute, Inc., a wholly owned subsidiary of Wyeth Corporation. Each party to the agreement has cross-licensed certain of its worldwide patent rights to each of the other parties, royalty-free, in the bone morphogenic/osteogenic protein family. The agreement allows the companies to commercialize their respective lead compounds, which are now in clinical trials for bone repair and regeneration, free of the risk of patent litigation among the parties. Under the agreement, which covers both then issued patents and pending patent applications, we and Stryker have exclusive rights to OP-1, under both our and Genetics Institute's patents. Genetics Institute and Yamanouchi Pharmaceutical Company, Ltd., its collaborative partner in the worldwide development of certain bone growth factors, have exclusive rights to BMP-2, their lead compound, under both their own and each of our and Stryker's patents. In addition, each party has granted to each other royalty-free, non-exclusive cross-licenses to patents and patent applications covering certain other related morphogenic proteins. Neither we nor Genetics Institute have any rights under the other party's patents and patent applications to methods, devices or formulations directed towards specific uses outside the fields of orthopedic and dental reconstruction and metabolic bone diseases.

*Aegera Therapeutics Inc.*

We entered into a license and collaboration agreement, effective January 5, 2001, with Aegera Therapeutics Inc., a privately-held biotechnology company headquartered in Montreal, Canada. This agreement provides us with an exclusive worldwide license of Aegera's skin-derived, adult stem cell technologies outside the field of

ophthalmology. The agreement establishes a broad collaboration to investigate the therapeutic potential of these technologies in neurological, pancreatic and cardiovascular disorders. Research is being conducted by us, Aegera and McGill University, Aegera's academic collaborator. We believe that our expertise with stem cells, signaling factors and small molecules, combined with Aegera's technologies, will represent a dynamic development paradigm for innovative regenerative therapeutics.

#### *AGY Therapeutics*

On January 17, 2002, we announced that we entered into an agreement with AGY Therapeutics, Inc., a privately-held biotechnology company headquartered in San Francisco, California. Through this collaboration, the companies will endeavor to discover and develop novel small molecule drugs from stem cells for therapeutic, diagnostic and other applications relevant to neurodegenerative diseases, diabetes, oncology, and central nervous system diseases. Under the terms of the collaboration agreement, we will share our stem cell and developmental biology expertise with AGY, who will apply its proprietary imAGYne technology platform to identify, analyze and validate novel small molecule targets. Products of this collaboration will be used by both companies to further their own internal drug development programs, as well as in partnerships with third parties.

#### *Elan Corporation, plc*

In July 2001, we formed a joint venture, Curis Newco, with affiliates of Elan, for the purpose of researching and developing molecules that stimulate the Hh signaling pathway. Curis Newco will focus upon the development of therapeutics targeting a number of neurological disorders. In addition to providing clinical expertise and support for the program, Neuralab, Ltd., an affiliate of Elan, sold to Curis Newco a non-exclusive license to an important animal model. At the time Curis Newco was formed, Elan International Services, Ltd., an affiliate of Elan, purchased \$4,000,000 of our common stock at \$7.32 per share. Additionally, Elan Pharma International, Ltd., another affiliate of Elan, agreed to provide funding, subject to Elan Pharma International's continuing consent, for our share of Curis Newco's operating expenses through an \$8,010,000 line of credit which is evidenced by a convertible promissory note issued by us.

#### *EVOTEC Biosystems AG (formerly Oxford Assymetry International PLC)*

We have renewed our contract services agreement with EVOTEC Biosystems AG ("EVOTEC") under which we have access to the EVOTEC chemical library and may utilize EVOTEC to perform high throughput screening of small molecules that regulate our proprietary developmental biology pathways. EVOTEC provides its services on a contract basis, and we own the intellectual property relating to small molecules discovered through these screening activities. The EVOTEC contract activities have played an important role in the identification of small molecules that regulate the Hh protein biological pathway and other pathways that we are exploring.

#### *Micromet AG*

On June 29, 2001, we entered into a purchase and sale agreement with Micromet AG pursuant to which we assigned our single-chain-polypeptide technology to Micromet AG in exchange for certain consideration. Effective December 31, 2001, we entered into a target research and license agreement and a product development agreement with Micromet. These agreements will provide us with royalties on Micromet's product 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 exclusive access for us to Micromet's proprietary single cell analysis of gene expression technology in the field of stem cell research. The product development agreement provides us with the right but not the obligation to jointly fund research to develop antibodies against up to four potential targets through the proof of principle stage. We will also have 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.

### *Academic Collaborations*

We have relationships with a number of academic institutions and investigators who are focused on areas of interest to us, including morphogenic proteins and developmental biology. In these collaborations, we seek to expand our scientific knowledge concerning internal research programs as well as the activities and characteristics of various proteins under development by our scientists. The academic collaborators are not our employees. As a result, we have limited control over their activities and limited amounts of their time are dedicated to our projects. From time to time, academic collaborators have relationships with other commercial entities, some of which may be competitors of ours. Although the precise nature of each relationship varies, the collaborators and their primary affiliated institutions generally sign agreements that provide for confidentiality of our proprietary technology and results of studies. We seek to obtain exclusive rights to license developments that may result from these studies; however, there is no guarantee that such licenses can be obtained.

### **COMPETITION**

The therapeutic products that we are developing would compete with existing and new products being developed by others for treatment of the same indications. Competition in the development of human therapeutics is particularly intense and includes many large pharmaceutical and biopharmaceutical companies, as well as specialized biotechnology and medical device firms. Many of these companies have extensive financial, marketing and human resource capacities, which may result in significant competition. Others have extensive experience in undertaking clinical trials, in obtaining regulatory approval to market products and in manufacturing on a large scale, which may enhance their competitive position. 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. In the future, our technological and commercial success will be based on our ability to develop proprietary positions in key scientific areas and efficiently evaluate potential product opportunities.

In addition to a product's patent position, efficacy and price, 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, the relative speed with which we or our collaborative partners can complete preclinical and clinical testing, obtain regulatory approvals, and supply commercial quantities of a product is expected to 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. If any research and development by others renders any of our products obsolete or noncompetitive, then our potential for success and profitability may be limited.

We are aware that a number of companies are engaged in the research and development of morphogenic proteins for the repair of bone and cartilage. Genetics Institute, Inc. and its collaborative partners are pursuing the development of bone morphogenic proteins for the repair of orthopaedic and other skeletal defects. Genetics Institute has entered into relationships with Yamanouchi Pharmaceuticals Co., Ltd. and Medtronic Sofamor Danek, Inc. covering development and marketing of bone morphogenic proteins. Based upon clinical results completed by Genetics Institute, American Home Products filed a PMA in the United States for the indication of tibial fresh fractures. American Home Products received a "not approvable" letter in 2001 based on problems with the trial design. In 2001, a partner of Genetics Institute in the spine field, Medtronic Sofamor Danek, filed a PMA for the use of rhBMP-2 in an interbody fusion cage. Medtronic Sofamor Danek obtained a unanimous

approval recommendation from a FDA advisory panel in January 2002. This vote will likely lead to FDA approval in the first half of 2002. This product is a combination of a Medtronic LT Cage which is used with a collagen sponge soaked with bone morphogenetic protein (rhBMP-2). A number of other companies currently provide various other therapies, including allografts, bone fillers and electrical stimulation devices for the treatment, repair or replacement of bone and joint tissue. The Company believes that its OP-1 Implant, which is approved for limited trauma indications in certain markets and is currently in clinical trials for certain other indications, would ultimately compete with these products and traditional therapies, such as autografts. Other companies may attempt to develop products incorporating proteins purified from bone, which may include BMPs, for orthopaedic applications. In addition, we believe that a number of biopharmaceutical companies are developing other recombinant human proteins, primarily growth factors, for use in the repair of bone and cartilage defects and in other indications. Several other companies are pursuing traditional therapies, including autografts, allografts and electrical stimulation devices, as well as cell and gene therapies for the repair of bone and cartilage defects, that may compete with our products.

We believe that any potential dental or periodontal products that Stryker may develop will compete primarily with traditional therapies and therapies incorporating other morphogenic proteins or growth factors. We are aware that Genetics Institute also may be pursuing the development of BMPs for the repair of dental and periodontal tissue.

Research in the field of developmental biology and genomics is highly competitive. Competitors in the field of developmental biology include, among others, Amgen, Inc., Chiron Corporation, Exelixis, Inc., Genentech, Inc., Geron Corporation, and Regeneron Corporation, as well as other private companies and major pharmaceutical companies. Competitors in the genomics area include, among others, public companies such as Axys Pharmaceuticals, Inc., Genome Therapeutics Corporation, Human Genome Sciences, Inc., Incyte Pharmaceuticals, Inc., Millennium Pharmaceuticals, Inc. and Myriad Genetics, Inc., as well as private companies and major pharmaceutical companies. We also compete with universities and other research institutions, including those receiving funding from the federally funded Human Genome Project. 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. We also face competition in gaining access to DNA samples used in our research and development projects. We expect competition to intensify in genomics research as technical advances in the field are made and become more widely known.

We rely on or will rely on our strategic partners for support in our disease research programs and may turn to our strategic partners 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 potential product under development by a strategic partner.

## **PATENTS AND PROPRIETARY RIGHTS**

Our ability to commercialize our products and compete effectively with other companies will depend, in part, on our ability to maintain proprietary rights to our products and technology. We currently own or have rights to approximately 125 issued and 171 pending patent applications in the United States and have foreign counterpart patent filings for most of these patents and patent applications. These 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. The patent positions of pharmaceutical, biopharmaceutical, and biotechnology companies, including us, are generally uncertain and involve complex legal and factual questions. There can be no assurance that any of these pending patent applications will result in issued patents, that we will develop additional proprietary technologies or products that

are patentable, that any of our patents or those of our collaborative partners will provide a basis for commercially viable products or will provide us with any competitive advantages or will not be challenged by third parties, or that the patents of others will not have an adverse effect on our ability to conduct our business.

Our success will depend in part on our ability to obtain marketing exclusivity for our products for a period of time sufficient to establish a market position and achieve an adequate return on our investment in product development. We believe that protection of our products and technology under United States and international patent laws and other intellectual property laws is an important factor in securing such market exclusivity.

Although we pursue patent protection for our technology, significant legal issues remain as to the extent to which patent protection may be afforded in the field of biotechnology, in both the United States and foreign countries. Furthermore, the scope of protection has not yet been broadly tested. Therefore, we also rely upon trade secrets, know-how and continuing technological advancement to develop and maintain our competitive position. Disclosure of our know-how is generally protected under confidentiality agreements. We do not know, however, whether all of our confidentiality agreements will be honored, that third parties will not develop equivalent technology independently, that disputes will not arise as to the ownership of technical information or that wrongful disclosure of our trade secrets will not occur.

Our academic 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 academic institutions to publish discoveries in the genetics and genomics fields. Any such publication could affect our ability to obtain patent protection in the areas in which we may have an interest.

We are party to various license agreements that give us rights to commercialize various technologies and to use certain technologies in our research and development processes. The consideration paid in exchange for these licenses include up-front fees, issuances of shares of common stock, annual royalties, milestone payments and running royalties on net sales by us and our sub-licensees. 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.

Others may have filed, and in the future are likely to file, patent applications covering molecules, genes or gene products that are similar or identical to our technologies or products. These third party patent applications may have priority over patent applications filed by us. Any legal action against us or our strategic partners claiming damages and seeking to enjoin commercial activities relating to the affected products and processes could, in addition to subjecting us to potential liability for damages, require us or our strategic partners to obtain a license in order to continue to manufacture or market the affected products and processes. There can be no assurance that we or our strategic partners would prevail in any such action or that any license required under any such patent would be made available upon commercially acceptable terms, or at all. Litigation, which could result in substantial costs to us, may be necessary to enforce any patents issued or licensed to us or to determine the scope and validity of third party proprietary rights. Some of our competitors have, or are affiliated with companies having, substantially greater resources than we have, and such competitors may be able to sustain the costs of complex patent litigation to a greater degree and for longer periods of time than us.

## **MANUFACTURING**

We have limited experience and capabilities in large-scale commercial manufacturing of protein, cell therapy, biomaterials and small molecule products. Creative established manufacturing facilities to produce the OP-1 Implant, which facilities were sold to Stryker in 1998. We do not currently have any commercial manufacturing operations in-house and do not have a qualified cGMP commercial manufacturing facility for any of our products. We or our collaborative partners will need to establish commercial manufacturing capacity, either internally or through third parties, for future products that we or our collaborative partners may develop.

## **SALES AND MARKETING**

Currently, we have no sales, marketing and distribution experience or infrastructure and we do not intend to develop a sales, marketing and distribution capability. We plan to rely significantly on sales, marketing and distribution arrangements with our corporate partners until we develop broader capabilities, if at all.

## **REGULATORY MATTERS**

Regulation by governmental agencies in the United States and other countries is a significant factor in the clinical evaluation and licensing of our potential products as well as in the development and research of new products. All of our products currently under development will require regulatory approval by the FDA under the Food, Drug, and Cosmetic Act, as drugs or devices, or under the Public Health Service Act, as biologicals, to be marketed in the United States and by similar governmental agencies outside the United States. Regardless of the classification assigned to our products, all human diagnostic and therapeutic products are subject to rigorous testing to demonstrate their safety and efficacy. Generally, considerable time and expense are required to demonstrate safety for use in humans, to design an acceptable clinical trial to enroll patients and to clinically evaluate the safety and efficacy of a new product. Moreover, even after extensive preclinical testing, unanticipated side effects can arise during clinical trials and in the course of related or unrelated research (within or outside our control) that can halt or substantially delay the regulatory process at any point. Seeking and obtaining regulatory approval for a new therapeutic or diagnostic product is likely to take several years and will require the expenditure of substantial resources. We cannot predict whether any product which enters preclinical or clinical development will be approved for sale by the FDA or any other regulatory authorities.

Products developed through genetic engineering, such as some developed by us, are relatively new, and state and local regulation may increase, as genetically engineered products become more common. The federal government oversees certain recombinant DNA research activity through the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules, known as the NIH Guidelines. We believe that our activities comply with the NIH Guidelines. Discussions have been underway since 1996 between the NIH and the FDA regarding alternative models for regulation of recombinant DNA research and the products resulting from such research, and the appropriateness of any continued NIH role. It is not possible to predict the effect of such potential regulatory changes on our business or our potential competitors.

Cellular and tissue-based (tissue engineering) medicinal products are a more recent development than even genetically engineered products. No regulations and only minimal guidance have been published by the FDA that are specific to products of this type. The FDA's Center for Biologics Evaluation and Review (CBER) currently has the primary review responsibility for all cell therapy products regardless of whether they are, according to established definitions, considered biologicals, medical devices or combination products. The relative inexperience of regulatory authorities with the review and approval of tissue engineered products may lead to increased review times or to significant changes in local, state and national requirements which could have a significant impact on the progress of these programs.

Our ability to conduct preclinical research is also subject to new and evolving regulations governing the use of human and embryonic tissues for isolating new growth factors and genes which may be useful in identifying and developing new therapeutic product candidates. Our ability to conduct critical research on which our development activities are based could be restricted or delayed depending on the outcome of pending rulemaking proceedings governing the use of these tissues and the collection of related genetic information.

### *Pharmaceutical and Biological Products*

We expect that certain of our potential products will be regulated by the FDA or other regulatory authorities as pharmaceuticals or biologicals. In the United States, the regulatory approval process for pharmaceutical and biological products intended for therapeutic use in humans involves several steps. Similar requirements are imposed by other regulatory authorities in major market countries.



Clinical testing usually occurs in three phases to demonstrate safety and efficacy of the product:

- Phase I clinical trials consist of testing for the safety and tolerance of the product with a small group of subjects and may also yield preliminary information about the efficacy and dosage levels of the product;
- Phase II clinical trials involve testing for efficacy, determination of optimal dosage and identification of possible side effects in a larger patient group; and
- Phase III clinical trials consist of additional testing for efficacy and safety with an expanded patient group.

Currently, the FDA requires the filing of new information for each distinct clinical study. After product approval, the FDA may request or require an additional phase (Phase IV) of clinical studies to provide further information on safety and/or efficacy.

Many of the biomaterials, cell types and ingredients used in our products and product candidates have not previously been used as components in medicinal products. Historically, neither the FDA nor other regulatory authorities have determined the safety and efficacy of these materials for pharmaceutical or other medical use. Therefore, the acceptability or approvability of these materials has not been demonstrated.

#### *Devices*

We expect that certain of our products, if developed, would be regulated by the FDA as Class III devices and as regulated devices by other regulatory authorities. Preclinical evaluations of Class III devices are similar to those of pharmaceuticals and biologicals, with additional emphasis on implant persistence, implant sensitization, and carrier characterization and specifications. Upon completion of preclinical testing, an Investigational Device Exemption (IDE) application is filed with the Center for Devices and Radiological Health in the FDA. Similar requirements are imposed by other regulatory authorities in major market countries.

Following the completion of clinical studies, under the IDE, a company would then file a pre-market approval application (PMA) with the FDA. The FDA is required to respond to the PMA submission within 180 days, although the FDA may not adhere to this schedule and further review may take additional time. After the FDA completes its review of the application, the product is typically reviewed by a panel of medical experts, and the applicant is required to answer questions on the product's safety and effectiveness. Following the recommendation of the panel, a PMA may be granted by the FDA based on the PMA submission. Based on the data filed, the FDA regulates the indications or uses for which the product is approved and the precautions and warnings, if any, applicable to the product. If so approved, the product may then be marketed for the indications set forth in the FDA approved labeling.

#### *Employees*

As of February 28, 2002, we had 105 full time employees, of whom 52 hold Ph.D. or other advanced degrees. Approximately 58 of these employees are currently involved in research and approximately 19 are currently involved in closing out the INDs for our suspended clinical trials. 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 located in Cambridge, Massachusetts. Two of the facilities are located next to each other at 45 and 61 Moulton Street, and consist of approximately 34,000 and 18,000 square feet, respectively. Both Moulton Street facilities are leased until April 2007. We have sublet 5,300 square feet at 45 Moulton Street for a period of 30 months beginning March 1, 2002. The third facility, located at 21 Erie Street, has approximately 50,000 square feet and is leased through the end of 2007. The Moulton Street buildings are used primarily by our research and administration groups, and the Erie Street building was used primarily by our

development and manufacturing groups prior to the realignment announced in February 2002. We intend to reduce the carrying cost relating to the Erie Street building by sublease or partnership with another company. We believe that our facilities will be adequate through at least the end of 2003.

**ITEM 3. LEGAL PROCEEDINGS**

There are no material pending legal proceedings, other than ordinary routine litigation incidental to our business, to which we are a party or of which our property is the subject. To our knowledge, no material legal proceeding is being contemplated by any governmental authority.

**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 . . . . .	41	President and Chief Executive Officer
George A. Eldridge . . . . .	38	Vice President, Chief Financial Officer, Secretary and Treasurer
Lee L. Rubin, Ph.D. . . . .	51	Senior Vice President of Research and Chief Scientific Officer

Daniel R. Passeri . . . . . Mr. Passeri has served as President and Chief Executive Officer and as a Director of the Company 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.S. in biotechnology, and of Northeastern University, with a B.S.

George A. Eldridge . . . . . Mr. Eldridge has served as Vice President, Chief Financial Officer and Treasurer of the Company since March 2000 and Secretary since December 2000. Mr. Eldridge joined Ontogeny in April 1996 as Vice President of Finance. From April 1993 to April 1996, Mr. Eldridge was employed by Boston Life Sciences, Inc. where he was Vice President, Corporate Development and Finance. Prior to that, Mr. Eldridge worked with the investment banking firm, Kidder, Peabody & Co., Incorporated for a total of five years in its New York and Boston offices. A graduate of Dartmouth College, Mr. Eldridge received his

M.B.A. from the University of Chicago Graduate School of Business. Mr. Eldridge expects to depart the Company during 2002 after completion of his transitional responsibilities under the realignment of the Company's programs announced during the first quarter of 2002.

Lee L. Rubin, Ph.D . . . . . Dr. Rubin has served as Senior Vice President of Research and Chief Scientific Officer of the Company since September 2000 and prior to that as Vice President of Research of the Company since March 2000. Dr. Rubin joined Ontogeny in October 1997 as vice president of Research. Prior to joining Ontogeny, Dr. Rubin spent six years at Eisai London Laboratories at University College London, where he was director and professor of neurobiology. Prior to that, Dr. Rubin worked for four years with Athena NeuroSciences, Inc. 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.

## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDERS MATTERS

Our Common Stock was first traded on the Nasdaq National Market on August 1, 2000. Our trading symbol is "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>Fiscal Year 2000</u>	<u>Our Common Stock</u>	
	<u>High</u>	<u>Low</u>
Third Quarter (from August 1, 2000) .....	\$27.25	\$13.88
Fourth Quarter .....	\$19.94	\$ 6.88
 <u>Fiscal Year 2001</u>		
First Quarter .....	\$13.00	\$ 3.25
Second Quarter .....	\$ 6.90	\$ 3.00
Third Quarter .....	\$ 7.00	\$ 3.01
Fourth Quarter .....	\$ 5.75	\$ 3.25

There were 285 holders of record of our Common Stock as of March 20, 2002. 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.

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 the Board of Directors after taking into account various factors, including our financial condition, operating results, capital requirements and any plans for expansion.

On July 18, 2001, we issued certain securities to Elan International Services, Ltd. ("EIS") in a private placement, which was a part of our joint venture with Elan. The securities that we sold as a part of this private placement consisted of 1,000 shares of convertible exchangeable preferred stock, par value \$0.01 per share (the "Preferred Stock"), 546,448 shares of Common Stock and a warrant to purchase up to 50,000 shares of Common Stock (the "Securities"). In exchange for the Securities, we received an aggregate value of \$16,015,000 from EIS which consisted of \$4,000,000 in cash and \$12,015,000 in a non-cash cross receipt. In turn, we used this amount to fund our pro-rata share of a \$15,000,000 technology license purchased by Curis Newco from Neuralab, Ltd., an affiliate of EIS.

We determined that the offering of the Securities to EIS was exempt from registration under Section 4 of the Securities Act of 1933, as amended. We based our conclusion that the above transaction was exempt from registrations on representations by EIS that it is an accredited investor and that it would not seek to transfer the Securities without registration under the Securities Act or pursuant to an available exemption from registration.

The shares of Preferred Stock are convertible at the option of EIS into shares of Common Stock at any time until July 18, 2007. Each share of Preferred Stock will be convertible into shares of Common Stock at a rate of 12,015 plus any accrued but unpaid dividends divided by 14.12. Alternately, EIS may exchange all of the shares of Preferred Stock into 3,612 shares of non-voting convertible preference shares of Curis Newco. These preference shares would in turn be convertible at EIS's option into 30.1% of Curis Newco's voting common shares. The effect of an exchange by EIS of the Preferred Stock followed by a conversion by EIS of all of its preference shares of Curis Newco would be to give EIS 50% of Curis Newco's voting common shares.

The warrant to purchase 50,000 shares of Common Stock may be exercised at the option of EIS in exchange for the payment by EIS of the exercise price, which is \$10.46 per share.

## 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 in this Annual Report on Form 10-K.

	Years Ended December 31,				
	2001	2000	1999	1998	1997
	(in thousands, except per share data)				
Consolidated Statement of Operations Data:					
Revenues:					
Research and development contracts and government grants	\$ 968	\$ 997	\$ 3,160	\$ 10,419	\$ 12,693
License fees and royalties	119	26	52	10	—
Manufacturing contracts	—	—	—	—	394
Total revenues	<u>1,087</u>	<u>1,023</u>	<u>3,212</u>	<u>10,429</u>	<u>13,087</u>
Costs and expenses:					
Research and development (A)	29,072	17,424	10,435	24,856	25,122
General and administrative (A)	10,492	9,330	5,524	6,946	5,827
Stock-based compensation (A)	10,358	16,628	64	322	254
Amortization of and impairment charged related to intangible assets	23,339	14,451	808	207	392
Loss on disposition of fixed assets	—	204	—	—	—
In-process research and development	—	294,800	—	—	—
Cost of manufacturing contracts	—	—	—	—	274
1999 reorganization and 1998 sale of manufacturing operations	—	(38)	256	1,362	—
Total costs and expenses	<u>73,261</u>	<u>352,799</u>	<u>17,087</u>	<u>33,693</u>	<u>31,869</u>
Loss from operations	<u>(72,175)</u>	<u>(351,776)</u>	<u>(13,875)</u>	<u>(23,264)</u>	<u>(18,782)</u>
Equity in loss from joint venture	(13,453)	—	—	—	—
Other income (expense)					
Interest and other income	4,548	1,906	1,926	2,196	2,346
Interest expense	(784)	(481)	(161)	(327)	(216)
Total other income	<u>3,764</u>	<u>1,425</u>	<u>1,765</u>	<u>1,869</u>	<u>2,130</u>
Net loss	<u>(81,864)</u>	<u>(350,351)</u>	<u>(12,110)</u>	<u>(21,395)</u>	<u>(16,652)</u>
Accretion and repurchase costs on Series 1998/A Preferred Stock	—	—	(2,395)	(987)	—
Accretion of Series A Redeemable Preferred Stock	(326)	—	—	—	—
Net loss applicable to common stockholders	<u>\$(82,190)</u>	<u>\$(350,351)</u>	<u>\$(14,505)</u>	<u>\$(22,382)</u>	<u>\$(16,652)</u>
Basic and diluted net loss per common share	<u>\$ (2.58)</u>	<u>\$ (19.80)</u>	<u>\$ (1.36)</u>	<u>\$ (2.22)</u>	<u>\$ (1.68)</u>
Weighted average common shares used for basic and diluted net loss computation					
	<u>31,859</u>	<u>17,694</u>	<u>10,682</u>	<u>10,102</u>	<u>9,923</u>
(A) The following summarizes the departmental allocation of the stock-based compensation charge:					
Research and development	\$ 6,156	\$ 8,358	\$ —	\$ —	\$ —
General and administrative	4,202	8,270	64	322	254
Total stock-based compensation	<u>\$ 10,358</u>	<u>\$ 16,628</u>	<u>\$ 64</u>	<u>\$ 322</u>	<u>\$ 254</u>

	As of December 31,				
	2001	2000	1999	1998	1997
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and marketable securities	\$ 52,107	\$ 75,799	\$ 21,371	\$ 57,935	\$ 30,598
Working capital	42,848	67,364	17,116	49,613	32,381
Total assets	144,756	182,682	28,892	66,164	59,038
Debt and lease obligations, net of current portion	4,951	4,155	1,009	713	2,005
Convertible notes payable	2,507	—	—	—	—
Series A Redeemable Preferred Stock	12,341	—	—	—	—
Series 1998 A Preferred Stock	—	—	—	23,053	—
Accumulated deficit	(554,136)	(471,946)	(121,595)	(109,485)	(88,090)
Total stockholders' equity	<u>101,020</u>	<u>168,814</u>	<u>23,422</u>	<u>33,105</u>	<u>52,709</u>

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

You should read the following discussion and analysis in conjunction with "Selected Financial Data" and our financial statements and notes included elsewhere in this Annual Report on Form 10-K.

### *Overview*

On July 31, 2000, Creative BioMolecules, Inc. ("Creative"), Ontogeny, Inc. ("Ontogeny") and Reprogenesis, Inc. ("Reprogenesis") merged with and into Curis, Inc. ("Curis" or "the Company"), pursuant to an Agreement and Plan of Merger dated as of February 14, 2000. On July 31, 2000, Curis, as the surviving company of the merger, assumed the rights and obligations of Creative, Ontogeny and Reprogenesis. Immediately after the merger, Curis was owned approximately 43% by the former stockholders of Creative, 38% by the former stockholders of Ontogeny and 19% by the former stockholders of Reprogenesis. Consequently, for accounting purposes, Curis is deemed to be the successor to Creative, and the historical financial statements of Creative have become the historical financial statements of Curis. The merger has been accounted for as a purchase by Creative of Ontogeny and Reprogenesis in accordance with Accounting Principles Board (APB) Opinion No. 16, Accounting for Business Combinations, and accordingly, Ontogeny's and Reprogenesis' operating results since the merger date are included in the accompanying financial statements.

In accordance with APB No. 16, the purchase price for Ontogeny and Reprogenesis has been allocated to the assets and liabilities of Ontogeny and Reprogenesis based on their fair values. The aggregate purchase price based on the fair market value of Creative common stock was \$300,731,000 and \$149,000,000 for Ontogeny and Reprogenesis, respectively, including the value of the outstanding options and warrants exchanged for options and warrants to purchase the common stock of Curis and the transaction costs related to the merger.

The purchase price of Ontogeny and Reprogenesis was allocated to the assets acquired based upon an independent appraisal which used proven valuation tools and techniques. Significant portions of the purchase price were identified as intangible assets which included in-process research and development (IPR&D) of \$294,800,000 and assembled workforce of \$500,000. The fair value of the IPR&D relating to current in-process research and development projects was recorded as an expense as of the merger date. The excess of the purchase price over the fair value of identified tangible and intangible net assets of \$105,477,000 has been allocated to goodwill. Through December 31, 2001, intangible assets were being amortized over their estimated useful lives of four to five years. Beginning January 1, 2002, the Company will adopt Statement of Financial Accounting Standards ("SFAS") No. 142, Goodwill and Other Intangible Assets, and will cease amortization of goodwill and assembled workforce. Going forward, the goodwill will be subject to an annual assessment for impairment based on fair value.

The Company announced on February 14, 2002 that it is realigning its research and development programs and narrowing the focus of its resources on its signaling pathway and stem cell technologies. As part of this realignment, the Company suspended its clinical product development efforts on Vascugel for coronary artery disease. The Company also terminated clinical development efforts on Chondrogel, its program for the treatment of vesicoureteral reflux, and its basal cell carcinoma oncology candidate. In connection with the above, the Company reduced its staff by 35 employees, including three executive officers. The Company will incur cash expenditures in 2002 of approximately \$3,500,000 related to the realignment that include severance payments of approximately \$1,300,000 and costs associated with the termination and suspension of its clinical programs and related facility decommissioning costs of approximately \$2,200,000.

Certain research programs affected by the realignment were acquired by the Company from Reprogenesis and Ontogeny through the merger. The net book value of intangibles as a result of the acquisitions of Reprogenesis and Ontogeny was approximately \$26,215,000 and \$46,857,000, respectively, as of December 31, 2001.

In

conjunction

with SFAS No.142, the Company is in the process of completing the first step of the transitional goodwill impairment test. If the carrying amount of the net assets of the reporting unit (including goodwill) from which these programs have been derived exceeds the fair value of that reporting unit, the impairment loss recognized as a result of a transitional goodwill impairment test will be recognized by the Company as an effect of a change in accounting principle effective as of the first quarter in 2002. The Company has not determined the potential impairment loss, if any, from adopting SFAS No. 142. The Company does believe that the realignment in February 2002 may result in a goodwill and assembled workforce impairment beyond any impairment recognized due to the adoption of SFAS No. 142. This impairment charge would be recognized as a charge to operations in the first quarter of fiscal 2002. The Company has not yet assessed the amount, if any, of this impairment charge.

In addition to its assessment of impairment as a result of the realignment in February 2002, the Company performed an assessment of impairment on its goodwill and assembled workforce intangible assets as of December 31, 2001. The Company determined that the recoverability of these intangible assets was not impaired based on the future undiscounted net cash flows for the products underlying these intangible assets as of December 31, 2001. The underlying products included in this assessment were based on the Company's focus as of December 31, 2001.

### **Collaborations**

To date, revenues from research and development contracts and license fees have been generated from agreements between Curis and its collaborative partners. Over the next few years, Curis anticipates deriving most of its revenues from royalties from Stryker, from the recognition of deferred revenue under its collaboration with Micromet AG, and from additional collaboration agreements which Curis may enter into in the future. There can be no assurance that Curis will be able to enter into such collaborations on acceptable terms, or at all and, therefore may not generate future research and development contract revenues.

Since January 2001, we have entered into four new collaborations, including (i) a license and collaboration agreement with Aegera Therapeutics, Inc. which granted the Company an exclusive worldwide license of Aegera's skin-derived, adult stem cell technologies outside the field of ophthalmology, (ii) purchase and sale, target identification and product development agreements with Micromet AG, a German corporation, relating to the Company's single-chain-polypeptide technology, (iii) the formation of Curis Newco with an affiliate of Elan Corporation, plc ("Elan") that is committed to the research and development of molecules that stimulate the hedgehog (Hh) signaling pathway in the area of neurological indications, and (iv) an agreement with AGY Therapeutics, Inc., a privately-held biotechnology company headquartered in San Francisco, California, to attempt to discover and develop novel small molecule drugs from stem cells for therapeutic, diagnostic and other applications relevant to neurodegenerative diseases, diabetes, oncology, and central nervous system diseases.

The Company's research and development contract revenue is and is anticipated to be primarily derived from contracts with biotechnology and pharmaceutical companies. These contracts may include payments for research related activities, technology access and license fees, research and development milestones and royalties. The Company follows the provisions of the Securities and Exchange Commission's Staff Accounting Bulletin No. 101 (SAB No. 101), Revenue Recognition. In accordance with SAB No. 101, 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. For the years ended December 31, 2001 and 2000, the Company has not recognized revenue relating to research and development services provided under its corporate collaboration agreements.

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 percentage of the services performed through that date or the non-refundable cash received would be recognized. The percentage of services performed is based on the ratio of the number of direct labor hours performed to date to total direct labor hours the Company is obligated to perform under the related contract, as determined on a full time equivalent basis. The remainder will be recognized proportionately as the remaining services are performed. Royalty revenue will be recognized upon the sale of the related products, provided the royalty amounts are fixed or determinable and collection of the related receivable is probable.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue. Amounts not expected to be recognized during the year ended December 31, 2002 are classified as long-term deferred revenue. As of December 31, 2001, the Company has short- and long-term deferred revenue of approximately \$82,000 and \$12,064,000, respectively, related to the Micromet AG agreements.

The Company has an agreement with Stryker in the area of bone-inducing proteins and dental therapeutics. Under this agreement, in exchange for research funding, future royalties and revenue from commercial manufacturing, Creative developed OP-1 as a therapy for orthopaedic 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 has the exclusive right to develop, market, manufacture and sell products based on OP-1 proteins for use in orthopaedic reconstruction and dental therapies. Beginning May 2001, Stryker has received regulatory approval to market its OP-1 Implant product in Australia, the European Union, the United States (on a Humanitarian Device Exemption basis), and Canada.

Curis did not receive significant revenue from Stryker during 2001. The Company will only receive significant revenue if sales of OP-1 grow in 2002 and future years or if additional indications of OP-1 receive regulatory approval in future years.

Curis has been awarded \$4,000,000 of government grants from the National Institute of Standards and Technology ("NIST"). These grants are to be received over the period ending on December 31, 2003, are cancelable at the discretion of NIST and are subject to annual appropriation by the US government. Curis recognizes grant revenue as the services are provided and costs are incurred under the terms of the grants. During the first quarter of 2002, the Company requested that these awards be suspended while the Company reviewed its desire to continue development efforts on these projects. The awards can be reinstated, if approved by NIST, upon the Company's election to continue its development program as outlined under the terms of the grant awards.

Future operating results will depend largely on the magnitude of royalty payments from Stryker and the outcome of other product candidates currently in the Company's research and development pipeline. The Company cannot be sure of either the future growth rate of these royalties or the likelihood of successful outcomes for products currently in the Company's pipeline. Curis has never been profitable and expects to incur additional operating losses in the next several years. Curis' results of operations will vary significantly from year to year and quarter to quarter and depend on, among other factors, the timing of entering into collaboration agreements and receiving payments from collaborative partners, the magnitude of OP-1 royalties received and the cost and outcome of clinical trials. Curis currently expects that it has sufficient cash to operate into the fourth quarter of 2003.

### **Critical Accounting Policies**

In December 2001, the SEC requested that all registrants list their most "critical accounting policies" in MD&A. The SEC indicated that a "critical accounting policy" is one which is both important to the portrayal of the company's financial condition and results and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Management believes that the following accounting policies fit this definition:



*Revenue recognition.* The Company's revenue recognition policy is significant because revenue is a key component of the Company's results of operations. The Company follows detailed guidelines in measuring revenue; however, certain judgments affect the application of its revenue policy. For example, the Company has entered into purchase and sale, product development and target research agreements with Micromet AG, under which the Company has recorded on its balance sheet short- and long-term deferred revenue based on its best estimate of when such revenue will be recognized. A portion of the consideration received from this sale was equity securities and a convertible note. The estimate of deferred revenue includes management's assessment of the value attributable to the equity securities and realization of the convertible note. Revenue for the upfront payments received from Micromet AG for the sale of technology will be recognized as services are performed over the Company's estimated performance period under the product development agreement. Additionally, the Company records royalty revenue under its agreements with Stryker. Royalty revenues are recorded by the Company as sales are reported to the Company by Stryker and collection of the resulting receivable is reasonably assured. Revenue results are difficult to predict, and any shortfall in revenue or delay in recognizing revenue could cause our operating results to vary significantly from quarter to quarter.

*Valuation of Long-Lived Assets.* The Company assesses the impairment of identifiable intangibles, long-lived assets and goodwill whenever events or changes in circumstances indicate that the carrying value may not be recoverable. If it is determined that the carrying value of intangible, long-lived assets and goodwill might not be recoverable based upon the existence of one or more indicators of impairment, the Company would measure any impairment based on a projected cash flow method. During the third quarter of the year ended December 31, 2000, the Company recorded an impairment charge of approximately \$4,611,000 to reduce the carrying value of patents determined not to be beneficial or not expected to be utilized in future operations and which have no alternative future use. As a result of the adoption of SFAS No. 142 in the first quarter of 2002, the Company will cease to amortize goodwill. In lieu of amortization, the Company is required to perform an initial assessment of impairment of its goodwill in 2002, an annual impairment review thereafter or whenever events or changes in circumstances indicate that the carrying value may not be recoverable. As a result of a realignment of its research and development programs announced on February 14, 2002, the Company may record an impairment charge relating to its goodwill and assembled workforce assets. This impairment charge would be recognized as a charge to operations in the first quarter of 2002. The Company has not yet determined the amount of such impairment loss.

In addition to its assessment of impairment as a result of the realignment in February 2002, the Company performed an assessment of impairment on its goodwill and assembled workforce intangible assets as of December 31, 2001. The Company determined that the recoverability of these intangible assets was not impaired based on the future undiscounted net cash flows for the products underlying these intangible assets as of December 31, 2001. The underlying products included in this assessment were based on the company's focus as of December 31, 2001.

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. See the Company's audited consolidated financial statements and notes thereto which begin on page F-1 which contain accounting policies and other disclosures required by generally accepted accounting policies.

## **RESULTS OF OPERATIONS**

The consolidated statement of operations data for the year ended December 31, 2001 include only the operating expenses of Curis for such period. The consolidated statement of operations data for the year ended December 31, 2000 include the operating results of Creative for the seven months ended July 31, 2000 and the operating results of Curis, comprising the combined operations of Creative, Ontogeny and Reprogenesis, for the five months ended December 31, 2000. Accordingly, comparisons of operating expenses between the 2001 and

the 2000 periods may not prove to be meaningful. Additionally, in the year ended December 31, 2000, the Company incurred significant non-cash charges associated with the merger and cash expenses for merger related fees and expenses. The consolidated balance sheet data as of December 31, 2001 and 2000 reflects the balance sheets of Curis post merger.

*Years Ended December 31, 2001 and 2000*

Total revenues for the year ended December 31, 2001 were \$1,087,000 as compared to \$1,024,000 for the year ended December 31, 2000. A majority of revenues for both the years ended December 31, 2001 and 2000 were derived from research and development contracts and government grants. Revenues recognized from these sources totaled \$968,000 and \$997,000 for the years ended December 31, 2001 and 2000, respectively.

License fees and royalties increased \$93,000 to \$119,000 for the year ended December 31, 2001 as compared to \$26,000 for the year ended December 31, 2000. The increase in royalties was primarily due to revenues received in 2001 from Stryker on sales of OP-1.

Research and development expenses increased 67% to \$29,072,000 for the year ended December 31, 2001 from \$17,424,000 for the year ended December 31, 2000. The increase was primarily due to the impact of the merger which occurred on July 31, 2000. Research and development expenses for the year ended December 31, 2001 include the costs incurred by the combined companies for the entire twelve-month annual period. Research and development expenses for the year ended December 31, 2000 include the costs incurred by only Creative for the seven-month period of January 1, 2000 to July 31, 2000 and the combined companies for the five-month period from August 1, 2000 to December 31, 2000. This general increase based on the timing of the merger was offset in part by severance payments made by Creative in the year ended December 31, 2000.

Research and development expenses for the year ended December 31, 2001 include the cost of employees involved in research and development of \$8,625,000, external lab services including clinical trials, medicinal chemistry, consulting and sponsored research collaborations of \$9,594,000, lab and clinical trial manufacturing supplies of \$3,711,000, occupancy and depreciation charges of \$4,502,000 and legal fees associated with the Company's intellectual property of \$2,427,000. Research and development expenses for the year ended December 31, 2001 are net of \$1,774,000 in expenses that were charged by the Company to Curis Newco. However, 80.1% of these costs are included in Equity in Loss from Joint Venture in the Company's consolidated statement of operations.

Research and development expenses for the year ended December 31, 2000 include the cost of employees involved in research and development of \$5,100,000, external lab services including clinical trials, medicinal chemistry, consulting and sponsored research collaborations of \$3,200,000, and facility related costs of \$1,300,000. In addition, research and development expenses for the year ended December 31, 2000 include severance paid to former officers of Creative totaling \$656,000, and severance payments relating to the termination of seven other employees totaling \$251,000.

General and administrative expenses increased 12% to \$10,493,000 for the year ended December 31, 2001 from \$9,330,000 for the year ended December 31, 2000. The increase was primarily due to the impact of the merger which occurred on July 31, 2000. General and administrative expenses for the year ended December 31, 2001 include the costs incurred by the combined companies for the entire twelve -month annual period. General and administrative expenses for the year ended December 31, 2000 include the costs incurred by only Creative for the seven-month period of January 1, 2000 to July 31, 2000 and the combined companies for the five-month period from August 1, 2000 to December 31, 2000. This general increase based on the timing of the merger was offset in part by severance payments made by Creative in the year ended December 31, 2000.

General and administrative expenses for the year ended December 31, 2001 include the cost of employees of \$3,769,000, occupancy and depreciation charges of \$1,545,000, legal and professional fees of \$1,066,000 and consulting expense of \$775,000.

General and administrative expenses for the year ended December 31, 2000 included personnel related costs of \$1,400,000, legal and professional fees of \$875,000, and insurance expense of \$600,000. In addition, general and administrative expenses for the year ended December 31, 2000 include severance paid to former officers of Creative of \$1,048,000 and severance payments relating to the termination of approximately eight other employees totaling \$122,000.

Stock-based compensation decreased by \$6,270,000, or 38%, to \$10,358,000 for the year ended December 31, 2001 from \$16,628,000 for the year ended December 31, 2000. The decrease was partially due to two merger-related stock-based compensation charges that were recorded in the year ended December 31, 2000 including (i) \$3,538,000 that was related to the acceleration of certain stock options and the extension of the exercise period for options held by Creative's executive officers, outside directors and employees, and (ii) \$1,623,000 based on the fair value of 57,094 shares of restricted common stock granted to a former Reprogenesis executive officer that became fully vested upon the merger. In addition, the Company's stock-based compensation expense related to deferred compensation resulting from the merger which was amortized over the vesting period of the underlying options through August 1, 2001, decreased to \$6,257,000 in the year ended December 31, 2001 from \$9,563,000 in the year ended December 31, 2000. These decreases in merger-related stock-based compensation were partially offset by an increase in stock-based compensation expense related to Curis' issuance on August 18, 2000 of options to purchase 3,473,006 with an exercise price below fair market value. The resulting stock-based compensation, net of terminations, of \$17,330,000 is being amortized over the four-year vesting period of the underlying stock options for options granted to employees and as earned for nonemployees in accordance with EITF 96-18. The total deferred compensation expense related to these options was \$3,964,000 and \$1,904,000 for the years ended December 31, 2001 and 2000, respectively.

Amortization of intangible assets increased by \$8,888,000, or 62%, to \$23,339,000 for the year ended December 31, 2001, as compared to \$14,451,000 for the year ended December 31, 2000. The increase was principally due to the amortization of goodwill increasing to \$23,114,000 from \$9,641,000 for the years ended December 31, 2001 and 2000, respectively. The increase in the amortization of goodwill in 2001 was partially offset by an impairment charge in the year ended December 31, 2000 of approximately \$4,611,000 to reduce the carrying value of certain capitalized patents determined not to be beneficial or expected to be utilized in future operations and which have no alternative future use.

Fixed asset disposition charges totaling \$204,000 were incurred during the year ended December 31, 2000 for the net book value of equipment disposed of as a result of the merger. No such charges were incurred for the year ended December 31, 2001.

A charge of \$294,800,000 was incurred on July 31, 2000 resulting from that portion of the purchase price of Ontogeny and Reprogenesis that was identified as in-process research and development.

The purchase price of Ontogeny and Reprogenesis was allocated to the assets acquired, including IPR&D, based upon an independent appraisal, which used proven valuation tools and techniques.

During the year ended December 31, 2001, the Company incurred an equity loss in Curis Newco of \$13,453,000, which represented 80.1% of the total net loss incurred by Curis Newco. The Company financed a majority of this loss with the issuance of 1,000 shares of Series A convertible exchangeable preferred stock, which were valued at \$12,015,000, to Elan International Services, Ltd., an affiliate of Elan. The Company anticipates financing its share of the development funding of Curis Newco through July 18, 2003 with drawdowns, which are subject to Elan's consent, under an \$8,010,000 convertible promissory note entered into between the Company and Elan Pharma International, Ltd., also an affiliate of Elan. The Company's portion of Curis Newco's other operating expenses for the twelve-month period ended December 31, 2001 was \$1,438,000.

For the year ended December 31, 2001, interest and other income was \$4,548,000 as compared to \$1,906,000 for the year ended December 31, 2000, an increase of \$2,642,000 or 139%. This increase was

principally due to a \$1,470,000 gain recognized on the sale of Exelixis, Inc. common stock. Additionally, the increase in interest income resulted partially from the consolidation into Curis of the investable cash and marketable security balances and income earned thereon from the three companies prior to the merger for an entire twelve-month annual period in the year ended December 31, 2001 versus only a five-month period in the year ended December 31, 2000. The increase in interest income is also partially attributed to the Company holding a higher average investable cash balance as a result of net proceeds from a private placement of approximately \$43,348,000 in December 2000, offset in part by lower average investment yields in the year ended December 31, 2001 as compared to the year ended December 31, 2000.

For the year ended December 31, 2001, interest expense was \$784,000 as compared to \$481,000 for the year ended December 31, 2000, an increase of \$303,000 or 63%. The increase in interest expense resulted partially from the consolidation into Curis of the outstanding lease obligations from the three companies prior to the merger for an entire twelve-month annual period in the year ended December 31, 2001 versus only a five-month period in the year ended December 31, 2000. In addition, the Company recognized \$135,000 of interest expense related to a \$5,000,000 debt facility, which was fully drawn down by December 31, 2001. Lastly, the Company incurred \$72,000 in non-cash interest expense related to a \$2,000,000 convertible subordinated note payable issued in 2001.

Accretion on Series A Redeemable Preferred Stock of \$326,000 was recorded for the year ended December 31, 2001. This amount related to a 6% mandatory dividend on Series A convertible exchangeable preferred stock issued to Elan International Services, Ltd. in connection with the formation of Curis Newco.

As a result of the foregoing, Curis incurred a net loss applicable to common stockholders of \$82,190,000 for the year ended December 31, 2001 as compared to \$350,351,000 for the year ended December 31, 2000.

#### *Years Ended December 31, 2000 and 1999*

Total revenues for the year ended December 31, 2000 were \$1,023,000 as compared to \$3,212,000 for the year ended December 31, 1999. Research and development contracts and government grants decreased 68% to \$997,000 for the year ended December 31, 2000 from \$3,160,000 for the year ended December 31, 1999. The decrease in research and development contract and government grant revenues from 1999 to 2000 was primarily the result of the termination of a research agreement with Biogen, Inc. in 1999 partially offset by revenues of \$319,000 earned under the NIST grant received by Replenogenesis in November 1999.

License fees and royalties decreased 50% to \$26,000 for the year ended December 31, 2000 as compared to \$52,000 for the year ended December 31, 1999. The decrease in license fees and royalties was primarily due to revenues received in 1999 from licensing patent rights and know-how associated with certain protein technology.

Research and development expenses increased 67% to \$17,424,000 for the year ended December 31, 2000 from \$10,435,000 for the year ended December 31, 1999. The increase was primarily due to the impact of the merger which occurred on July 31, 2000. Research and development expenses for the year ended December 31, 2000 include the costs incurred by the combined companies for the period from August 1, 2000 to December 31, 2000. These include the cost of 111 people involved in research and development of \$5,100,000, external lab services including clinical trials of \$3,200,000, and facility related costs of \$1,300,000. In addition, research and development expenses for the year ended December 31, 2000 include severance paid to former officers of Creative totaling \$656,000, and severance payments relating to the termination of seven other employees totaling \$251,000.

General and administrative expenses increased 69% to \$9,330,000 for the year ended December 31, 2000 from \$5,524,000 for the year ended December 31, 1999. The increase was primarily due to costs incurred by the combined companies for the period from August 1, 2000 to December 31, 2000 which included personnel related costs of \$1,400,000, legal and professional fees of \$875,000, and insurance expense of \$600,000. In addition, general and administrative expenses for the year ended December 31, 2000 include severance paid to former officers of Creative of \$926,000 and severance payments relating to the termination of approximately eight other employees totaling \$122,000.

Stock-based compensation increased to \$16,628,000 for the year ended December 31, 2000 from \$64,000 for the year ended December 31, 1999. The increase was primarily due to \$9,563,000 of amortization expense related to deferred compensation resulting from the merger which is being amortized over the vesting period of the underlying options through August 1, 2001. Additionally, a charge of \$3,538,000 was recorded related to the acceleration of certain stock options and the extension of the exercise period for options held by Creative's executive officers, outside directors and employees. Also, 57,094 shares of restricted common stock granted to a former Reprogenesis executive officer became fully vested upon the merger. Compensation expense of \$1,623,000 was recognized based on the fair value of the shares on the date of the merger. Lastly, on August 18, 2000, Curis issued 3,473,006 options to its employees as well as to nonemployees with an exercise price below fair market value resulting in deferred compensation, net of terminations, of \$17,330,000. The deferred compensation is being amortized over the four-year vesting period of the underlying stock options for options granted to employees and as earned for nonemployees in accordance with EITF 96-18. The total deferred compensation expense related to these options was \$1,904,000 for the year ended December 31, 2000.

Amortization of intangible assets was \$14,451,000 for the year ended December 31, 2000, as compared to \$808,000 for the year ended December 31, 1999. The increase was partially due to the amortization of goodwill totaling \$9,641,000 and the amortization of assembled workforce totaling \$42,000 incurred as a result of the merger. In addition, Curis incurred an impairment charge of approximately \$4,611,000 to reduce the carrying value of certain capitalized patents determined not to be beneficial or expected to be utilized in future operations and which have no alternative future use. Patent impairment charges for the year ended December 31, 1999 were approximately \$538,000. Amortization of patent costs were \$157,000 for the year ended December 31, 2000 as compared to \$270,000 for the year ended December 31, 1999.

Fixed asset disposition charges totaling \$204,000 were incurred during the year ended December 31, 2000 for the net book value of equipment disposed of as a result of the merger.

A charge of \$294,800,000 was incurred on July 31, 2000 resulting from that portion of the purchase price of Ontogeny and Reprogenesis that was identified as in-process research and development. The purchase price of Ontogeny and Reprogenesis was allocated to the assets acquired, including IPR&D, based upon an independent appraisal which used proven valuation tools and techniques.

For the year ended December 31, 2000, interest and other income was \$1,906,000 as compared to \$1,926,000 for the year ended December 31, 1999, a decrease of \$20,000 or 1%. The decrease in interest income resulted primarily from a slightly lower average available investment balance as compared to the prior year.

For the year ended December 31, 2000, interest expense was \$481,000 compared to \$161,000 for the year ended December 31, 1999, an increase of \$320,000 or 199%. The increase in interest expense resulted primarily from the consolidation into Curis of the outstanding lease obligations from the three companies prior to the merger.

As a result of the foregoing, Curis incurred a net loss of \$350,351,000 for the year ended December 31, 2000 as compared to a net loss of \$12,110,000 for the year ended December 31, 1999.

#### *Liquidity and Capital Resources*

At December 31, 2001, our principal sources of liquidity consisted of cash, cash equivalents and unrestricted marketable securities of \$51,217,000. We have financed our operations primarily through placements of equity securities, payments received under agreements with collaborative partners and government grants, amounts received under debt and capital lease agreements, manufacturing contracts and the sale of certain of our OP-1 manufacturing rights and facilities to Stryker.

Net cash used in operating activities was \$24,877,000, \$23,701,000 and \$14,768,000 for the years ended December 31, 2001, 2000 and 1999, respectively. Cash used in operating activities during 2001 was primarily the result of the Company's net loss for the period partially offset by non-cash charges including amortization of intangibles, stock-based compensation and equity in the loss of Curis Newco. The 2001 net loss was also offset by an increase in deferred revenue related to certain consideration received under the assignment of the Company's single-chain-polypeptide technology to Micromet. Net cash used in operating activities for the year ended December 31, 2000 was primarily the result of the Company's net loss for the period offset by non-cash charges including the write-offs of in-process research and development costs and certain patents deemed by the Company to be impaired, stock-based compensation and amortization of intangibles. In the year ended December 31, 1999, net cash used in operating activities was primarily the result of the Company's net loss for the period combined with decreases in accounts payable, accrued liabilities and deferred revenue of the company.

Net cash provided by investing activities was \$6,429,000, \$25,842,000 and \$20,585,000 for the years ended December 31, 2001, 2000 and 1999, respectively. Cash provided by investing activities in 2001 was primarily the result of net proceeds from the sale of marketable securities totaling \$8,862,000. These proceeds were partially offset by net expenditures for leasehold improvements and equipment of \$1,746,000. Cash provided by investing activities in 2000 was primarily the result of \$28,619,000 of cash and marketable securities from Ontogeny and Reprogenesis acquired at the time of the merger. This amount was partially offset by cash expenditures for the purchase of marketable securities of \$2,530,000. In the year ended December 31, 1999, cash provided by investing activities was largely the result of \$21,544,000 in net sales of marketable securities.

Financing activities generated approximately \$5,116,000 of cash in the year ended December 31, 2001 resulting primarily from the sale of 546,448 shares of common stock at \$7.32 for total net proceeds of \$3,853,000, proceeds received from the issuance of a convertible subordinated note payable to Becton Dickinson of \$2,000,000 and proceeds from other issuances of common stock totaling approximately \$951,000. These amounts were partially offset by repayments on debt and capital lease arrangements by the Company of \$1,603,000. Financing activities generated approximately \$47,521,000 of cash in the year ended December 31, 2000 resulting primarily from the sale of 5.2 million shares of common stock at \$9.00 for total net proceeds of \$43,348,000 and proceeds from the exercise of options and warrants totaling approximately \$5,357,000. Financing activities used cash of \$20,182,000 in the year ended December 31, 1999, primarily resulting from Creative's repurchase of 20,486 shares which represented all of the outstanding Series 1998/A Preferred Stock following final conversions, for approximately \$22,470,000 in cash. The Series 1998/A Preferred Stock has been retired and there will be no subsequent conversions into common stock.

On July 18, 2001, the Company and Elan International Services, Ltd. formed Curis Newco, an entity that is committed to the research and development of molecules that stimulate the hedgehog (Hh) signaling pathway. As part of the joint venture arrangement, the Company entered into an \$8,010,000 convertible promissory note agreement (the "Note Agreement") with Elan Pharma International Limited ("EPIL"). The Note Agreement bears interest at 8% per annum through July 18, 2005 and 6% per annum thereafter, compounded and payable semi-annually. The borrowings under the Note Agreement are subject to Elan's consent and restricted to the Company's development funding of Curis Newco. As of December 31, 2001, there was approximately \$675,000, including approximately \$1,000 in capitalized interest, outstanding under the Note Agreement.

On June 29, 2001, the Company entered into a purchase and sale agreement with Micromet AG, a German corporation, pursuant to which the Company assigned its single-chain-polypeptide technology to Micromet in exchange for \$8,000,000 in cash received, 3,003 shares of Micromet common stock valued at approximately \$686,000 and a convertible promissory note ("Note") of EUR 4,068,348 (approximately \$3,604,000 at December 31, 2001). In addition, during the first quarter of 2002, the Company entered into a target research and license agreement and a product development agreement with Micromet. These agreements will provide the Company with royalties on Micromet's product 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 exclusive access by Curis to Micromet's proprietary single cell analysis of gene expression technology in the

field of stem cell research. The product development agreement provides the Company the right but not the obligation to jointly fund research to develop antibodies against up to four potential targets through the proof of principle stage. The Company estimates that its portion of funding costs for each of the potential targets through proof of principle is approximately \$1,000,000. The Company will also have the right, but not the obligation, to jointly fund the development of two such antibodies from the proof of principle stage through the completion of Phase I Clinical Trials. Lastly, the Company will be obligated to pay milestones to Micromet upon the attainment of certain development goals.

On June 26, 2001, the Company 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 is repayable at any time up to its maturity date of June 26, 2006 by the Company, at its discretion, in either cash or upon issuance to Becton Dickinson of shares of the Company's common stock. The note bears interest at 7%.

On December 27, 2000, the Company entered into a term loan agreement with a financial institution under which it was able to borrow up to \$5,000,000 to finance fixed asset purchases and capital improvements through December 31, 2001. Advances under this facility are to be repaid over 12 quarterly installments beginning on March 31, 2002. Interest on the advances is payable at risk-adjusted LIBOR (4.38% as of December 31, 2001). Advances under the facility are collateralized by all capital equipment and leasehold improvements purchased with the funds under this facility. At December 31, 2001, outstanding borrowings under this agreement totaled \$5,000,000.

The Company leases equipment under various capital lease arrangements. Monthly payments range from \$363 to \$21,170 and maturities range from January 2002 to July 2004. The initial terms of the leases range from 36 to 60 months and bear interest at rates ranging from 11.0% to 16.3%. As of December 31, 2001, approximately \$2,660,000 was outstanding under these agreements.

On October 5, 2000, the Company announced the receipt of its 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. Previously, Reprogenesis had been awarded a \$2,000,000 grant from NIST to support the development of its cardiovascular products, Vascugel and Vascuject. The grant period for the NIST grant made to Reprogenesis is from November 1, 1999 to October 31, 2002. During the first quarter of 2002, the Company requested that these awards be suspended while the Company reviewed its desire to continue development efforts on these projects. The awards can be reinstated, if approved by NIST, upon the Company's election to continue its development programs as outlined under the terms of the grant awards.

In November 1998, certain OP-1 manufacturing rights and facilities were sold to Stryker. In accordance with the terms of the sale, we have received royalties from sales of Stryker products which were approved for commercial sale in 2001.

As of December 31, 2001, the Company held 53,571 shares of common stock of Exelixis, Inc. ("Exelixis") with a fair market value as of that date of approximately \$890,000, included in the Company's consolidated balance sheet as of December 31, 2001 under the category "Marketable securities -Restricted." The sale of these shares by the Company is restricted under an agreement between the Company and Exelixis, which restricts their sale until the one-year holding period has been satisfied on March 13, 2002. The value of these shares could fluctuate based on the price of Exelixis common stock and market conditions.

As of December 31, 2001, the Company had future payments required under contractual obligations and other commitments approximately as follows:

	<u>Total</u>	<u>Less than One Year</u>	<u>1-3 Years</u>	<u>4-5 Years</u>
Long-term debt . . . . .	\$ 8,882,000	\$2,139,000	\$ 4,236,000	\$2,507,000
Capital lease obligations . . . . .	2,998,000	1,682,000	1,316,000	—
Operating lease obligations . . . . .	10,883,000	2,000,000	6,145,000	2,738,000
Sponsored research obligations . . . . .	4,807,000	3,415,000	1,392,000	—
Licensing obligations . . . . .	700,000	700,000	—	—
Total future obligations . . . . .	<u>\$28,270,000</u>	<u>\$9,936,000</u>	<u>\$13,089,000</u>	<u>\$5,245,000</u>

The Company anticipates that existing capital resources, royalties to be received from Stryker for the sale of OP-1, and amounts to be received pursuant to the EPIL Note Agreement should enable it to maintain current and planned operations into the fourth quarter of 2003. Beyond the fourth quarter of 2003, the Company expects to incur substantial additional research and development and other costs, including costs related to preclinical studies and clinical trials. The Company's ability to continue funding planned operations is dependent upon its ability to generate sufficient cash flows from its royalty arrangements with Stryker, its collaboration with Elan, its other collaborative arrangements and from additional funds raised through equity or debt financings, or from other sources of financing, as may be required. With respect to the Stryker royalty arrangements, as with the Company's other collaborative arrangements, the Company's ability to generate sufficient cash flows depends on a number of factors including the ability to obtain regulatory approval to market and commercialize products to treat additional indications in major commercial markets. The Company is seeking additional collaborative arrangements and also expects to raise funds through one or more financing transactions, if conditions permit. Over the longer term, because of the Company's significant long-term capital requirements, it intends to raise funds through the sale of debt or equity securities when conditions are favorable, even if the Company does not have an immediate need for additional capital at such time. There can be no assurance that additional financing will be available or that, if available, it would be available on favorable terms. In addition, the sale of additional debt or equity securities could result in dilution to the Company's stockholders. If OP-1 is not approved for commercial sale in the United States beyond its limited approval under the Humanitarian Device Exemption provision and the Company does not receive significant royalties from Stryker for product sales and/or if substantial additional funding is not available, the Company's business will be materially and adversely affected.

### **New Accounting Pronouncements**

In July 2001, the Financial Accounting Standards Board ("FASB") issued SFAS No. 141, Business Combinations, and SFAS No. 142, Goodwill and Other Intangible Assets. SFAS No. 141 requires that all business combinations initiated after June 30, 2001 be accounted for using the purchase method of accounting. Effective January 1, 2002, the Company will adopt the provisions of SFAS No. 142. This statement affects the Company's treatment of goodwill and other intangible assets. The statement requires that goodwill existing at the date of adoption be reviewed for possible impairment and that impairment tests be periodically repeated, with impaired assets written down to fair value. Additionally, existing goodwill and intangible assets must be assessed and classified within the SFAS No. 142's criteria. Intangible assets with finite useful lives will continue to be amortized over those periods. Amortization of goodwill and intangible assets with indeterminable lives will cease.

The Company has until June 30, 2002 to complete the first step of the transitional goodwill impairment test. However, the amounts used in the transitional goodwill impairment test shall be measured as of the beginning of the year of initial application. If the carrying amount of the net assets of a reporting unit (including goodwill) exceeds the fair value of that reporting unit, the second step of the transitional goodwill impairment test will be completed by the Company as soon as possible, but no later than the end of fiscal year 2002.



An impairment loss recognized as a result of a transitional goodwill impairment test, if any, shall be recognized by the Company as the effect of a change in accounting principle. Although a transitional impairment loss for goodwill may be measured by the Company in other than the first interim reporting period of fiscal year 2002, the Company is required to report the loss, if any, in the first interim period of fiscal year 2002, irrespective of the period in which it is measured, consistent with paragraph 10 of SFAS No. 3, Reporting Accounting Changes in Interim Financial Statements. The Company currently intends to complete its transitional assessment during the first quarter of 2002 and to record the impairment, if any, at such time. In the event that the assessment is not completed in the first quarter of 2002 and the Company has a transitional impairment loss relating to its goodwill, the Company will restate its reported fiscal year 2002 interim periods to effect the change in accounting.

In August 2001, the FASB issued SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, which supercedes SFAS No. 121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of. SFAS No. 144 further refines the requirements of SFAS No. 121 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 will be required to adopt SFAS No. 144 on January 1, 2002. The adoption of this statement is not expected to have a material impact on its financial position or results of operations.

## **RISK FACTORS**

Investing in our securities involves a high degree of risk. Before making an investment decision, you should carefully consider the following information about these risks as well as other information we include or incorporate by reference in this Annual Report on Form 10-K. The risks and uncertainties we have described are not the only ones facing our Company. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our business operations. If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer, and you could lose all or part of your investment.

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

**Other than the approval of OP-1 for bone repair, we have not commercialized any other products to date. If we are not able to commercialize any other products, or if we are not able to develop and commercialize OP-1 for a wider array of indications, we will not be profitable.**

Even though Stryker has received approval to market OP-1 in the United States, Europe, Australia and Canada for bone repair, we will need to develop and commercialize OP-1 and other products for use in the treatment of a wider array of indications in order to be profitable. While Stryker is focusing its efforts on other orthopaedic indications such as spinal fusion, we are focusing our efforts on identifying and elucidating products that may have application for indications such as kidney disease, cancer and diseases of the central nervous system. Many of the products currently in our pipeline require additional research and development, clinical trials and/or regulatory resources and/or expertise prior to any commercial sale.

In 2001, Stryker began selling OP-1 in Europe, Australia and the United States. Other than OP-1, we currently have no other products for sale by us or by our collaborative partners. If we or our collaborative partners are not successful in developing and commercializing additional products in the United States and globally, we will not become profitable.

We are dependent on collaborative partners for the development and commercialization of many of our products. Any failure or delay by these partners in developing or commercializing our products could eliminate significant portions of our anticipated product pipeline.

Our strategy for development and commercialization of products depends upon the formation of collaborations and strategic alliances. To date, we have entered into strategic alliances with Stryker Corporation, Micromet AG, Elan, Aegera Therapeutics Inc. and others. In the coming year, we intend to enter into additional strategic alliances. If these strategic alliances do not develop any products, or if the products developed as a result of these alliances are not approved for commercial sale in the United States and/or globally, our expected royalty revenues will be diminished and our business will be materially and adversely affected. In addition, we may not be able to form new strategic alliances necessary to develop and commercialize products based upon our research efforts on terms favorable to us.

We have limited control over the resources that are dedicated or the development schedule set by our alliance partner in these collaborations and thereby may not be able to control the efforts that our alliance partners may devote to their respective programs with us. The timing and amount of any future royalties and manufacturing revenues with respect to product sales and product development under such collaborative arrangements will therefore depend on the level of commitment, timing and success of such collaborative partners' efforts. Accordingly, we cannot predict the success of current or future strategic alliances.

As we proceed with our research and development efforts, we regularly review opportunities to establish new collaborations, joint ventures and strategic alliances to develop, commercialize, manufacture and market products in our development pipeline. For example, as a part of our recent restructuring, we have ceased funding to our Chondrogel, Vascugel and basal cell carcinoma projects pending the establishment of favorable arrangements to commercialize these products. If we determine it is necessary to establish certain new collaborations, joint ventures, or strategic alliances and we are unable to establish favorable arrangements to commercialize our products, we may elect to limit funding for other products in our development pipeline.

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

The products that we seek to develop could compete with existing and new products being created by pharmaceutical, biopharmaceutical, biotechnology and medical device companies, as well as universities and other research institutions. Many of our competitors are substantially larger than we are and have substantially greater capital resources, research and development staffs and facilities than we have. Efforts by other

biotechnology or pharmaceutical companies could render our programs or products uneconomical or result in therapies superior to those that we develop. Furthermore, many of our competitors 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. These competitors may discover, develop and commercialize products which render the products that we or our collaborative partners are seeking to develop and commercialize non-competitive or obsolete.

Other companies are engaged in the research and development of proteins for various applications. We believe that other biopharmaceutical companies also are developing proteins, primarily growth factors, for use in the local repair of orthopaedic and skeletal defects and in other indications. In addition, a number of other companies are pursuing traditional therapies that may compete with our products, including bone grafts and electrical stimulation devices for the repair of orthopaedic and other skeletal defects.

Research in the fields of developmental biology and functional genomics, which includes our work in oncology and renal disease, is highly competitive. Our competitors in the field of developmental biology include, among others, Amgen, Inc., Chiron Corporation, Exelixis, Inc., Genentech, Inc. and Geron Corporation, as well as other private companies and major pharmaceutical companies. Competitors in the genomics area include, among others, public companies such as Axys Pharmaceuticals, Inc., Genome Therapeutics Corporation, Human Genome Sciences, Inc., Incyte Pharmaceuticals, Inc., Millennium Pharmaceuticals, Inc. and Myriad Genetics, Inc., as well as private companies and major pharmaceutical companies. We also compete with universities and other research institutions, including those receiving funding from the federally funded Human Genome Project. A number of entities are attempting to identify and patent rapidly randomly sequenced genes and gene fragments, typically without specific knowledge of the function of such genes or gene fragments. In addition, we believe that certain entities are pursuing a gene identification and characterization and product development strategy based on positional cloning. 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. We expect competition to intensify in genomics research and developmental biology as technical advances in the field are made and become more widely known.

Research in the field of stem cells is also highly competitive. Our competitors in the field of stem cells include, among others, Advance Tissue Sciences, Inc., Bresagen, Ltd., Geron Corporation, Incara Pharmaceuticals Corporation, StemCells, Inc. and Titan Pharmaceuticals, Inc., as well as other private companies and major pharmaceutical companies.

In the field of tissue engineering and the treatment of damaged or diseased tissue, we compete with several companies that are developing various tissue replacement products. In addition, a number of biotechnology, pharmaceutical and medical device companies are developing other types of products as alternatives to tissue replacement/augmentation for a variety of indications.

In the area of cardiovascular medicine, several approaches are currently being developed by major medical device, pharmaceutical and biotechnology companies to reduce restenosis or the re-narrowing of treated blood vessels, associated with current cardiovascular therapies. These approaches include, among others, local and systemic drug therapy, locally delivered radiation, gene therapy, and improved stents and stenting techniques.

We rely on our strategic partners for support in our disease research programs and intend to rely on our strategic partners 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 a strategic partner from pursuing competing internal development efforts. Any of our product candidates, therefore, may be subject to competition with a potential product under development by a strategic partner.

**Public attitudes towards stem cell research may negatively affect regulatory approval or public perception of our products.**

Our strategy for the development and commercialization of several of our product candidates will depend in part on our collaboration with Aegera Therapeutics, which involves stem cell research. Public acceptance of the use of stem cell research in the development of new cell-based therapies for the prevention or treatment of human diseases may negatively affect our ability to execute on this part of our strategy. Public attitudes towards our business may be influenced by claims that stem cell research is unsafe or unethical, and cell therapy may not gain the acceptance of the public or the medical community. Adverse effects in the field of cell therapy that have occurred or may occur in the future also may result in greater governmental regulation of our product candidates and potential regulatory delays relating to the testing or approval of our product candidates.

The use of certain human stem cells gives rise to ethical, legal and social issues regarding the appropriate use of these cells. In the event that our research related to human stem cells becomes the subject of adverse commentary or publicity, the market price for our common stock could be significantly harmed.

**The market may not be receptive to any products we develop due to their use of new technologies or cost. Such a lack of reception would adversely affect expected license revenues.**

The commercial success of our products that are approved for marketing will depend upon their acceptance by patients, the medical community and third-party payors. OP-1, for instance, is a new form of treatment for orthopaedic reconstruction, and will require a change from the current standard of care. Products such as OP-1 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 license revenues from sales of these products would be adversely affected.

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

Our success is substantially dependent on our ability to attract, train and retain qualified scientific and technical personnel for the research and development activities we conduct or sponsor. The loss of services of one or more of our key employees or consultants could have a material adverse effect on our business and operating results. Competition for hiring personnel in the biotechnology industry is intense and locating candidates with the appropriate qualifications is difficult. Although we expect to be able to attract and retain sufficient numbers of highly-skilled employees for the foreseeable future, there can be no assurance that we will be able to do so.

Any growth and expansion into areas and activities requiring additional resources or expertise, such as regulatory affairs, compliance, manufacturing and marketing, will require the addition of new key personnel. The pool of personnel with the skills that we require is limited. Competition to hire from this limited pool is intense, and we may not be able to hire, train, retain or motivate such additional personnel.

**If we fail to obtain an adequate level of reimbursement for our future products or services by third-party payors, there may be no commercially viable markets for our products.**

The availability of reimbursement by governmental and other third-party payors affects the market for any pharmaceutical product. These third-party payors continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for medical products. In some foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. We may not be able to sell our products profitably if reimbursement is unavailable or limited in scope or amount.

In both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system. Further proposals are likely. The potential for adoption of some or all of these proposals affects or will affect our ability to raise capital, obtain additional collaborative partners and market our products.

If we or our collaborative partners obtain marketing approval for our products, we expect to experience pricing pressure due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals.

**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 that are inherent in the testing, manufacturing, marketing and sale of human health care products. These claims could expose us to significant liabilities that could prevent or interfere with the development or commercialization of our products. Product liability claims could require us to spend significant time and money in litigation or to pay significant damages. Product liability insurance is generally expensive for biopharmaceutical companies such as ours. Although we maintain limited product liability insurance coverage for the clinical trials of our products, it is possible that we will not be able to obtain further product liability insurance on acceptable terms, if at all, and that our present insurance levels and insurance subsequently obtained will not provide adequate coverage against all potential claims.

## **RISKS RELATING TO 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. We currently have no material sources of revenue from product sales or license fees. It is uncertain when, if ever, we will develop significant revenue sources or become profitable, even if we are able to commercialize products. In addition, because certain of our product candidates consist of living cells, they may be more expensive to manufacture than conventional therapeutic products.

We expect to spend significant capital to fund all of our programs. 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.

**We may 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, including clinical trials of our product candidates, and to manufacture and market any products that are approved for commercial sale. Our future capital requirements will depend on many factors, including the following:

- continued progress in our research and development programs, as well as the magnitude of these programs;
- the cost of any additional facilities requirements;
- the timing, receipt and amount of milestone and other payments from collaborative partners such as Stryker;
- the timing, payment and amount of milestone license, royalty payments, research funding and royalties 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 royalties from our potential products in the market;
- the cost of clinical trials, manufacturing and commercialization activities; and
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including litigation costs and the costs of obtaining any required licenses to technologies.

In 2002, we expect that we will seek additional funding through collaborative arrangements and may seek additional funding through public or private financings. However, the biotechnology market is highly volatile and, depending on market conditions and the state of our research, development and commercialization programs, additional financing may not be available to us on acceptable terms or at all. If we fail to obtain such additional financing, our ability to continue all of our research, development, commercialization, manufacturing and marketing activities may be significantly diminished.

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 the holdings or the rights of our stockholders. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail one or more of our research or development programs. We also could be required to seek funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies, product candidates or products which we would otherwise pursue independently.

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

**We expect to rely primarily on others for clinical trials. If these clinical trials are not successful, or if we are not able to obtain the necessary regulatory approvals, we will not be able to complete development and commercialization of our products.**

In order to obtain regulatory approval for the commercial sale of our product candidates, we will be required to complete extensive preclinical studies as well as clinical trials in humans to demonstrate the safety and efficacy of our products. 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.

We cannot assure you that clinical trials of OP-1 or other product candidates under development will be sufficient to obtain regulatory approvals for the indications being studied. Furthermore, the timing and completion of Stryker's current and planned clinical trials of OP-1, as well as clinical trials of other products, 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, these products 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.

Progress in the area of orthopaedic reconstruction and dental applications is within the exclusive control of Stryker. Even though Stryker has received approval for the commercialization of OP-1 for nonunion fractures in the United States, Europe, Australia and Canada, our business could be adversely affected if Stryker is unable to obtain regulatory approval for the commercialization of OP-1 to treat additional orthopaedic indications. For example, Stryker filed a Pre-Market Approval (PMA) application for OP-1 to treat nonunion fractures, which was accepted by the FDA in June 1999. On January 29, 2001, Stryker announced that it had received a not-approvable letter from the FDA regarding its PMA for OP-1. As reported by Stryker, the deficiencies cited in the letter related primarily to the lack of statistical equivalence as compared to the control treatment of autograft in the clinical trial for tibial nonunions. On October 18, 2001, Stryker received U.S. HDE approval for use as an alternative to autograft in recalcitrant long bone nonunions where use of autograft is unfeasible and alternative

treatments have failed. The FDA has recommended that Stryker conduct a new study to obtain approval without the HDE limitation. As shown by the Stryker example, the timing of the regulatory process is unpredictable and it is uncertain whether or when approvals will be obtained from the FDA or other regulatory agencies for any use of OP-1.

We could also experience delays in our preclinical trials of any of our product candidates, unfavorable results in any development program, failure to obtain regulatory approval for the commercialization of any of our products or failure to achieve market acceptance of any approved products. Any of these events would have a negative impact on our ability to market a product.

**The development process necessary to obtain regulatory approval is complex, costly and lengthy and we may not obtain necessary regulatory approvals.**

We and our collaborative partners must obtain regulatory approval for ongoing development activities as well as for marketing or selling any of our products. We may not receive regulatory approvals to conduct clinical trials of our products or to manufacture or market our products. In addition, regulatory agencies may not grant approvals on a timely basis or may revoke or significantly modify previously granted approvals. Any delay in obtaining, or failure to obtain, approvals could adversely affect the marketing of our products and our ability to generate product revenue.

The process of obtaining FDA and other required regulatory approvals is lengthy and expensive. The time required for FDA and other clearances or 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 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. We have only limited experience in filing and prosecuting applications for the conduct of clinical studies and for obtaining marketing approval. Any delay in obtaining or failure to obtain required clearance or approvals would reduce our ability to generate revenues from the affected product. We also plan to rely significantly on contract research organizations and collaborative partners as we build internal capabilities.

Our analysis of data obtained from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory 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.

We also are subject to numerous foreign regulatory requirements governing the design and conduct of the clinical trials and the manufacturing and marketing of our 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.

Our ability to conduct preclinical research is also subject to new and evolving regulations governing the use of human and embryonic tissues for isolating new growth factors and genes which may be useful in identifying and developing new therapeutic product candidates. Our ability to conduct critical research on which our future development activities are based could be restricted or delayed depending on the outcome of pending rulemaking proceedings governing the use of these tissues and the collection of related genetic information.

**Even if we obtain marketing approval, our products will be subject to ongoing regulatory oversight which may affect our ability to successfully commercialize any products we develop.**

Even if we receive regulatory approval of a product, the approval may be subject to limitations on the indicated uses for which the product is marketed or contain requirements for costly post-marketing follow-up

studies. After we obtain marketing approval for any product, the manufacturer and the manufacturing facilities for that product will be subject to continual review and periodic inspections by the FDA and other regulatory authorities. 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 we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecution.

**We may not be able to comply with other governmental regulations, which could subject us to penalties and otherwise result in the limitation of our operations.**

In addition to comprehensive regulation 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, regulations administered by the Nuclear Regulatory Commission, national restrictions on technology transfer, import, export and customs regulations and certain other local, state or federal regulation. 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 dispersing of such materials comply with all applicable laws and regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials.

## **RISKS RELATING TO PRODUCT MANUFACTURING AND SALES**

**We have no commercial manufacturing capabilities and may be unable to expand our manufacturing capabilities as required to meet demand for our products.**

We have limited experience or capabilities in large-scale commercial manufacturing of any of our product candidates. Our current facilities and staff are inadequate for commercial production and distribution of products. We have no current plans to manufacture any of our products in-house. We may not be able to attract, train and retain the required personnel or to expand our manufacturing capability to manufacture commercial quantities of any of our products in a timely manner should the need arise. Our manufacturing scale-up efforts may not be successful, and we may not be able to establish or maintain reliable, high-volume manufacturing capabilities at commercially reasonable costs on a timely basis, or at all.

**We currently have no sales capabilities and may be unable to create a sales force as required to effectively commercialize our products.**

We currently have no sales capabilities and may be unable to create a sales force as required to effectively commercialize our products. We have no current plans to maintain our own sales force and intend to rely upon our alliance partners to market and sell products developed as a result of our collaborations. We may not be able to establish such arrangements on terms that are favorable to us. In addition, we may not be able to attract, train and retain the required personnel or to expand our sales capabilities in a timely manner should the need arise.



## **RISKS RELATING TO INTELLECTUAL PROPERTY**

### **We may not be able to obtain patent protection for our discoveries and we may infringe patent rights of third parties.**

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

Our success depends in significant part on our ability to:

- obtain patents;
- protect trade secrets;
- 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. 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 have been maintained in secrecy until patents issue, third parties may have filed or maintained patent applications for technology used by us or covered by our pending patent applications without our being aware of these applications.

We may not hold proprietary rights to some patents related to our proposed products. In some cases, these patents may be owned or controlled by third parties. 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 proposed products or services. If licenses are not available to us on acceptable terms, we or our collaborative partners will not be able to develop and commercialize these products or services.

### **If we are not able to keep our trade secrets confidential, our technology and information may be used by others to compete against us.**

We also rely significantly upon unpatented proprietary technology, information, processes and know-how. 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 any 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 have been substantial litigation and other proceedings regarding the complex 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 in which we may become involved in patent litigation or other intellectual property proceedings 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 products or 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 products or the intended use of our products 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 cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the cost of such litigation or 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 to us, 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, and we could be liable for lost profits if we are found to infringe a valid patent, and treble damages if we are found to have willfully infringed such patent rights. Patent cases frequently involve highly complex scientific matters, and each party has the right to seek a trial by jury. Accordingly, litigation results are highly unpredictable and we or our collaborative partners may not prevail in any patent proceeding.

Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could damage our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time and expense.

**If we breach any of the agreements under which we license or acquire 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 fail to comply with these requirements, we could lose intellectual property rights that are important to our business.

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. With respect to the agreement with Stryker regarding OP-1 and the agreement with Micromet regarding our single chain antibody technology, the assignment of intellectual property is irrevocable in the event of a breach of the agreement. Accordingly, it may be more difficult to enforce our rights under these agreements in the absence of litigation.

**RISKS RELATED TO OUR COMMON STOCK**

**We expect that our stock price will fluctuate significantly.**

Our common stock is listed on the Nasdaq National Market under the ticker symbol “CRIS.” The stock market, particularly in recent years, has experienced significant volatility particularly with respect to

biopharmaceutical and biotechnology based stocks. The volatility of biopharmaceutical and biotechnology based stocks often does not relate to the operating performance of the companies represented by the stock. Factors that could cause such volatility in the market price of the common stock include:

- announcements of the introduction of new products by us or our competitors;
- market conditions in the biotechnology 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;
- FDA or international regulatory actions; and
- general market conditions.

**If stockholders do not receive dividends, stockholders must rely on stock appreciation for any return on their investment in us.**

We have not declared or paid cash dividends on any of our capital stock. We currently intend to retain earnings, if any, for future growth and, therefore, do not anticipate paying cash dividends in the future. As a result, only appreciation of the price of the common stock will provide a return to investors.

**We have anti-takeover defenses that could delay or prevent an acquisition and could adversely affect our stock price.**

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. Our certificate of incorporation permits the board of directors to issue preferred stock without stockholder approval. In addition to delaying or preventing an acquisition, the issuance of a substantial number of preferred shares could adversely affect the price of the common stock.

Our certificate of incorporation provides for staggered terms to be served by the board of directors which makes it difficult for stockholders to change the composition of the board of directors in any one year. In addition, our bylaws restrict the ability of stockholders to call a special meeting of the stockholders. These provisions may have the effect of preventing or delaying changes in control of our management.

#### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We invest cash balances in excess of operating requirements in short-term marketable securities, generally corporate debt and government securities with an average maturity of less than one year. All marketable securities are considered available for sale. At December 31, 2001, the fair market value of these securities amounted to approximately \$12,279,000 with net unrealized gains of approximately \$14,000 included as a component of stockholders' equity. Because of the quality of the investment portfolio and the short-term nature of the marketable securities, we do not believe that interest rate fluctuations would impair the principal amount of the securities. 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 debt to maturity.

As of December 31, 2001, in addition to the marketable securities discussed above, we held 53,571 shares of Exelixis, Inc. common stock with a fair market value as of that date of approximately \$890,000. The value of these shares could fluctuate based on the price of Exelixis common stock and market conditions.

At December 31, 2001, we had approximately \$3,061,000 outstanding under fixed rate debt and capital lease agreements which are not subject to fluctuations in interest rates and approximately \$5,000,000 outstanding under a term loan agreement with an adjustable rate equal to risk-adjusted LIBOR. In addition, approximately \$2,072,000, including accrued interest of \$72,000, was outstanding under a convertible subordinated note payable to Becton Dickinson. Lastly, approximately \$675,000, including accrued interest of \$1,000, was outstanding under a convertible promissory note payable to an affiliate of Elan in connection with Curis Newco.

#### **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The financial statements are included beginning at F-1. See Index to the Financial Statements.

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

Not applicable.

### **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 the proxy statement to be provided to stockholders in connection with our 2002 Annual Meeting of Stockholders (the "Proxy Statement") under the headings "Directors and Nominees for Director" and "Section 16(a) Beneficial Ownership Reporting Compliance," which information is incorporated herein by reference. The name, age, and position of each executive officer of the Company is set forth under the heading "Executive Officers of the Company" 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 the Proxy Statement under the headings "Compensation of Executive Officers" and "Director Compensation," which information is incorporated herein by reference. Information specified in Items 402(k) and 402(1) of Regulation S-K and set forth in the Proxy Statement is not incorporated by reference.

#### **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

Information required by this Item 12 is set forth in the Proxy Statement under the heading "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 the Proxy Statement under the heading "Compensation of Executive Officers Employment Agreements," which information is incorporated herein by reference.

## PART IV

### ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

(23) Documents Filed as a Part of this Annual Report on Form 10-K:

(23) *Financial Statements.* The Consolidated Financial Statements are included in the 2001 Annual Report, portions of which are filed as an exhibit to this Annual Report on Form 10-K. The Consolidated Financial Statements include: Consolidated Balance Sheets, Consolidated Statements of Operations, Consolidated Statements of Cash Flows, Consolidated Statements of Changes in Stockholder's Equity, and Notes to Consolidated Financial Statements.

(23) *Exhibits.* The Exhibits listed in the Exhibit Index immediately preceding such Exhibits are filed as part of this Annual Report on Form 10-K.

(23) Current Reports on Form 8-K.

(23) On February 19, 2002, the Company filed a Current Report on Form 8-K to report under Item 5 (Other Events) that the Company had realigned its business to focus its strategic directions. No financial statements were required to be filed with this Report.

## SIGNATURES

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

CURIS, INC.

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

Date: March 28, 2002

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ DANIEL R. PASSERI</u> <b>Daniel R. Passeri</b>	President and Chief Executive Officer (Principal Executive Officer)	March 28, 2002
<u>/s/ GEORGE A. ELDRIDGE</u> <b>George A. Eldridge</b>	Vice President, Chief Financial Officer, Secretary and Treasurer (Principal Financial and Accounting Officer)	March 28, 2002
<u>/s/ DOROS PLATIKA, M.D.</u> <b>Doros Platika, M.D.</b>	Chairman of the Board of Directors	March 28, 2002
<u>/s/ SUSAN B. BAYH</u> <b>Susan B. Bayh</b>	Director	March 28, 2002
<u>/s/ MARTYN D. GREENACRE</u> <b>Martyn D. Greenacre</b>	Director	March 28, 2002
<u>/s/ RUTH B. KUNATH</u> <b>Ruth B. Kunath</b>	Director	March 28, 2002
<u>/s/ JAMES R. McNAB, JR.</u> <b>James R. McNab, Jr.</b>	Director	March 28, 2002
<u>/s/ DOUGLAS A. MELTON</u> <b>Douglas A. Melton</b>	Director	March 28, 2002
<u>/s/ JAMES A. TOBIN</u> <b>James R. Tobin</b>	Director	March 28, 2002

**CURIS, INC. AND SUBSIDIARIES**

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## **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



## **Independent Auditors' Report**

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

We have audited the consolidated balance sheet of Curis, Inc. (f.k.a. Creative BioMolecules, Inc.) and its subsidiary as of December 31, 1999 and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for the year ended December 31, 1999. These financial statements are the responsibility of the Curis, Inc.'s management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with generally accepted auditing standards. Those standards require that we plan and perform the audits 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, such financial statements present fairly, in all material respects, the financial position of Curis, Inc. and its subsidiary at December 31, 1999 and the results of their operations and their cash flows for the year ended December 31, 1999 in conformity with generally accepted accounting principles.

As discussed in Note 1 to the Consolidated Financial Statements, on February 14, 2000, Curis, Inc. entered into a merger agreement with Ontogeny, Inc. and Reprogenesis, Inc. to form Curis, Inc.

DELOITTE & TOUCHE LLP

Boston, Massachusetts  
February 15, 2000

**CURIS, INC. AND SUBSIDIARIES**

**Consolidated Balance Sheets**

	December 31,	
	2001	2000
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 38,938,062	\$ 52,414,312
Marketable securities	12,278,916	22,654,393
Marketable securities—Restricted	890,350	729,905
Accounts receivable	374,600	358,388
Prepaid expenses and other current assets	781,019	920,485
Notes receivable—Officer	500,000	—
Due from joint venture	957,798	—
Total current assets	54,720,745	77,077,483
Property and Equipment, net	11,060,711	7,866,591
Other Assets:		
Notes receivable—Officer	200,000	230,000
Intangible assets, net (Note 4)	73,807,125	97,145,664
Deposits and other assets	4,967,636	362,252
Total other assets	78,974,761	97,737,916
	\$ 144,756,217	\$ 182,681,990
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Debt and lease obligations, current portion	\$ 3,109,613	\$ 1,971,609
Accounts payable	1,967,260	2,187,824
Accrued liabilities	5,942,511	5,553,641
Deferred revenue, current portion	81,688	—
Due to joint venture	772,097	—
Total current liabilities	11,873,169	9,713,074
Debt and Lease Obligations, net of current portion	4,951,324	4,155,150
Convertible Notes Payable	2,506,852	—
Deferred Revenue, net of current portion	12,063,845	—
Preferred stock, \$0.01 par value—		
Authorized—5,000,000 shares at December 31, 2001 and 2000		
Issued and outstanding—1,000 shares at December 31, 2001		
Series A Redeemable Preferred Stock—1,426 shares authorized and 1,000 shares issued and outstanding	12,341,381	—
Commitments (Notes 7 and 9)		
Stockholders' Equity:		
Common stock, \$0.01 par value—		
Authorized 125,000,000 shares at December 31, 2001 and 2000		
Issued and outstanding—32,329,228 and 31,383,585 shares at December 31, 2001 and 2000, respectively	323,292	313,836
Additional paid-in capital	664,889,578	662,339,492
Notes receivable	(1,291,932)	(1,204,596)
Deferred compensation	(9,616,795)	(22,893,619)
Accumulated deficit	(554,135,679)	(471,945,648)
Accumulated other comprehensive income	851,182	2,204,301
Total stockholders' equity	101,019,646	168,813,766
	\$ 144,756,217	\$ 182,681,990

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,		
	2001	2000	1999
Revenues:			
Research and development contracts and government grants	\$ 967,928	\$ 997,078	\$ 3,159,460
License fees and royalties	118,575	26,491	52,400
Total revenues	<u>1,086,503</u>	<u>1,023,569</u>	<u>3,211,860</u>
Costs and Expenses:			
Research and development (a)	29,072,068	17,423,895	10,434,560
General and administrative (a)	10,492,525	9,330,256	5,524,077
Stock-based compensation (a)	10,358,302	16,628,218	64,000
Amortization and impairment charge related to intangible assets	23,338,539	14,450,894	808,017
Loss on disposition of fixed assets	—	203,904	—
In-process research and development	—	294,800,000	—
Reorganization costs (reversal)	—	(38,391)	255,701
Total costs and expenses	<u>73,261,434</u>	<u>352,798,776</u>	<u>17,086,355</u>
Loss from operations	<u>(72,174,931)</u>	<u>(351,775,207)</u>	<u>(13,874,495)</u>
Equity in Loss from Joint Venture (Note 9)	<u>(13,453,140)</u>	—	—
Other Income (Expenses):			
Interest income	2,854,027	1,900,693	1,924,313
Other income	1,694,193	5,200	1,777
Interest expense	(783,799)	(481,310)	(161,385)
Total other income	<u>3,764,421</u>	<u>1,424,583</u>	<u>1,764,705</u>
Net loss	<u>(81,863,650)</u>	<u>(350,350,624)</u>	<u>(12,109,790)</u>
Accretion and Repurchase Costs on Series 1998/A			
Preferred Stock	—	—	(2,395,559)
Accretion on Series A Redeemable Preferred Stock	(326,381)	—	—
Net loss applicable to common stockholders	<u>\$(82,190,031)</u>	<u>\$(350,350,624)</u>	<u>\$(14,505,349)</u>
Basic and Diluted Net Loss per Common Share	<u>\$ (2.58)</u>	<u>\$ (19.80)</u>	<u>\$ (1.36)</u>
Weighted Average Common Shares for Basic and Diluted Net Loss Computation	<u>31,858,923</u>	<u>17,693,966</u>	<u>10,681,547</u>
Net Loss	<u>\$(81,863,650)</u>	<u>\$(350,350,624)</u>	<u>\$(12,109,790)</u>
Unrealized Gain (Loss) on Marketable Securities	<u>116,398</u>	<u>2,235,102</u>	<u>(136,262)</u>
Comprehensive loss	<u>\$(81,747,252)</u>	<u>\$(348,115,522)</u>	<u>\$(12,246,052)</u>
(a) The following summarizes the departmental allocation of the stock-based compensation charge:			
Research and development	\$ 6,156,323	\$ 8,358,400	\$ —
General and administrative	4,201,979	8,269,818	64,000
Total stock-based compensation	<u>\$ 10,358,302</u>	<u>\$ 16,628,218</u>	<u>\$ 64,000</u>

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>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, 1998	10,337,241	\$103,372	\$142,381,729	\$ —	\$ —	\$(109,485,234)	\$ 105,461	\$ 33,105,328
Conversions of Series 1998/A Preferred								
Stock into common stock	393,418	3,934	2,974,065	—	—	—	—	2,977,999
Warrant exercises into common stock	119,198	1,192	946,430	—	—	—	—	947,622
Other issuances of common stock	149,677	1,497	966,751	—	—	—	—	968,248
Stock-based compensation	—	—	64,000	—	—	—	—	64,000
Unrealized loss on marketable securities	—	—	—	—	—	—	(136,262)	(136,262)
Accretion and repurchase costs on Series 1998/A Preferred Stock	—	—	(2,395,559)	—	—	—	—	(2,395,559)
Net loss	—	—	—	—	—	(12,109,790)	—	(12,109,790)
Balance, December 31, 1999	10,999,534	109,995	144,937,416	—	—	(121,595,024)	(30,801)	23,421,586
Issuance of common stock, net of issuance costs of approximately \$3.5 million	5,200,000	52,000	43,296,458	—	—	—	—	43,348,458
Issuance of common stock related to the acquisitions of Ontogeny and Reprogenesis	14,452,913	144,529	447,249,424	—	(19,146,230)	—	—	428,247,723
Stock-based compensation from issuance of Reprogenesis restricted common stock for services	—	—	1,623,000	—	—	—	—	1,623,000
Warrant exercises into common stock	113,119	1,131	306,430	—	—	—	—	307,561
Other issuances of common stock	478,313	4,784	5,044,174	—	—	—	—	5,048,958
Exercise of common stock options through issuance of notes receivable	139,706	1,397	1,129,983	(1,131,380)	—	—	—	—
Interest on notes receivable	—	—	—	(73,216)	—	—	—	(73,216)
Stock-based compensation from modification of option agreements	—	—	3,538,440	—	—	—	—	3,538,440
Reversal of deferred compensation related to common stock options	—	—	17,329,822	—	(17,329,822)	—	—	—
Amortization of deferred compensation	—	—	—	—	11,466,778	—	—	11,466,778
Deferred compensation related to forfeited options	—	—	(2,115,655)	—	2,115,655	—	—	—
Unrealized gain on marketable securities	—	—	—	—	—	—	2,235,102	2,235,102
Net loss	—	—	—	—	—	(350,350,624)	—	(350,350,624)
Balance, December 31, 2000	31,383,585	\$313,836	\$662,339,492	\$(1,204,596)	\$(22,893,619)	\$(471,945,648)	\$2,204,301	\$ 168,813,766

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>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, 2000 . . . . .	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 . . . . .	<u>32,329,228</u>	<u>\$323,292</u>	<u>\$664,889,578</u>	<u>\$(1,291,932)</u>	<u>\$ (9,616,795)</u>	<u>\$(554,135,679)</u>	<u>\$ 851,182</u>	<u>\$101,019,646</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,		
	2001	2000	1999
<b>Cash Flows from Operating Activities:</b>			
Net loss	\$(81,863,650)	\$(350,350,624)	\$(12,109,790)
Adjustments to reconcile net loss to net cash used in operating activities—			
Depreciation and amortization	3,288,575	1,308,673	989,490
Amortization of intangible assets	23,338,539	9,839,437	—
Stock-based compensation expense	10,358,302	16,628,218	64,000
Equity in loss of joint venture	13,453,140	—	—
Issuance of common stock in lieu of cash for license fee	98,003	—	—
Reorganization expense adjustment	—	39,141	—
Noncash interest expense on notes payable	83,487	12,811	—
Noncash interest income on notes receivable	(215,189)	(73,216)	—
Impairment costs of patents	—	4,611,261	—
Loss on disposition of fixed assets	—	203,904	—
Write-off of in-process research and development	—	294,800,000	—
Deferred patent and application costs	—	—	537,781
Increase (decrease) in operating assets and liabilities, net of assets acquired—Accounts receivable	(16,212)	(97,507)	608,936
Prepaid expenses and other current assets	147,352	52,660	154,137
Accounts payable and accrued liabilities	(591,183)	(14,002)	(2,012,555)
Due to joint venture	(957,798)	—	—
Deferred contract revenue	8,000,000	(661,279)	(3,000,000)
Total adjustments	56,987,017	326,650,101	(2,658,211)
Net cash used in operating activities	(24,876,633)	(23,700,523)	(14,768,001)
<b>Cash Flows from Investing Activities:</b>			
Purchase of marketable securities	(24,387,748)	(15,036,205)	(9,359,549)
Sale of marketable securities	33,249,661	12,506,525	30,903,094
Expenditures for property and equipment	(1,745,949)	(479,036)	(298,932)
Proceeds from sale of assets	—	687,500	—
Expenditures for patents	—	(563,882)	(776,586)
Notes receivable from related parties	(500,000)	—	—
Repayment of note receivable from officer	—	—	116,668
Decrease (increase) in other long-term assets	(187,366)	108,919	—
Marketable securities received in acquisition of Ontogeny and Reprogenesis	—	17,829,518	—
Cash received from acquisition of Ontogeny and Reprogenesis, net	—	10,788,955	—
Net cash provided by investing activities	6,428,598	25,842,294	20,584,645
<b>Cash Flows from Financing Activities:</b>			
Proceeds from issuance of common stock, net of issuance costs	3,852,732	43,348,458	—
Proceeds from other issuances of common stock	950,759	5,048,958	968,248
Proceeds from warrant exercises	—	307,561	947,622
Issuance of convertible note payable	2,000,000	—	—
Repayment of note payable to Genetics Institute	(83,800)	—	—
Repurchase of Series 1998/A Preferred Stock	—	—	(22,470,347)
Repayments of obligations under capital leases	(1,603,273)	(1,183,505)	(249,142)
Net cash provided by (used in) financing activities	5,116,418	47,521,472	(20,803,619)
Effect of Exchange Rates on Cash and Cash Equivalents	(144,632)	—	—
Net (Decrease) Increase in Cash and Cash Equivalents	(13,476,250)	49,663,243	(14,986,975)
Cash and Cash Equivalents, beginning of period	52,414,312	2,751,069	17,738,044
Cash and Cash Equivalents, end of period	\$ 38,938,062	\$ 52,414,312	\$ 2,751,069

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,		
	2001	2000	1999
Supplemental Disclosure of Noncash Investing and Financing Activities:			
Property and equipment purchased under financing or capital lease obligations .....	\$ 3,905,542	\$ 1,094,458	\$ 313,512
Repayment of notes payable by issuance of 60,000 shares of common stock .....	\$ 310,200	\$ —	\$ —
Conversion of Series 1998/A Preferred Stock .....	\$ —	\$ —	\$2,977,999
Issuance of notes receivable for exercise of stock options .....	\$ —	\$ 1,131,380	\$ —
Issuance of note receivable and receipt of common stock in Micromet .....	\$ 4,145,533	\$ —	\$ —
Issuance of convertible note payable to EPIL to fund the Company's 80.1% interest in joint venture .....	\$ 673,929	\$ —	\$ —
Issuance of Series A redeemable preferred stock to acquire initial 80.1% interest in joint venture .....	\$12,015,000	\$ —	\$ —
Acquisition of Ontogeny and Reprogenesis:			
Fair value of assets acquired .....	\$ —	\$ 38,952,383	\$ —
Assumed liabilities .....	—	(9,143,881)	—
Cost in excess of net assets acquired .....	—	125,123,232	—
In-process research and development cost acquired .....	—	294,800,000	—
Acquisition costs incurred .....	—	(2,337,781)	—
Fair value of common stock issued .....	\$ —	\$447,393,953	\$ —

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

**CURIS, INC. AND SUBSIDIARIES**  
**Notes to Consolidated Financial Statements**  
**December 31, 2001**

**(1) OPERATIONS**

On February 14, 2000, Creative BioMolecules, Inc. (Creative) announced that it would merge with Ontogeny, Inc. (Ontogeny) and Reprogenesis, Inc. (Reprogenesis) to form a public company named Curis, Inc. (Curis or the Company). Curis, the successor to Creative, recorded the merger as a purchase of Reprogenesis and Ontogeny.

Curis is engaged in the discovery of drug targets and the development of therapeutics based upon the human body's own mechanisms for tissue formation, maintenance and repair. The Company has identified key regulators responsible for turning on the mechanisms for tissue repair used by the body in response to trauma, injury or disease. We believe this approach has been validated with the approval of OP-1 for bone repair in four major markets (United States Humanitarian Device Exemption, Europe, Australia and Canada). Independently and in strategic alliances, the Company is focusing its research efforts on identifying and elucidating key regulators of tissue repair having application for diseases representing potentially large market opportunities that are underserved by current therapeutic alternatives. These diseases include kidney disease, cancer and diseases of the central nervous system.

The Company announced on February 14, 2002 that it is realigning its research and development programs and narrowing the focus of its resources on its signaling pathway and stem cell technologies. As part of this realignment, the Company suspended clinical product development efforts on Vascugel for coronary artery disease and terminated clinical development efforts on Chondrogel, its program for the treatment of vesicoureteral reflux, and its basal cell carcinoma oncology candidate. In connection with the above, the Company reduced its staff by 35 employees, including three executive officers. The Company estimates that it will incur cash expenditures in 2002 of approximately \$3,500,000 related to the realignment that include severance payments of approximately \$1,300,000, and costs associated with the termination and suspension of its clinical programs and related facility decommissioning costs of approximately \$2,200,000. As a result of the realignment, the Company may record an impairment charge to its goodwill and assembled workforce intangible assets in the first quarter of 2002 in accordance with the provisions of Statement of Financial Accounting Standards (SFAS) No.142, Goodwill and Other Intangible Assets (See Notes 3(n) and 19).

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology and compliance with FDA government regulations and approval requirements as well as the ability to grow the Company's business and obtain adequate financing to fund this growth.

**(2) MERGER**

Curis, Inc. was incorporated on February 14, 2000, and was formed on July 31, 2000. Creative (a Delaware corporation), Ontogeny (a Delaware corporation), and Reprogenesis (a Texas corporation), merged (the Merger) with and into the Company, pursuant to an Agreement and Plan of Merger dated as of February 14, 2000 (the Merger Agreement). On July 31, 2000, the Company, as the surviving company of the Merger, assumed the rights and obligations of Creative, Ontogeny and Reprogenesis. Immediately after the Merger, the Company was owned approximately 43% by the former stockholders of Creative, 38% by the former stockholders of Ontogeny and 19% by the former stockholders of Reprogenesis. Consequently, for accounting purposes, the Company is deemed to be the successor to



## CURIS, INC. AND SUBSIDIARIES

### Notes to Consolidated Financial Statements—Continued

December 31, 2001

Creative, and the historical financial statements of Creative have become the historical financial statements of the Company. The Merger has been accounted for as a purchase of Ontogeny and Reprogenesis in accordance with Accounting Principles Board (APB) Opinion No. 16, Accounting for Business Combinations, and accordingly, Ontogeny's and Reprogenesis' operating results since the Merger date are included in the accompanying financial statements.

Pursuant to the Merger Agreement, the following conversion ratios were applied to the outstanding securities of Creative, Ontogeny and Reprogenesis:

- Creative's common stockholders and the holders of options or warrants to acquire the common stock of Creative received, or are entitled to receive, upon the exercise of options or warrants, an aggregate number of shares of the Company's common stock equal to 0.3000 multiplied by the number of shares of Creative common stock outstanding or subject to options or warrants;
- Ontogeny's capital stockholders and the holders of options or warrants to acquire the capital stock of Ontogeny received, or are entitled to receive, upon the exercise of options or warrants, an aggregate number of shares of the Company's common stock equal to 0.2564 multiplied by the number of shares of Ontogeny capital stock outstanding or subject to options or warrants; and
- Reprogenesis' capital stockholders and the holders of options or warrants to acquire the capital stock of Reprogenesis received, or are entitled to receive, upon the exercise of options or warrants, an aggregate number of shares of the Company's common stock equal to 0.1956 multiplied by the number of shares of Reprogenesis capital stock outstanding or subject to options or warrants.

In connection with the Merger, the Company approved a 0.30-for-1 stock split of the Company's common stock. All share and per share amounts of common stock for all periods have been retroactively adjusted to reflect the stock split. In addition, the Company's certificate of incorporation was amended and restated among other things, to change its authorized capital stock to 125,000,000 shares of \$0.01 par value common stock and 5,000,000 shares of \$0.01 par value preferred stock.

In accordance with APB Opinion No. 16, the purchase price for Ontogeny and Reprogenesis has been allocated to the assets and liabilities of Ontogeny and Reprogenesis based on their fair values. The aggregate purchase price based on the fair market value of Creative common stock was \$300,731,000 and \$149,000,000 for Ontogeny and Reprogenesis, respectively, including the value of the outstanding options and warrants exchanged for options and warrants to purchase the common stock of Curis and the transaction costs related to the Merger.

The purchase price of Ontogeny and Reprogenesis was allocated to the assets acquired based upon an independent appraisal which used proven valuation tools and techniques. Significant portions of the purchase price were identified as intangible assets which included in-process research and development (IPR&D) of \$294,800,000 and assembled workforce of \$500,000. The fair value of the IPR&D relating to current in-process research and development projects was recorded as an expense as of the merger date. The excess of the purchase price over the fair value of identified tangible and intangible net assets of \$105,477,000 has been allocated to goodwill. Through December 31, 2001, intangible assets were being amortized over their estimated useful lives of four to five years. Beginning January 1, 2002, the Company will adopt SFAS No. 142, Goodwill and Other Intangible Assets, and will cease amortization of goodwill and assembled workforce. Going forward, the goodwill will be subject to an annual assessment for impairment based on fair value.

**CURIS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements—Continued**

**December 31, 2001**

The acquired IPR&D consists of development work to date on 11 primary projects and six primary projects for Ontogeny and Reprogenesis, respectively. The technology resulting from these development efforts offer no alternative uses in the event that they prove not to be feasible. If a technology fails to achieve FDA approval or was considered for an alternate use, it would be subjected to the risk associated with another series of clinical trials. The new use would also face regulatory risk associated with the FDA approval process.

The aggregate purchase price of \$449,731,000, including acquisition costs, was allocated as follows:

Current assets .....	\$ 32,082,000
Property, plant and equipment .....	6,328,000
Assembled workforce .....	500,000
In-process research and development .....	294,800,000
Deferred compensation .....	19,146,000
Other assets .....	542,000
Goodwill .....	105,477,000
Assumed liabilities .....	(9,144,000)
	<u>\$449,731,000</u>

Unaudited pro forma operating results for the Company, assuming the Merger occurred at the beginning of the periods presented are as follows:

	Year Ended December 31,	
	2000	1999
Revenues .....	\$ 4,486,633	\$ 9,966,730
Net loss .....	\$(98,674,701)	\$(74,393,085)
Net loss per share .....	\$ (3.78)	\$ (3.40)

For purposes of these pro forma operating results, the IPR&D was assumed to have been written off prior to the pro forma periods, so that the operating results presented only include recurring costs.

**(3) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

The Company considers its most critical accounting policies, defined as those which are both important to the portrayal of the Company's financial condition and results and require management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. The Company has identified its critical accounting policies to be those related to revenue recognition and the valuation of intangibles and long-lived assets.

**(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 collectability 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.

## CURIS, INC. AND SUBSIDIARIES

### Notes to Consolidated Financial Statements—Continued

December 31, 2001

(b) RECLASSIFICATIONS

Certain amounts in the prior years have been reclassified to conform to the current year's presentation.

(c) CONSOLIDATION

The accompanying consolidated financial statements include the Company and its wholly owned subsidiaries. Intercompany balances have been eliminated in consolidation.

(d) 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 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 No. 101 (SAB No. 101), Revenue Recognition. In accordance with SAB No. 101, 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. For the years ended December 31, 2001 and 2000, the Company has not recognized revenue relating to research and development services provided under its corporate collaboration agreements.

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 percentage of the services performed through that date or the non-refundable cash received will be recognized. The percentage of services performed is based on the ratio of the number of direct labor hours performed to date to total direct labor hours the Company is obligated to perform under the related contract, as determined on a full-time equivalent basis. The remainder will be recognized proportionately as the remaining services are performed. Royalty revenue will be 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, 2002 are classified as long-term deferred revenue. As of December 31, 2001, the Company has short- and long-term deferred revenue of approximately \$82,000 and \$12,064,000, respectively, related to the Micromet AG (see Note 9(c)) multiple element arrangement.

Government grant revenues consist of grant awards from the Department of Health and Human Services and the National Institute of Standards and Technology (NIST) (see Note 8). Revenue is recognized under government grants as the services are provided and payment is assured under the terms of the grant.

**CURIS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements—Continued**

**December 31, 2001**

During the years ended December 31, 2001, 2000 and 1999, total revenues from major customers as a percent of total revenues of the Company were as follows:

	<u>Year Ended December 31,</u>		
	<u>2001</u>	<u>2000</u>	<u>1999</u>
Biogen, Inc . . . . .	—%	—%	95%
Stryker Corporation . . . . .	9%	69%	3%
NIST . . . . .	88%	24%	—%

(e) RESEARCH AND DEVELOPMENT

Research and development costs are charged to operations as incurred. Certain research and development projects are partially funded by research and development contracts and government grants, and the expenses related to these activities are included in research and development costs.

(f) CASH EQUIVALENTS AND MARKETABLE SECURITIES

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, 2001, with maturity dates ranging between one and 11 months and with a weighted average maturity of 5.2 months are as follows:

	<u>Amortized Cost</u>	<u>Unrealized Gain (Loss)</u>	<u>Fair Value</u>
U.S. government obligations . . . . .	\$ 4,682,000	\$ 12,000	\$ 4,694,000
Commercial paper . . . . .	1,273,000	1,000	1,274,000
Corporate bonds and notes . . . . .	6,310,000	1,000	6,311,000
Corporate equity securities . . . . .	53,000	837,000	890,000
Available-for-sale marketable securities . . . . .	<u>\$12,318,000</u>	<u>\$851,000</u>	<u>\$13,169,000</u>

**CURIS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements—Continued**

**December 31, 2001**

The amortized cost, unrealized gains (losses) and fair value of marketable securities available-for-sale as of December 31, 2000, with maturity dates ranging between one and 12 months and with a weighted average maturity of 3.7 months are as follows:

	<u>Amortized Cost</u>	<u>Unrealized Gain (Loss)</u>	<u>Fair Value</u>
U.S. government obligations . . . . .	\$ 2,575,000	\$ 3,000	\$ 2,578,000
Commercial paper . . . . .	8,265,000	1,000	8,266,000
Corporate bonds and notes . . . . .	10,286,000	(43,000)	10,243,000
Corporate equity securities . . . . .	54,000	2,243,000	2,297,000
Available-for-sale marketable securities . . . . .	<u>\$21,180,000</u>	<u>\$2,204,000</u>	<u>\$23,384,000</u>

At December 31, 2001, the Company held 53,571 shares of Exelixis, Inc. (Exelixis) common stock. The shares were obtained through the exercise of a warrant to purchase common stock on March 12, 2001. The sale of the underlying common shares is prohibited until March 13, 2002, one year from the date the warrant was exercised. As a result of this restriction, the market value of the shares is included in the accompanying consolidated balance sheet under the category “Marketable securities—Restricted” with a fair market value of approximately \$890,000 and \$730,000 as of December 31, 2001 and 2000, respectively.

At December 31, 2000, the Company held 107,142 shares of Exelixis common stock which are included in the Company’s balance sheet as of December 31, 2000, under the category “Marketable securities” with a fair market value of approximately \$1,567,000.

During the first quarter of 2001, the Company sold all shares of Exelixis common stock for total net proceeds of approximately \$1,470,000, which was also the gain recognized as the Company had recorded a zero cost basis in these shares.

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

The Company’s financial instruments consist mainly of cash and cash equivalents, marketable securities, accounts receivable, notes receivable, accounts payable, convertible notes payable, and debt 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, accounts and notes receivable, and accounts payable are reflected in the accompanying consolidated financial statements at cost, which approximates fair value due to the short-term nature of these instruments. The fair value of marketable securities is based on current quoted market values. The convertible notes payable, and certain other debt and lease obligations have fixed rates of interest and will be subject to fluctuations in fair value during their terms. As of December 31, 2001, the fair value of these instruments approximates their carrying amount due to the short-term maturity of these instruments and the short lapse of time from their issuance. The Company has a term loan with a lender to finance equipment purchases and leasehold improvements that has a variable rate of interest. The carrying amount of this debt obligation approximates fair value due to the underlying market conditions and short lapse of time from its issuance (see Note 6).

**CURIS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements—Continued**

**December 31, 2001**

(h) **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

(i) **OTHER INTANGIBLE ASSETS**

The Company has filed applications for United States and foreign patents covering aspects of its technology. Certain costs related to successful patent applications and certain costs related to pending applications from which the Company is currently deriving economic benefit, are capitalized and amortized over the estimated useful life of the patent, generally 16 to 20 years, using the straight-line method. Accumulated amortization was approximately \$570,000 and \$445,000 at December 31, 2001 and 2000, respectively. During the year ended December 31, 2000, the Company recognized an impairment charge of approximately \$4,611,000 to reduce the carrying value of certain patents (see Note 3(j)). The Company evaluates all patent costs and, to the extent there is uncertainty as to the realizability of such costs, they are expensed as incurred.

(j) **LONG-LIVED ASSETS**

The Company applies the provisions of SFAS No. 121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of. SFAS No. 121 requires that the Company continually evaluates whether events or circumstances have occurred that indicate the carrying value of these assets may have been impaired. Any write-downs are to be treated as permanent reductions in the carrying amounts of the assets. Accordingly, the Company evaluates the possible impairment of goodwill and other long-lived assets based on the projected cash flows of the related asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds the fair value of the asset. Assets to be disposed of are reported at the lower of the carrying amount or fair value less the cost to sell.

During the third quarter of the year ended December 31, 2000, the Company performed a review of its capitalized patent costs as part of evaluating its post-merger strategy. This review resulted in an impairment charge of approximately \$4,611,000 to reduce the carrying value of those patents determined not to be beneficial or not expected to be utilized in future operations and which have no alternative future use. This amount has been included under amortization of intangibles in the accompanying consolidated statement of operations for the year ended December 31, 2000.

(k) **BASIC AND DILUTED LOSS PER COMMON SHARE**

The Company applies SFAS No. 128, Earnings per Share, which establishes standards for computing and presenting earnings per share. Basic and diluted net loss per share were determined by dividing net

## CURIS, INC. AND SUBSIDIARIES

### Notes to Consolidated Financial Statements—Continued

December 31, 2001

loss, after giving effect to the accretion on Series A Redeemable Preferred Stock in 2001 and the accretion and repurchase costs on Series 1998/A Preferred Stock in 1999, by the weighted average common shares outstanding during the period. Diluted net loss per common share is the same as basic net loss per common share for all periods presented, as the effect of the potential common stock equivalents is antidilutive due to the Company's net loss position for all periods presented. Antidilutive securities, which consist of stock options and warrants, that are not included in diluted net loss per common share were 8,272,803, 6,899,088 and 1,834,513 as of December 31, 2001, 2000 and 1999, respectively.

(l) 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 (see Note 14). 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.

(m) DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES

SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities, establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities. SFAS No. 133, as amended by SFAS No. 137 and SFAS No. 138, is effective for all fiscal quarters of fiscal years beginning after June 15, 2000. The Company's adoption of SFAS No. 133 during fiscal 2000 did not have an impact on its financial position or results of operations. As of December 31, 2001 and 2000, the Company did not have any derivative instruments.

(n) NEW ACCOUNTING PRONOUNCEMENTS

In July 2001, the Financial Accounting Standards Board (FASB) issued SFAS No. 141, Business Combinations, and SFAS No. 142, Goodwill and Other Intangible Assets. SFAS No. 141 requires that all business combinations initiated after June 30, 2001 be accounted for using the purchase method of accounting. Effective January 1, 2002, the Company will adopt the provisions of SFAS No. 142. This statement affects the Company's treatment of goodwill and other intangible assets. The statements require that goodwill existing at the date of adoption be reviewed for possible impairment and that impairment tests be periodically repeated at least annually, with impaired assets written down to fair value. Additionally, existing goodwill and intangible assets must be assessed and classified within the SFAS No. 142's criteria. Intangible assets with finite useful lives will continue to be amortized over those periods. Amortization of goodwill and intangible assets with indeterminable lives will cease.

The Company has until June 30, 2002 to complete the first step of the transitional goodwill impairment test. However, the amounts and assumptions used in the transitional goodwill impairment test shall be measured as of the beginning of the year of initial application. If the carrying amount of the net assets of a reporting unit (including goodwill) exceeds the fair value of that reporting unit, the second step of the transitional goodwill impairment test will be completed by the Company as soon as possible, but no later than the end of fiscal year 2002. The Company has not determined the amount, if any, of impairment due to the adoption of SFAS No. 142.

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**Notes to Consolidated Financial Statements—Continued**

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An impairment loss recognized as a result of a transitional goodwill impairment test, if any, shall be recognized by the Company as the effect of a change in accounting principle. Although a transitional impairment loss for goodwill may be measured by the Company in other than the first interim reporting period of fiscal year 2002, the Company is required to report the loss, if any, in the first interim period of fiscal year 2002, irrespective of the period in which it is measured, consistent with paragraph 10 of SFAS No. 3, Reporting Accounting Changes in Interim Financial Statements. The Company currently intends to complete its transitional assessment during the first quarter of 2002 and to record the impairment, if any, at such time. In the event that the assessment is not completed in the first quarter of 2002 and the Company has a transitional impairment loss relating to its goodwill, the Company will restate its reported fiscal year 2002 interim periods to effect the change in accounting.

The Company recorded expense related to the amortization of goodwill of approximately \$23,114,000 and \$9,641,000 during the years ended December 31, 2001 and 2000, respectively. The Company recorded expense related to the amortization of assembled workforce of \$100,000 and \$42,000 during the years ended December 31, 2001 and 2000, respectively. As of December 31, 2001, 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.

In August 2001, the FASB issued SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, which supercedes SFAS No. 121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of. SFAS No. 144 further refines the requirements of SFAS No. 121 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 will be required to adopt SFAS No. 144 on January 1, 2002. The adoption of this statement is not expected to have a material impact on its financial position or results of operations.

**(4) INTANGIBLE ASSETS**

Intangible assets consist of the following:

	<b>December 31,</b>	
	<b>2001</b>	<b>2000</b>
Goodwill .....	\$105,477,000	\$105,477,000
Patents .....	1,297,000	1,297,000
Assembled workforce .....	500,000	500,000
	107,274,000	107,274,000
Less—Accumulated amortization .....	(33,467,000)	(10,128,000)
	\$ 73,807,000	\$ 97,146,000

Through December 31, 2001, goodwill totaling \$105,477,000 and assembled workforce of \$500,000 were being amortized over their estimated useful lives of four to five years. Beginning January 1, 2002, the Company will adopt SFAS No. 142 and will cease amortization of goodwill and assembled workforce. Going forward, the goodwill and certain purchased intangibles will be subject to an annual assessment for impairment based on fair



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**Notes to Consolidated Financial Statements—Continued**

**December 31, 2001**

value. Accumulated amortization as of December 31, 2001 was approximately \$32,755,000 and \$142,000 for goodwill and assembled workforce, respectively. Accumulated amortization as of December 31, 2000 was approximately \$9,641,000 and \$42,000 for goodwill and assembled workforce, respectively. Patent accumulated amortization (see Note 3(i)) was approximately \$570,000 and \$445,000 at December 31, 2001 and 2000, respectively.

**(5) PROPERTY AND EQUIPMENT**

Property and equipment consist of the following:

	<u>December 31,</u>	
	<u>2001</u>	<u>2000</u>
Laboratory equipment and computers . . . . .	\$ 1,542,000	\$ 1,710,000
Equipment and furniture under notes payable and capital leases . . . . .	7,413,000	5,538,000
Leasehold improvements . . . . .	5,158,000	2,752,000
Leasehold improvements under notes payable and capital leases . . . . .	4,973,000	3,431,000
Office furniture and equipment . . . . .	458,000	462,000
	<u>19,544,000</u>	<u>13,893,000</u>
Less—Accumulated depreciation and amortization . . . . .	(8,483,000)	(6,026,000)
Total . . . . .	<u>\$11,061,000</u>	<u>\$ 7,867,000</u>

**(6) LONG-TERM DEBT AND CAPITAL LEASE OBLIGATIONS**

Long-term debt and capital lease obligations consist of the following at December 31, 2001 and 2000:

	<u>December 31,</u>	
	<u>2001</u>	<u>2000</u>
Notes payable to financing agencies for capital purchases . . . . .	\$ 5,450,000	\$ 1,946,000
Obligations under capital leases, net of approximately \$49,000 and \$73,000 discount at December 31, 2001 and 2000, respectively . . . . .	2,611,000	3,787,000
Notes payable to Genetics Institute for technology purchases . . . . .	—	394,000
Convertible subordinated note payable to Becton Dickinson, net of \$240,000 discount, including approximately \$72,000 of capitalized interest . . . . .	1,832,000	—
Convertible promissory note agreement with Elan Pharma International, including approximately \$1,000 of capitalized interest . . . . .	675,000	—
	<u>10,568,000</u>	<u>6,127,000</u>
Less—Current portion . . . . .	(3,110,000)	(1,972,000)
Total long-term debt and capital lease obligations, including convertible debt . . . . .	<u>\$ 7,458,000</u>	<u>\$ 4,155,000</u>

In December 2000, the Company entered into a term loan agreement with a lender to finance equipment purchases and leasehold improvements in its facilities. The agreement made available to the Company an aggregate principal amount of \$5,000,000, of which \$5,000,000 was outstanding as of December 31, 2001. Interest is variable and is computed based on risk-adjusted LIBOR (4.38% as of December 31, 2001).

## CURIS, INC. AND SUBSIDIARIES

### Notes to Consolidated Financial Statements—Continued

December 31, 2001

Interest is payable on any outstanding principal on a monthly basis beginning December 2000. Principal amounts outstanding related to equipment purchases are payable in 12 equal quarterly installments beginning on March 31, 2002. Amounts outstanding for leasehold improvements are payable in 11 equal quarterly installments beginning on March 31, 2002, with a final balloon payment due on December 31, 2004. Substantially all of the assets of the Company, excluding intellectual property and assets already pledged under existing financing arrangements, serve as collateral for the loan. Additionally, the Company must comply with certain financial covenants related to minimum liquidity ratio, minimum tangible capital base, and a minimum unencumbered cash balance. As of December 31, 2001, the Company was in compliance with all covenants under this agreement.

In June 1998, Reprogenesis entered into equipment and leasehold improvements loan agreements with a maximum borrowing capacity of \$2,000,000. The total amount borrowed under these agreements was \$1,772,000 at an interest rate of 12.84%. The principal and interest on any borrowings are to be repaid over 48 equal monthly installments. The Company assumed these loan agreements as part of the Merger. As of December 31, 2001, approximately \$450,000 was outstanding under these agreements and the Company was in compliance with all covenants under these agreements.

The Company leases equipment under various capital lease arrangements. Monthly payments range from \$363 to \$21,170 and maturities range from January 2002 to July 2004. The initial terms of the leases range from 36 months to 60 months and bear interest at rates ranging from 11.0% to 16.3%. As of December 31, 2001, approximately \$2,660,000 was outstanding under these agreements and the Company was in compliance with all covenants under these agreements.

On May 31, 2001 the Company issued 60,000 shares of common stock valued at \$310,000 and paid cash totaling \$195,000, including accrued interest of \$111,000, to repay in full all notes payable due to Genetics Institute for technology purchases.

On June 26, 2001, the Company received \$2,000,000 from Becton Dickinson under a convertible subordinated note payable (the Note) in connection with the exercise of an option to negotiate a collaboration agreement. The Note is repayable, at the option of the Company, in either cash or upon 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 is below the fair market interest rate on date of issue which the Company estimates to be 11%. The difference between the market interest rate of 11% and the coupon interest rate of 7% is being amortized as interest expense over the remaining term of the Note. As of December 31, 2001, approximately \$2,072,000, including approximately \$72,000 of accrued interest, was outstanding under the Note.

On July 18, 2001, the Company entered into an \$8,010,000 convertible promissory note agreement (Note Agreement) with Elan Pharma International Limited (EPIL). The Note Agreement bears interest at 8% per annum through July 18, 2005 and 6% per annum thereafter, compounded and payable semi-annually. Under the terms of the Note Agreement, the default maturity date is July 18, 2007. However, EPIL has the option to convert all or any portion of the outstanding principal amount into the Company's common stock under certain circumstances at any time after July 18, 2003, at a per share price of \$8.63, subject to adjustment under certain circumstances, as defined. The borrowings under the Note Agreement are subject to Elan's consent and restricted to the Company's development funding of Curis Newco (see Note 9(b)). On December 27, 2001, the Company received approximately \$674,000

**CURIS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements—Continued**

**December 31, 2001**

from EPIL under the Note Agreement. As of December 31, 2001, approximately \$675,000, including approximately \$1,000 of capitalized interest, was outstanding under the Note Agreement.

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

<u>Year Ending December 31,</u>	
2002 .....	\$ 3,821,000
2003 .....	2,510,000
2004 .....	3,042,000
2005 .....	—
2006 .....	1,832,000
Thereafter .....	<u>675,000</u>
Total minimum payments .....	11,880,000
Less—Amount representing interest .....	<u>(1,312,000)</u>
Principal obligation .....	10,568,000
Less—Current portion .....	<u>(3,110,000)</u>
	<u><u>\$ 7,458,000</u></u>

**(7) COMMITMENTS**

(a) Operating Leases

The Company has noncancellable operating lease agreements for office and laboratory space and certain office and laboratory equipment through December 2007. The Company's remaining operating lease commitments for all leased facilities and equipment with an initial or remaining term of at least one year, net of anticipated sublease revenues, are approximately as follows:

<u>Year Ending December 31,</u>	
2002 .....	\$ 2,000,000
2003 .....	2,060,000
2004 .....	2,043,000
2005 .....	2,042,000
2006 .....	1,488,000
Thereafter .....	<u>1,250,000</u>
Total minimum payments .....	<u><u>\$10,883,000</u></u>

Rent expense for all operating leases was approximately \$2,017,000, \$1,372,000 and \$841,000 for the years ended December 31, 2001, 2000 and 1999, respectively, net of facility sublease income of approximately \$405,000 and \$268,000 in 2001 and 2000, respectively.

In November 2000, the Company entered into a sublease for the remaining facility lease in Hopkinton, Massachusetts, previously occupied by Creative. The sublease commenced on November 15, 2000 and terminated on June 30, 2001, also the termination date of the Company's original lease on this facility. In April 2000, the Company amended one of its Hopkinton, Massachusetts, facility leases previously occupied by Creative whereby the lease terminated on July 31, 2000.

**CURIS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements—Continued**

**December 31, 2001**

During 2000, the Company entered into a sublease for its Boston, Massachusetts, facility previously occupied by Creative, commencing on July 1, 2000. The sublease terminates on July 31, 2002, also the termination date of the Company's original lease on this facility.

(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 pay an annual license fee and is obligated to pay royalties on future product sales, if any, resulting from the underlying licensed technology. In addition, many 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 estimates that the achievement of the milestone is probable. The Company incurred the following amounts for license fees, milestone payments and royalties payable on licensed technology for the years ended December 31, 2001, 2000 and 1999 as follows:

	<u>Year Ended December 31,</u>		
	<u>2001</u>	<u>2000</u>	<u>1999</u>
License fees .....	\$691,000	\$188,000	\$23,000
Milestone payments .....	—	—	—
Royalties .....	—	—	23,000
Total expenses incurred in connection with license agreements .....	<u>\$691,000</u>	<u>\$188,000</u>	<u>\$46,000</u>

In connection with Reprogenesis' 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, as defined. No milestone payments have been made on this agreement through December 31, 2001.

**(8) 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.

Effective November 1, 1999, Reprogenesis 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 Vascuject. 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

## CURIS, INC. AND SUBSIDIARIES

### Notes to Consolidated Financial Statements—Continued

December 31, 2001

assistance award and annual government appropriations for the award. During the first quarter of 2002, the Company requested that this award be suspended while the Company reviewed its desire to continue development efforts on this project. The award can be reinstated, if approved by NIST, upon the Company's election to continue its development program as outlined under the terms of the grant award.

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. During the first quarter of 2002, the Company requested that this award be suspended while the Company reviewed its desire to continue development efforts on this project. The award can be reinstated, if approved by NIST, upon the Company's election to continue its development program as outlined under the terms of the grant award.

The Company recognized approximately \$968,000 and \$319,000 of government grant revenue under these awards for the years ended December 31, 2001 and 2000, respectively.

#### **(9) RESEARCH AND DEVELOPMENT AND SIGNIFICANT COLLABORATIONS**

##### **(a) STRYKER CORPORATION**

Creative had an original 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 has the exclusive right to develop, market, manufacture and sell products based on OP-1 proteins for use in orthopedic reconstruction and dental therapies and is required to pay the Company royalties on such commercial sales. In 2001, Stryker paid the Company approximately \$97,000 in royalties.

Under the agreement with Stryker, as amended, Stryker has exclusive rights to develop, market and sell products incorporating bone and cartilage-inducing proteins developed under the research program, including OP-1, for use in the field of orthopaedic reconstruction and dental therapeutics. The Company has agreed not to undertake any bone morphogenic protein (BMP)-related research, development or commercialization of any products in the fields of orthopaedic reconstruction and dental therapeutics, on its own behalf or for third parties, for the term of certain patents to the extent that the activities utilize technology, patents or certain personnel acquired from Creative in the Merger. The Company has the exclusive and irrevocable right to develop, market and sell products incorporating morphogenic proteins developed under the research program, including OP-1, for all uses and applications other than orthopaedic and dental reconstruction, such as neurological diseases, osteoporosis, renal failure and others. Subject to certain exceptions in connection with an acquisition or

## CURIS, INC. AND SUBSIDIARIES

### Notes to Consolidated Financial Statements—Continued

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merger of Stryker, Stryker has agreed not to undertake any research, development or commercialization of any products in our field (applications other than orthopaedic reconstruction and dental therapies), on its own behalf or for third parties, for the term of those patents. Each company has the right to grant licenses to third parties in their respective fields, and each is obligated to pay royalties to the other on its sales of such products and to share royalties received from licensees.

The Company maintains an exclusive license under certain patents and claims that were assigned to Stryker in November 1998, as part of the sale of certain of Creative's manufacturing rights and assets to Stryker. In addition, Stryker was granted an exclusive license under patents in Creative's morphogen portfolio for use in the fields of orthopaedic reconstruction and dental therapeutics.

#### (b) ELAN INTERNATIONAL SERVICES

On July 18, 2001, the Company and Elan International Services, Ltd. (EIS) formed Curis Newco, Ltd. (Curis Newco), an entity that is committed to the research and development of molecules that stimulate the hedgehog (Hh) signaling pathway. This pathway had previously been shown to play a role in the development of the central and peripheral nervous systems. At the time Curis Newco was formed, EIS purchased 546,448 shares of the Company's common stock for \$4,000,000, or \$7.32 per share, and received a warrant to purchase up to 50,000 shares of the Company's common stock at \$10.46 per share. The warrant is exercisable for five years. Also, EIS was issued 1,000 shares of the Company's newly created Series A convertible exchangeable preferred stock ("Series A Preferred Stock") valued at \$12,015,000 (See Note 12(a)). The Series A Preferred Stock is, at EIS's option, convertible into the Company's common stock at \$14.12 per share or exchangeable for non-voting preference shares of Curis Newco ("Newco Preference Shares"), originally issued to the Company and representing 30.1% of the aggregate outstanding shares of Curis Newco ("Aggregate Newco Shares"). The Company used the \$12,015,000 in value from its issuance of the Series A Preferred Stock sale to acquire 80.1% of the Aggregate Newco Shares. The issuance of Series A Preferred Stock and the acquisition of the Aggregate Newco Shares were simultaneously completed in the form of a non-cash cross-receipt. This acquisition consisted of 100% of the voting common shares of Curis Newco ("Newco Common Shares") and 60.2% of the Newco Preference Shares, which represent 50% and 30.1%, respectively, of the Aggregate Newco Shares. In addition, EIS contributed \$2,985,000 to Curis Newco to acquire 39.8% of the Newco Preference Shares, which represent 19.9% of the Aggregate Newco Shares. Curis Newco transferred the aggregate value of \$15,000,000 in a non-cash cross-receipt transaction to Neuralab Limited, an affiliate of EIS, for a non-exclusive license giving Curis Newco rights to use an important animal model, a mouse strain that develops many of the features of human neurodegenerative diseases. Upon Curis Newco's completing this transaction, the cost of this license was expensed as a research and development cost by Curis Newco as the technology acquired had not yet reached technological feasibility and there was no future alternative use for the technology. The Company's share of this expense was approximately \$12,015,000 and is included in Equity in Loss from Joint Venture in the accompanying consolidated statement of operations for the year ended December 31, 2001. In addition, the Company contributed to Curis Newco an exclusive license with respect to certain technology related to human neurodegenerative diseases.

Curis Newco was formed by issuing Newco Common Shares and Newco Preference Shares valued at \$15,000,000 to the Company and EIS. The Company owns 100% of the outstanding Newco Common Shares, which represents 100% of the outstanding voting Curis Newco shares. The Newco Preference shares are non-voting and are convertible, at the option of the holder thereof, into voting Newco

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Common Shares at any time after July 18, 2003. While EIS currently does not own any Newco Common Shares and is unable to convert any of its Newco Preference Shares into Newco Common Shares until July 18, 2003, it has retained significant minority investor rights that the Company considers to be “participating rights” as defined in EITF Issue 96-16 Investors’ Accounting for an Investee When the Investor Has a Majority of the Voting Interest but the Minority Shareholder Has Certain Approval or Veto Rights. EIS’s participating rights prevent the Company from exercising sole control over Curis Newco with respect to certain enumerated actions related to the technology licensed from Neuralab Limited. Accordingly, the Company has not consolidated the financial statements of Curis Newco but instead accounted for its investment in Curis Newco under the equity method.

Subject to the continued agreement by the parties to the business plan of Curis Newco, the Company may choose to provide additional funding to Curis Newco as needed in relation to its 80.1% ownership interest in Curis Newco. On July 18, 2001, the Company entered into the Note Agreement for \$8,010,000 with EPIL to help finance the Company’s development funding of Curis Newco. The borrowings under the Note Agreement are restricted to this funding purpose (see Note 6).

The Company performs research for Curis Newco and incurred research expenses of approximately \$1,774,000 on behalf of Curis Newco during the period of inception (July 18, 2001) through December 31, 2001. In addition, Neuralab program management fees and other direct expenses of Curis Newco totaled approximately \$21,000. The Company’s 80.1% share of Curis Newco ongoing operating expenses for the year ended December 31, 2001 was approximately \$1,438,000 and is included in Equity in Loss from Joint Venture in the Company’s consolidated statement of operations. As of December 31, 2001, the Company has a receivable from Curis Newco of approximately \$958,000. This receivable represents research and development expenses from October 1, 2001 through December 31, 2001 paid for by Curis for services performed on behalf of Curis Newco. As of December 31, 2001, the Company has a payable recorded to Curis Newco of approximately \$772,000. This payable represents the Company’s 80.1% share in Curis Newco’s expenses for the period of October 1, 2001 through December 31, 2001.

(c) MICROMET AG

On June 29, 2001, the Company entered into a purchase and sale agreement with Micromet, AG (“Micromet”), a German corporation, pursuant to which the Company assigned its single-chain-polypeptide technology to Micromet in exchange for \$8,000,000 in cash, 3,003 shares of Micromet common stock valued at approximately \$686,000 and a convertible promissory note (“Convertible Note”) of EUR 4,068,348 (approximately \$3,604,000 at December 31, 2001). The Convertible Note bears interest at 7% and is due the earlier of (i) the closing date of an initial public offering of Micromet’s shares or (ii) June 30, 2005. The Company has recorded a long-term receivable of approximately \$128,000 relating to accrued interest on the Convertible Note. Upon reaching maturity, the Company has the option to receive either cash or shares of Micromet common stock.

In addition, effective December 31, 2001, the Company entered into a target research and license agreement and a product development agreement with Micromet. These agreements will provide the Company with royalties on Micromet’s product revenues, if any, arising out of the assigned technology, joint ownership of future product discoveries, if any, arising out of the collaboration, and access by Curis to Micromet’s proprietary single cell analysis of gene expression technology. In addition, the product development agreement will require the Company to jointly fund research for

## CURIS, INC. AND SUBSIDIARIES

### Notes to Consolidated Financial Statements—Continued

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potential targets through the proof of principle stage. The Company estimates that its portion of funding costs for each of the potential targets through proof of principle is approximately \$1,000,000. The Company will also have the right, but not the obligation, to jointly or solely fund the development of targets from the proof of principle stage through the completion of Phase I Clinical Trials. Lastly, the Company will be obligated to pay milestones to Micromet upon the attainment of certain development goals.

The Convertible Note and estimated value of the Micromet common stock have been recorded as a component of other assets in the accompanying consolidated balance sheet due to the long-term nature of the underlying instruments. The Company will recognize as revenue the value of all consideration received from Micromet under the purchase and sale agreement over the Company's estimated performance period under the product development agreement. No revenue has been recognized under this arrangement as of December 31, 2001. Accordingly, the Company has recorded short-term and long-term deferred revenue of approximately \$82,000 and \$12,064,000, respectively, in the accompanying consolidated balance sheet at December 31, 2001, based on when the Company believes revenue will be recognized.

(d) AEGERA THERAPEUTICS

The Company entered into a license and collaboration agreement, effective January 5, 2001, with Aegera Therapeutics, Inc. ("Aegera") granting the Company an exclusive worldwide license of Aegera's skin-derived, adult stem cell technologies. The agreement also stipulates a three-year research collaboration agreement in which the Company will fund a total of eighteen full-time equivalent researchers dedicated to the agreement, six of which shall be Aegera researchers. The committed costs associated with the Aegera researchers are \$600,000 per year. In consideration for the technology license, the Company paid a \$100,000 up-front license fee, paid \$250,000 for equity securities in privately-held Aegera, and issued approximately \$100,000 of Curis common stock to Aegera. In addition, under the terms of the agreement, the Company is required to make one additional license payment of \$100,000 in 2002.

The Company is required to make various milestone and royalty related payments to Aegera upon Aegera's achievement of scientific milestones and the recognition of product sales revenue, if any, respectively. Milestone payments range from \$250,000 to \$1,500,000 and are payable upon the achievement of certain research, development and regulatory goals. The aggregate number of potential milestone payments is not determinable at the onset of the agreement. No milestone payments have been made as of December 31, 2001.

(e) BECTON DICKINSON

In January 1999, Ontogeny and Becton Dickinson ("Becton") entered into a two-year research collaboration focusing on the application of cellular therapy and human pancreatic beta islets in the treatment of diabetes. Under the terms of the agreement, Becton provided one advanced researcher to work full time at one of the Company's facilities throughout the period of the research collaboration. All developments created by this researcher are the property of Curis.



## CURIS, INC. AND SUBSIDIARIES

### Notes to Consolidated Financial Statements—Continued

December 31, 2001

(f) BIOGEN

In December 1996, Creative entered into a Research Collaboration and License Agreement with Biogen to collaborate on the development of novel therapeutics based on OP-1 for the treatment of renal disorders. The initial focus of the collaboration was on advancing the development of Creative's morphogenic protein, OP-1, for the treatment of acute and chronic renal failure. Under the agreement, Creative granted to Biogen exclusive worldwide rights to manufacture, market and sell OP-1 and OP-1 products developed through the collaboration for the treatment of renal disease. The agreement provided for \$10,500,000 in research funding over a three-year period ending December 31, 1999, of which \$7,500,000 had been recognized through December 31, 1998. In December 1998, Biogen and Creative signed an Amendment Agreement and Biogen paid \$3,000,000 in research support for the year ending December 31, 1999. The \$3,000,000 has been recognized as collaborative research and development revenue through December 31, 1999. Under the Biogen Amendment, Creative assumed primary responsibility for the development of OP-1 for the treatment of renal disorders, and Biogen retained an option through 1999 to resume responsibility for development of OP-1 as a therapy for chronic renal failure. Biogen did not exercise its option by December 31, 1999, and Curis has assumed all rights to OP-1 renal therapies.

(10) NOTES RECEIVABLE—OFFICERS

On August 3, 2001, the Company entered into a loan agreement with an executive officer of the Company, totaling \$500,000. The loan is full recourse and bears interest at an annual rate of 8.0%. All principal and interest is due in full on December 31, 2002, as amended by the Company and the executive officer. The executive officer's obligations under the loan are secured by a pledge of all of the executive officers shares of the Company's common stock. In addition, during the term of the loan agreement, the executive officer has agreed not to transfer any rights he has to acquire additional shares of the Company's common stock. As of December 31, 2001, the Company estimated that the principal and interest on this loan would be forgiven by December 31, 2002 and, as such, is recording compensation expense to amortize the total of this loan over a period of seventeen months. This forgiveness is assumed to be contingent on the executive officer's continued employment with the Company. The amortized principal as of December 31, 2001 of \$146,000 and accrued taxes related to this commitment of approximately \$72,000 are included in accrued expenses. Accrued taxes are offset by a receivable in the accompanying consolidated balance sheets since taxes are not forgiven on this note (see Note 19).

On February 8, 2000, Creative loaned to two executive officers an aggregate of approximately \$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. These full recourse loans each bear interest at an annual rate of 7.0%. All principal and interest is due and payable on the earlier of May 8, 2002 or 30 days following the sale of the stock purchased with these funds.

In 1996, Ontogeny loaned an executive officer \$500,000, of which \$300,000 was being forgiven over a five-year period that commenced in 1996, contingent on the executive officer's continued employment with the Company. The remaining \$200,000 matures in 2003 and is being amortized over a seven-year period that commenced in 1996, contingent on the executive officer's continued employment with the Company. Upon forgiveness, the Company has committed to pay for any resulting income taxes to the

**CURIS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements—Continued**

**December 31, 2001**

executive officer. The Company is recording compensation expense for the total of these loans over a period of five to seven years and to accrue the related taxes. The amortized principal related to the \$200,000 as of December 31, 2001 is \$157,000 and accrued taxes related to this commitment of approximately \$196,000 are included in accrued expenses (see Note 19).

**(11) SALE OF MANUFACTURING OPERATIONS AND REORGANIZATION CHARGES**

In November 1998, Creative sold certain of its OP-1 manufacturing rights and facilities to Stryker. As a result of this transaction, Creative recorded a charge to operations of \$1,362,000 in the year ended December 31, 1998. The charge included \$885,000 primarily related to employee termination benefits and \$548,000 related to estimated health insurance claims on the terminated employees, which \$903,000 remained to be paid as of December 31, 1998. During the year ended December 31, 1999, Creative determined that health insurance claims were less than originally estimated. This resulted in a reduction in the loss on sale of manufacturing operations and the related accrual of approximately \$255,000.

Effective October 19, 1999, Creative was reorganized and the Creative Board approved a plan in order to focus its operations and financial resources on the development of its morphogenic protein-based clinical candidates for the treatment of stroke and renal disease. The reorganization charge included \$511,000 related primarily to termination benefits in the reduction of employees from 70 to 43. Salaries and termination benefits, either in the form of one-time or periodic payments, were made when the employee ceased employment. These employees were in management, research and development and administrative support. As of December 31, 1999, there was approximately \$96,000 of accrued costs, principally representing future cash outlays for employee-termination costs. As of December 31, 2000, all reorganization accruals were paid or reversed. A detailed rollforward of these accruals are as follows:

	<u>1999 Reorganization Charges</u>	<u>1998 Sale of Manufacturing Operations</u>
Accrued at December 31, 1998 .....		903,000
Expensed .....	\$ 511,000	—
Paid .....	(415,000)	(648,000)
Reversed .....	—	(255,000)
Accrued at December 31, 1999 .....	<u>96,000</u>	<u>\$ —</u>
Paid .....	(58,000)	
Reversed .....	<u>(38,000)</u>	
Accrued at December 31, 2000 .....	<u>\$ —</u>	

The following table summarizes the effect to the statement of operations for reorganization charges and sale of manufacturing operations for the year ended December 31, 1999:

Salaries and termination benefits accrued during 1999 .....	\$ 511,000
Salaries and termination benefits accrued during 1998 and settled for amounts less than anticipated .....	<u>(255,000)</u>
Total .....	<u>\$ 256,000</u>

## CURIS, INC. AND SUBSIDIARIES

### Notes to Consolidated Financial Statements—Continued

December 31, 2001

#### (12) PREFERRED STOCK

##### (a) SERIES A PREFERRED STOCK

On July 18, 2001, the Company issued 1,000 shares of a non-voting Series A Preferred Stock valued at \$12,015,000 to EIS in connection with the formation of Curis Newco (See Note 9(b)). The fair value of the Series A preferred shares was determined based on an arm's length negotiation between the Company and EIS. The Series A preferred stock is mandatorily redeemable as of July 18, 2007, however, it is redeemable at the Company's option, either in (i) cash at an amount equal to its liquidation preference plus all accrued and unpaid dividends or (ii) the issuance of shares of Curis common stock having a then fair market value equal to the liquidation preference plus all accrued and unpaid dividends. The Series A Preferred Stock is, at EIS's option and at any time, convertible into the Company's common stock at \$14.12 per share. The Series A Preferred Stock is also exchangeable for non-voting Newco Preference Shares at EIS's option at any time after July 18, 2003 (Exchange Right). The Company is required to account for this Exchange Right at fair value. The fair value of the Exchange Right would be recognized only in the event that the value of the Curis Newco joint venture shares exceeded that of the Company's common shares. If the fair value of the Curis Newco joint venture shares exceeds that of the Company's common stock issuable upon conversion, the Company would be required to record a liability for such excess and record a charge to operations. Subsequent changes in this amount would be reported currently in operations by the Company. As of December 31, 2001, the Company has determined that there was no incremental value of the Curis Newco joint venture shares as compared to its common shares, accordingly no amounts have been recognized for the Exchange Right.

The Series A Preferred Stock is entitled to dividends as and when declared by the board of directors and to participate equally on a pro rata basis in any dividend declared for the holders of common stock. Also, the Series A Preferred Stock is entitled to a mandatory dividend preference of 6%. Accordingly, the Company recorded a charge to accumulated deficit for the accretion of the 6% Series A Preferred Stock dividend of approximately \$326,000. Such amounts are included in the net loss applicable to common stockholders in the year ended December 31, 2001. The holders of Series A Preferred Stock are entitled to receive \$12,015 per share, respectively, plus all declared but unpaid dividends, 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.

##### (b) SERIES 1998/A REDEEMABLE PREFERRED STOCK

On May 27, 1998 (the Issue Date), Creative completed a private placement with three institutional investors (the Investors) for the sale of 25,000 shares of Series 1998/A Preferred Stock, \$0.01 par value per share (the Series 1998/A Preferred Stock), with a stated value of \$1,000 per share resulting in gross proceeds of \$25,000,000.

Through May 7, 1999, the holders converted a total of 4,514 shares of Series 1998/A Preferred Stock into 613,129 shares of common stock. On May 7, 1999, Creative repurchased 20,486 shares, which represented all of the then outstanding Series 1998/A Preferred Stock following final conversions, for approximately \$22,470,000 in cash. Accretion and Repurchase Costs on Series 1998/A Preferred Stock was \$21,396,000 for the year ended December 31, 1999, and included the following: \$385,000 calculated at the rate of 5% per annum of the stated value of the outstanding Series 1998/A Preferred Stock; \$144,000 of accretion of issuance costs related to the sales of Series 1998/A Preferred Stock;

## CURIS, INC. AND SUBSIDIARIES

### Notes to Consolidated Financial Statements—Continued

December 31, 2001

and, as a result of the repurchase of the Series 1998/A Preferred Stock on May 7, 1999, a one-time charge of approximately \$1,867,000 recorded in the second quarter of 1999 which represents accretion of the Series 1998/A Preferred Stock up to its repurchase amount and accretion of all remaining issuance costs. As a result of this transaction, the Series 1998/A Preferred Stock has been retired and there will be no subsequent conversions into common stock.

#### (13) WARRANTS

In connection with a private placement offering of common stock in 1994 and 1995, Creative sold 339,000 warrants, each to purchase one share of common stock. Each warrant is exercisable for a period of five years from the date of issuance at an exercise price of \$7.95. During the years ended December 31, 2000 and 1999, 74,194 and 119,198 Creative warrants were exercised, respectively. Proceeds to Creative were approximately \$308,000 and \$948,000, respectively. At December 31, 2000, all unexercised warrants had expired.

In connection with the Merger, the Company assumed 71,089 warrants from Ontogeny and Reprogenesis. The exercise price of these warrants ranges from \$3.40 to \$19.51 per share. During the fourth quarter of the year ended December 31, 2000, 55,685 warrants were exercised on a net issuance basis resulting in the issuance of 38,925 shares. At December 31, 2001, warrants to purchase 15,404 shares of common stock with prices ranging from \$9.76 to \$19.51 per share are outstanding.

On July 18, 2001 and in connection with its common stock issuance to EIS, the Company issued to EIS a warrant to purchase up to 50,000 shares of the Company's common stock at \$10.46 per share. The warrant is exercisable for five years. As of December 31, 2001, the warrant has not been exercised.

#### (14) STOCK PLANS

##### (a) OPTION PLANS

In March 2000, the Board of Directors adopted and, in June 2000, the stockholders approved the 2000 Stock Incentive Plan (the "2000 Plan"), which permits granting of incentive and non-qualified stock options as well as the issuance of restricted shares. The number of shares of common stock subject to issuance under the 2000 Plan is 11,000,000. At December 31, 2001, 2,372,614 shares are available for grant under the 2000 Plan.

The 2000 Plan permits the granting of incentive and nonqualified stock options to consultants, employees or officers of the Company and its subsidiaries at prices determined by the Board of Directors. Awards of stock may be made to consultants, employees or officers of the Company and its subsidiaries, and direct purchases of stock may be made by such individuals also at prices determined by the Board of Directors. Options become exercisable as determined by the Board of Directors and expire up to 10 years from the date of grant.

In March 2000, the 2000 Director Stock Option Plan (the "2000 Director Plan") was adopted by the Board of Directors and approved by the stockholders in June 2000. The 2000 Director Plan provides for the granting of options to non-employee directors. The number of shares of common stock subject to issuance under the 2000 Director Plan is 500,000. As of December 31, 2001, 440,000 shares are available for grant under the 2000 Director Plan.

**CURIS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements—Continued**

**December 31, 2001**

Activity under all the stock option plans is summarized as follows:

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price per Share</u>
Outstanding, December 31, 1998 (1,051,768 exercisable at a weighted average price of \$15.10 per share) . . . . .	1,729,442	\$16.47
Granted . . . . .	348,435	10.23
Exercised . . . . .	(130,141)	6.00
Canceled . . . . .	<u>(237,504)</u>	<u>22.60</u>
Outstanding, December 31, 1999 (1,060,589 exercisable at a weighted average price of \$15.47 per share) . . . . .	1,710,232	15.13
Granted . . . . .	4,447,620	13.77
Exchange of Ontogeny and Reprogenesis options for Curis options . . . . .	1,772,054	4.57
Exercised . . . . .	(601,287)	7.75
Canceled . . . . .	<u>(444,935)</u>	<u>7.27</u>
Outstanding, December 31, 2000 (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 . . . . .	<u>(1,914,044)</u>	<u>13.19</u>
Outstanding, December 31, 2001 (2,484,998 exercisable at weighted average price of \$9.40 per share) . . . . .	<u>8,207,399</u>	<u>\$ 8.37</u>

The table below summarizes options outstanding and exercisable at December 31, 2001:

<u>Exercise Price Range</u>	<u>Options Outstanding</u>			<u>Options Exercisable</u>	
	<u>Number of Shares</u>	<u>Weighted Average Remaining Contractual Life (in years)</u>	<u>Weighted Average Exercise Price per Share</u>	<u>Number of Shares</u>	<u>Weighted Average Exercise Price per Share</u>
\$ 0.39 - \$ 0.39	1,408	3.92	\$ 0.39	1,408	\$ 0.39
0.53 - 1.56	208,075	4.48	1.00	208,075	1.00
1.95 - 3.90	3,545,646	8.90	3.34	686,725	3.65
4.38 - 6.91	700,264	7.80	5.25	310,639	5.36
7.30 - 10.65	781,450	8.72	10.52	256,450	10.26
12.87 - 19.17	2,856,527	8.59	14.52	916,469	14.52
20.00 - 29.26	50,731	5.89	24.92	41,933	25.53
31.15 - 31.67	63,298	4.60	31.16	63,299	31.16
	<u>8,207,399</u>	<u>8.52</u>	<u>\$ 8.37</u>	<u>2,484,998</u>	<u>\$ 9.40</u>

## CURIS, INC. AND SUBSIDIARIES

### Notes to Consolidated Financial Statements—Continued

December 31, 2001

(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 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, 2001 and 2000, 53,888 and 16,732 shares were issued under the ESPP Plan.

The prior Employee Stock Purchase Plan permitted Creative employees to purchase common stock of Creative up to an aggregate of 225,000 shares. During the year ended December 31, 1999, 19,536 shares were issued under this plan at the fair market value prices of \$9.47 and \$9.83 per share.

(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 December 2001, the Company recorded a compensation charge of approximately \$113,000 and \$25,000 related to the issuance of fully vested options at below fair market value and to a modification of an option vesting period, respectively. The Company recorded a charge of \$399,000 and \$64,000 related to a change in the exercise terms of stock option agreements in connection with the Merger and the sale of manufacturing operations for the years ended December 31, 2000 and 1999, respectively.

On February 8, 2000, the Board of Directors approved the immediate acceleration of vesting of unvested stock options held by Creative’s executive officers and outside directors and the extension of the exercise period for one year. Vesting for approximately 397,200 options was accelerated and the exercise period for approximately 708,300 vested options was extended, resulting in a non-cash compensation charge of \$3,139,000, which was recorded in the year ended December 31, 2000.

In connection with stock options granted to employees and non-employees during the year ended December 31, 2000, the Company recorded deferred compensation, net of terminations, 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 will be recognized as an expense on a straight-line basis over the vesting period, generally four years, of the underlying stock options for options granted to employees and as earned for non-employees in accordance with EITF 96-18. The options granted to non-employees were valued based upon the fair value of the options granted. The Company recorded compensation expense of approximately \$3,934,000 and \$30,000 related to these option grants to employees and non-employees, respectively, for the year ended December 31, 2001. The Company recorded compensation expense of approximately \$1,864,000 and \$39,000 related to these option grants to employees and non-employees, respectively, for the year ended December 31, 2000. The Company did not grant stock options to non-employees in 1999. During the year ended December 31, 2001, the Company reversed approximately \$1,840,000 of unamortized compensation for options forfeited by terminated employees. The deferred compensation balance at December 31, 2001 relating to these stock option grants was \$9,576,000.

**CURIS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements—Continued**

**December 31, 2001**

On February 14, 2000, Reprogenesis issued 300,000 shares of restricted stock to an executive officer. These shares of restricted stock were fully vested upon the effective date of the Merger, at which time the Company recorded approximately \$1,623,000 of compensation expense representing the fair market value of the shares on that date.

As a result of the Merger, the Company recorded approximately \$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 Curis' common stock. The Company is amortizing this amount over the one-year vesting period of the stock options ending on August 1, 2001. During the years ended December 31, 2001 and 2000, compensation expense related to these options totaled \$6,257,000 and \$9,564,000, respectively. During the years ended December 31, 2001 and 2000, the Company also reversed approximately \$421,000 and \$2,116,000, respectively of unamortized deferred compensation for options forfeited by terminated employees. The deferred compensation balance at December 31, 2001 relating to the above unvested stock options was \$41,000.

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 tradeable, 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,		
	2001	2000	1999
Risk-free interest rate	5.0%	6.0%	6.4%
Expected dividend yield	—	—	—
Expected lives	7.0	7.4	6 months post-total vesting
Expected volatility	111%	113%	94%
Weighted average grant date fair value	\$3.20	\$15.84	\$2.26

Forfeitures for grants to executives are recognized as they occur. If the computed fair values of the 2001, 2000 and 1999 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,		
	2001	2000	1999
Net loss—			
As reported	\$(81,863,650)	\$(350,350,624)	\$(14,505,349)
Pro forma	(94,636,940)	(355,434,299)	(14,804,644)
Net loss per common share (basic and diluted)—			
As reported	\$ (2.57)	\$ (19.80)	\$ (1.36)
Pro forma	(2.97)	(20.09)	(1.39)

**CURIS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements—Continued**

**December 31, 2001**

**(15) INCOME TAXES**

No income tax provision or benefit has been provided for federal income tax purposes, as the Company has incurred losses since inception. As of December 31, 2001, the Company had available federal and state net operating loss carryforwards of approximately \$227,226,000 for income tax purposes. In addition, the Company had approximately \$4,656,000 of unused investment and research and development tax credits. These net operating loss and tax credit carryforwards will expire at various dates between 2002 and 2021.

The components of deferred income taxes at December 31, 2001 and 2000, consist primarily of the following:

	<u>2001</u>	<u>2000</u>
Deferred tax assets—		
Net operating loss carryforwards . . . . .	\$ 91,504,000	\$ 57,868,000
Investment credit and research and development tax credit carryforwards . . . . .	4,656,000	3,525,000
Amortizable research and development expenditures . . . . .	9,606,000	17,157,000
Other . . . . .	254,000	6,013,000
Total . . . . .	<u>106,020,000</u>	<u>84,563,000</u>
Valuation allowance . . . . .	<u>(106,020,000)</u>	<u>(84,563,000)</u>
Net deferred tax assets . . . . .	<u>\$ —</u>	<u>\$ —</u>

The Company has not yet achieved profitable operations. In addition, the future availability of the Company's tax benefits may be significantly limited under Section 382 of the Internal Revenue Code. Section 382 limits the use of net operating loss carryforwards, credit carryforwards and certain other tax attributes as a result of changes in a company's ownership. The Merger has caused a change in control under Section 382 of the Internal Revenue Code and, accordingly, the Company's ability to utilize the net operating loss carryforwards will be limited. The amount of the limitation has not yet been determined. Accordingly, management believes that the tax benefits as of December 31, 2001 and 2000, do not satisfy the realization criteria set forth in SFAS No. 109 and has recorded a valuation allowance for the entire net asset. The future realization, if any amount, of net operating loss carryback attributable to disqualifying dispositions will not be recognized as a tax benefit in the statement of operations but rather as a component of stockholders' equity.

In addition, as a result of the Merger, the historical net operating loss carryforwards of Ontogeny and Regeneration are available to Curis but are limited due to the provisions of Section 382 of the Internal Revenue Code. The amount and availability of the net operating loss carryforwards of Ontogeny and Regeneration have not been determined.

**(16) RETIREMENT SAVINGS PLAN**

The Company has a 401(k) retirement savings plan covering substantially all of the Company's employees. Matching Company contributions are at the discretion of the Board of Directors. The Board of Directors authorized matching contributions up to 3% of participants' salaries amounting to approximately \$213,000, \$141,000 and \$160,000 for the years ended December 31, 2001, 2000 and 1999, respectively. For the year ended December 31, 2001, the Company partially offset its matching contribution by transferring \$123,000 from the 401(k) Plan's forfeiture account.



**CURIS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements—Continued**

**December 31, 2001**

**(17) ACCRUED LIABILITIES**

Accrued liabilities consist of the following:

	<b>December 31,</b>	
	<b>2001</b>	<b>2000</b>
Collaboration and clinical costs .....	\$2,245,000	\$2,025,000
Professional fees .....	1,187,000	858,000
Accrued compensation .....	380,000	463,000
Other .....	2,131,000	2,208,000
<b>Total .....</b>	<b>\$5,943,000</b>	<b>\$5,554,000</b>

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

The following are selected quarterly financial data for the years ended December 31, 2001 and 2000:

	<b>Quarter Ended</b>			
	<b>March 31, 2001</b>	<b>June 30, 2001</b>	<b>September 30, 2001</b>	<b>December 31, 2001</b>
Revenues .....	\$ 249,165	\$ 202,638	\$ 287,915	\$ 346,785
Loss from operations .....	(20,097,033)	(19,854,146)	(16,624,108)	(15,599,644)
Net loss applicable to common stockholders .....	(17,807,229)	(19,277,008)	(28,525,447)	(16,434,192)
Basic and diluted net loss per share .....	\$ (0.57)	\$ (0.61)	\$ (0.89)	\$ (0.51)
Shares used in computing basic and diluted net loss per share .....	31,434,120	31,560,390	32,136,744	32,291,959

	<b>Quarter Ended</b>			
	<b>March 31, 2001</b>	<b>June 30, 2001</b>	<b>September 30, 2001</b>	<b>December 31, 2001</b>
Revenues .....	\$ 670,387	\$ 7,471	\$ 65,955	\$ 279,756
Loss from operations .....	(6,096,809)	(2,757,646)	(323,270,194)	(19,650,558)
Net loss applicable to Common stockholders .....	(5,841,548)	(2,514,016)	(322,870,195)	(19,124,865)
Basic and diluted net loss per share .....	\$ (0.52)	\$ (0.22)	\$ (15.19)	\$ (0.71)
Shares used in Computing basic and diluted net loss per share .....	11,267,071	11,471,672	21,250,137	26,786,175

**(19) SUBSEQUENT EVENT**

The Company announced on February 14, 2002 that it is realigning its research and development programs and narrowing the focus of its resources on its signaling pathway and stem cell technologies (the Realignment). As part of the Realignment, the Company suspended its clinical product development efforts on Vascugel for coronary artery disease. The Company also terminated clinical development efforts on Chondrogel, its program for the treatment of vesicoureteral reflux, and its basal cell carcinoma oncology candidate. In connection with the above, the Company reduced its staff by 35 employees, including three executive officers. The Company estimates that it will incur cash expenditures in 2002 of approximately \$3,500,000 related to the Realignment that include severance payments of approximately \$1,300,000, and costs associated with the termination and suspension of its clinical programs and related facility decommissioning costs of approximately \$2,200,000.

## **CURIS, INC. AND SUBSIDIARIES**

### **Notes to Consolidated Financial Statements—Continued**

**December 31, 2001**

Certain research programs affected by the realignment were acquired by the Company from Reprogenesis and Ontogeny through the merger. The net book value of intangibles as a result of the acquisitions of Reprogenesis and Ontogeny was approximately \$26,215,000 and \$46,857,000, respectively, as of December 31, 2001. In conjunction with SFAS No.142, the Company is in the process of completing the first step of the transitional goodwill impairment test. If the carrying amount of the net assets of the reporting unit (including goodwill) in which these programs have been derived from exceeds the fair value of that reporting unit, the impairment loss recognized as a result of a transitional goodwill impairment test, will be recognized by the Company as an effect of a change in accounting principle effective as of the first quarter in 2002. The Company has not determined the potential impairment loss from adopting SFAS No. 142. The Company does believe that the Realignment may result in a goodwill and assembled workforce impairment beyond any impairment recognized due to the adoption of SFAS 142. This impairment charge would be recognized as a charge to operations in the first quarter of fiscal 2002. The Company has not yet assessed the amount, if any, of this impairment charge.

In addition to its assessment of impairment as a result of the Realignment the Company performed an assessment of impairment on its goodwill and assembled workforce intangible assets as of December 31, 2001. The Company determined that the recoverability of these intangible assets was not impaired based on the future undiscounted net cash flows for the products underlying these intangible assets as of December 31, 2001. The underlying products included in this assessment were based on the Company's focus as of December 31, 2001.

In connection with separation arrangements with certain current and former executive officers (Executive Officers) of the Company, the Company will accelerate vesting of at least 158,000 shares, and as many as 433,000 shares, under options granted on April 3, 2001 at \$3.13 per share. Additionally, the exercise period for all remaining options shall be extended for up to twelve months following the respective Executive Officer's separation date. The Company will record stock-based compensation expense in the first and second quarter of 2002, as appropriate.

In addition, stock options granted to the Executive Officers on August 18, 2000 for the purchase of 1,200,000 shares at \$14.50 per share will terminate and the underlying shares will be returned to the 2000 Plan.

One of the Executive Officers will also receive accelerated forgiveness of a \$200,000 note originally scheduled to be forgiven in 2003 and a payment in an amount equal to any income tax obligations that this individual may incur resulting to such forgiveness. The Company will also forgive principal and interest on the \$500,000 loan entered into on August 3, 2001. Upon forgiveness, this individual is responsible for repayment of all taxes on the \$500,000 loan (See note 10).

## 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

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

	<u>December 31,</u> <u>2001</u>
<b>ASSETS</b>	
Current Assets:	
Cash .....	\$ 9,785
Total assets .....	<u>\$ 9,785</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>	
Current Liabilities:	
Due to Curis (Note 5) .....	957,798
Due to Elan (Note 5) .....	<u>6,118</u>
Total current liabilities .....	<u>963,916</u>
Stockholders' Deficit:	
Non-redeemable convertible preferred stock, \$1.00 par value-	
Authorized, issued and outstanding—6,000 shares as of December 31, 2001 .....	6,000
Common stock, \$1.00 par value—	
Authorized, issued and outstanding—6,000 shares as of December 31, 2001 .....	6,000
Additional paid-in capital	
Capital in excess of par value of stock .....	14,988,000
Additional capital .....	1,805,275
Due from stockholders .....	(963,916)
Deficit accumulated during the development stage .....	<u>(16,795,490)</u>
Total stockholders' equity .....	<u>(954,131)</u>
	<u>\$ 9,785</u>

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

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

	<u>For the Period from Inception (July 16, 2001) through December 31, 2001</u>
Costs and Expenses:	
Research and development .....	16,782,156
General and administrative .....	<u>13,334</u>
Net loss applicable to common stockholders .....	<u><u>\$(16,795,490)</u></u>
Basic and Diluted Net Loss per Common Share .....	<u><u>\$ (2,799.25)</u></u>
Basic and Diluted Weighted Average Shares Outstanding .....	<u><u>6,000</u></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>

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

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

	<b>For the Period from Inception (July 16, 2001) through December 31, 2001</b>
Cash Flows from Operating Activities:	
Net loss .....	\$(16,795,490)
Adjustments to reconcile net loss to net cash used in operating activities—	
Write-off of acquired technology .....	15,000,000
Noncash increase in capital contributions .....	963,916
Changes in operating assets and liabilities—	
Due from stockholders .....	(963,916)
Due to Curis .....	957,798
Due to Elan .....	6,118
Net cash used in operating activities .....	<u>(831,574)</u>
Cash Flows from Financing Activities:	
Capital contributions received .....	<u>841,359</u>
Net cash provided by financing activities .....	<u>841,359</u>
Net change in cash .....	9,785
Cash, beginning of period .....	—
Cash, end of period .....	<u>\$ 9,785</u>
Supplemental Disclosure of Noncash Financing Activities:	
Issuance of non-redeemable preferred stock	
And common stock for technology license .....	<u>\$ 15,000,000</u>

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

**CURIS NEWCO, LTD.**  
**(A DEVELOPMENT STAGE COMPANY)**  
**NOTES TO FINANCIAL STATEMENTS**

**(1) OPERATIONS**

Curis Newco, Ltd. (Curis Newco) was incorporated on July 16, 2001 as a Bermuda company. Curis Newco is owned by Curis, Inc. (Curis) and Elan International Services Ltd. (EIS), holding 80.1% and 19.9% (non-voting shares) interests, respectively. Curis Newco is 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 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 is 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 increase 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 \$15.0 million, 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.

While Curis owns 100% of the voting common stock, EIS has retained significant minority investor rights that are considered "participating rights" as defined in Emerging Issues Task Force (EITF) Issue 96-16, Investors' Accounting for an Investee When the Investor Has a Majority of the Voting Interest but the Minority Shareholder Has Certain Approval or Veto Rights. EIS's participating rights overcome the presumption that Curis exercises control over Curis Newco.

Within the period commencing on July 18, 2001 and ending on July 18, 2003, Curis and EIS may provide Curis Newco up to an aggregate amount of \$10,000,000 (Development Funding). Such Development Funding is 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 has funds available for its share of the Development Funding, Curis entered into a \$8,010,000 convertible promissory note agreement (the Note Agreement) with Elan Pharma International Ltd. (EPIL). The borrowings under the Note Agreement are subject to Elan's consent and restricted for Curis' funding of Curis Newco. As of December 31, 2001, borrowings of \$673,929 were outstanding under the Note Agreement. Based on the borrowing availability under the Note Agreement to Curis, and subject to the continued agreement of a business plan and funding requirements, Curis Newco believes it has enough available capital to fund operations through January 1, 2003.

Curis Newco is in the development stage and is devoting substantially all of its efforts toward product research and development. Curis Newco is subject to a number of risks similar to those of other development stage companies. Principal among these risks are the dependence on key individuals, the need to develop commercially usable products, competition from substitute products and larger companies, and the need to obtain adequate financing necessary from Curis and EIS to fund further product development.



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

**(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 LIMITED 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, 2001.

**(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.

**CURIS NEWCO, LTD.**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO FINANCIAL STATEMENTS—CONTINUED**

**(i) RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS**

In July 2001, the FASB issued SFAS No. 141, Business Combinations. SFAS No. 141 requires all business combinations initiated after June 30, 2001 to be accounted for using the purchase method. The adoption of SFAS No. 141 is not expected to have a material impact on Curis Newco's financial statements.

In July 2001, the FASB also issued SFAS No. 142, Goodwill and Other Intangible Assets. Under SFAS No. 142, goodwill is no longer subject to amortization over its estimated useful life. Rather, goodwill is subject to at least an annual assessment for impairment by applying a fair-value-based test. Intangible assets will continue to be amortized over their respective useful lives under SFAS No. 142. The adoption of SFAS No. 142 is not expected to have a material impact on Curis Newco's financial statements.

**(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' 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. The rights, preferences and privileges of the Preferred Stock are 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)**  
**NOTES 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 is 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 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,</u> <u>2000</u>
Due to Curis .....	\$957,798
Due to Elan .....	<u>6,118</u>
Total .....	<u>\$963,916</u>

These balances are 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, 2001, Curis and ESI are obligated to contribute \$772,097 and \$191,819, respectively.

## EXHIBIT INDEX

The following exhibits are filed herewith or incorporated herein by reference:

<u>Exhibit No.</u>	<u>Description</u>
3.1	Restated Certificate of Incorporation of Curis, Inc. (Previously filed with the SEC as Exhibit 3.3 to the Joint Proxy Statement—Prospectus on Form S-4 of Curis, Inc. on June 19, 2000 (File No. 333-32446), and incorporated herein by reference.)
3.2	Amended and Restated By-laws of Curis, Inc. (Previously filed with the SEC as Exhibit 3.2 to the Registration Statement on Form S-1 of Curis, Inc. on December 20, 2000 (File No. 333-50906), and incorporated herein by reference.)
3.3	Certificate of Designations of Curis, Inc. (Previously filed with the SEC as Exhibit 3.2 to the Post-Effective Amendment No. 1 on Form S-3 to the Registration Statement on Form S-1 of Curis, Inc. on August 10, 2001 (File No. 333-50906), and incorporated herein by reference.)
4.1	Form of Common Stock Certificate of Curis, Inc. (Previously filed with the SEC as Exhibit 4.1 to the Joint Proxy Statement—Prospectus on Form S-4 of Curis, Inc. on May 5, 2000 (File No. 333-32446), and incorporated herein by reference.)
4.2	Registration Rights Agreement, dated as of July 18, 2001, among Curis, Inc., Elan International Services, Ltd. and Elan Pharma International Limited. (Previously filed with the SEC as Exhibit 4.1 to the Quarterly Report on Form 10-Q of Curis, Inc. for the period ended June 30, 2001 (File No. 0-30347), and incorporated herein by reference.)
4.3	Convertible Promissory Note, dated July 18, 2001, made by Curis, Inc. in favor of Elan Pharma International Ltd. (Previously filed with the SEC as Exhibit 4.2 to the Quarterly Report on Form 10-Q of Curis, Inc. for the period ended September 30, 2001 (File No. 0-30347), and incorporated herein by reference.)
10.1	Master Lease Agreement, dated October 6, 1997, between Creative BioMolecules, Inc. and FINOVA Technology Finance, Inc. (Previously filed with the SEC as Exhibit 10.38 to the Annual Report on Form 10-K of Creative BioMolecules, Inc. for the period ended December 31, 1997 (File No. 0-19910), and incorporated herein by reference.)
10.2	Lease, dated as of November 16, 1995, as amended, between Ontogeny, Inc. and Moulton Realty Corp. (Previously filed with the SEC as Exhibit 10.42 to the Joint Proxy Statement—Prospectus on Form S-4 of Curis, Inc. on March 14, 2000 (File No. 333-32446), and incorporated herein by reference.)
10.3	Lease, dated as of March 15, 2001, between Curis, Inc. and Moulton Realty Company. (Previously filed with the SEC as Exhibit 10.3 to the Annual Report on Form 10-K of Curis, Inc. for the period ended December 31, 2000 (File No. 0-30347), and incorporated herein by reference.)
10.4	Lease, dated September 25, 1997, between Reprogenesis, Inc. and 21 Erie Realty Trust. (Previously filed with the SEC as Exhibit 10.36 to the Joint Proxy Statement—Prospectus on Form S-4 of Curis, Inc. on June 2, 2000 (File No. 333-32446), and incorporated herein by reference.)
10.5	First Amendment to Lease, dated October 1, 1998, between Reprogenesis, Inc. and 21 Erie Realty Trust. (Previously filed with the SEC as Exhibit 10.36 to the Joint Proxy Statement—Prospectus on Form S-4 of Curis, Inc. on June 2, 2000 (File No. 333-32446), and incorporated herein by reference.)

<u>Exhibit No.</u>	<u>Description</u>
10.6	Second Amendment to Lease, dated June 29, 2000, between Reprogenesis, Inc. and 21 Erie Street Trust. (Previously filed with the SEC as Exhibit 10.1 to the Quarterly Report on Form 10-Q of Curis, Inc. for the period ended June 30, 2000 (File No. 0-30347), and incorporated herein by reference.)
10.7	Third Amendment to Lease, dated July 31, 2000, between Curis, Inc. and 21 Erie Street Trust. (Previously filed with the SEC as Exhibit 10.29 to the Quarterly Report on Form 10-Q of Curis, Inc. for the period ended September 30, 2000 (File No. 0-30347), and incorporated herein by reference.)
10.8	Letter Agreement, dated December 27, 2000, between Curis, Inc. and Fleet National Bank. (Previously filed with the SEC as Exhibit 10.10 to the Annual Report on Form 10-K of Curis, Inc. for the period ended December 31, 2000 (File No. 0-30347), and incorporated herein by reference.)
10.9	Promissory Note, dated December 27, 2000, made by Curis, Inc. in favor of Fleet National Bank. (Previously filed with the SEC as Exhibit 10.10 to the Annual Report on Form 10-K of Curis, Inc. for the period ended December 31, 2000 (File No. 0-30347), and incorporated herein by reference.)
10.10	Pledge Agreement, dated December 27, 2000, from Curis, Inc. to Fleet National Bank. (Previously filed with the SEC as Exhibit 10.10 to the Annual Report on Form 10-K of Curis, Inc. for the period ended December 31, 2000 (File No. 0-30347), and incorporated herein by reference.)
10.11	Master Restructuring Agreement, dated as of October 15, 1998, between Creative BioMolecules, Inc. and Stryker Corporation. (Previously filed with the SEC as Exhibit 10.10 to the Annual Report on Form 10-K of Creative BioMolecules, Inc. for the period ended December 31, 1998 (File No. 0-19910), and incorporated herein by reference.)††
10.12	Asset Purchase Agreement, dated as of October 15, 1998, between Creative BioMolecules, Inc. and Stryker Corporation. (Previously filed with the SEC as Exhibit 10.11 to the Annual Report on Form 10-K of Creative BioMolecules, Inc. for the period ended December 31, 1998 (File No. 0-19910), and incorporated herein by reference.)††
10.13	Irrevocable License Agreement, dated November 20, 1998, between Creative BioMolecules, Inc. and Stryker Corporation. (Previously filed with the SEC as Exhibit 10.7 to the Annual Report on Form 10-K of Creative BioMolecules, Inc. for the period ended December 31, 1999 (File No. 0-19910), and incorporated herein by reference.)
10.14	Stryker Irrevocable License Agreement, dated November 20, 1998, between Creative BioMolecules, Inc. and Stryker Corporation. (Previously filed with the SEC as Exhibit 10.8 to the Annual Report on Form 10-K of Creative BioMolecules, Inc. for the period ended December 31, 1999 (File No. 0-19910), and incorporated herein by reference.)
10.15	Assignment from Creative BioMolecules, Inc. to Stryker Corporation, dated November 20, 1998. (Previously filed with the SEC as Exhibit 10.9 to the Annual Report on Form 10-K of Creative BioMolecules, Inc. for the period ended December 31, 1999 (File No. 0-19910), and incorporated herein by reference.)
10.16	CBM Cross-License Agreement, dated as of November 26, 1993, between Creative BioMolecules, Inc. and Enzon, Inc. (Previously filed with the SEC as Exhibit 10.42 to the Quarterly Report on Form 10-Q of Creative BioMolecules, Inc. for the period ended December 31, 1993 (File No. 0-19910), and incorporated herein by reference.)††
10.17	Enzon Cross-License Agreement, dated as of November 26, 1993, between Creative BioMolecules, Inc. and Enzon, Inc. (Previously filed with the SEC as Exhibit 10.43 to the Quarterly Report on Form 10-Q of Creative BioMolecule, Inc. for the period ended December 31, 1993 (File No. 0-19910), and incorporated herein by reference.) ††

<u>Exhibit No.</u>	<u>Description</u>
10.18	Cross-License Agreement, dated as of July 15, 1996, among Creative BioMolecules, Inc., Genetics Institute, Inc. and Stryker Corporation. (Previously filed with the SEC as Exhibit 10.1 to the Quarterly Report on Form 10-Q for the period ended September 30, 1996 of Genetics Institute, Inc. (File No. 0-14587), filed with the SEC on November 6, 1996 and incorporated herein by reference.)††
10.19	License Agreement, dated as of February 12, 1996, between Curis, Inc. and Leland Stanford Junior University. (Previously filed with the SEC as Exhibit 10.43 to the Joint Proxy Statement—Prospectus on Form S-4 of Curis, Inc. on June 2, 2000 (File No. 333-32446), and incorporated herein by reference.)††
10.20	License Agreement, dated as of September 26, 1996, and as amended January 15, 1997, among Curis, Inc., Johns Hopkins University and University of Washington School of Medicine. (Previously filed with the SEC as Exhibit 10.44 to the Joint Proxy Statement—Prospectus on Form S-4 of Curis, Inc. on June 2, 2000 (File No. 333-32446), and incorporated herein by reference.)††
10.21	License Agreement, dated as of January 1, 1995, and as amended July 19, 1995 and August 30, 1996, between Curis, Inc. and the Trustees of Columbia University in the City of New York. (Previously filed with the SEC as Exhibit 10.45 to the Joint Proxy Statement—Prospectus on Form S-4 of Curis, Inc. on April 3, 2000 (File No. 333-32446), and incorporated herein by reference.)††
10.22	License Agreement, dated as of February 9, 1995, and as amended January 1, 1997, between Curis, Inc. and the President and Fellows of Harvard University. (Previously filed with the SEC as Exhibit 10.46 to the Joint Proxy Statement—Prospectus on Form S-4 of Curis, Inc. on June 2, 2000 (File No. 333-32446), and incorporated herein by reference.)††
10.23	Amendment to License Agreement, September 11, 2000, between Curis, Inc. and the President and Fellows of Harvard College. (Previously filed with the SEC as Exhibit 10.2 to the Quarterly Report on Form 10-Q of Curis, Inc. for the period ended September 30, 2000 (File No. 0-30347), and incorporated herein by reference.)††
10.24	Exclusive License Agreement, dated as of November 2, 1998, among Curis, Inc. and the Board of Trustees of Leland Stanford Junior University and Johns Hopkins University. (Previously filed with the SEC as Exhibit 10.65 to the Joint Proxy Statement—Prospectus on Form S-4 of Curis, Inc. on June 2, 2000 (File No. 333-32446), and incorporated herein by reference.)††
10.25	License Agreement, dated as of February 1, 1997, between Curis, Inc. and the President and Fellows of Harvard College. (Previously filed with the SEC as Exhibit 10.69 to the Joint Proxy Statement—Prospectus on Form S-4 of Curis, Inc. on April 3, 2000 (File No. 333-32446), and incorporated herein by reference.)††
10.26	License and Collaboration Agreement, dated as of January 5, 2001, between Curis, Inc. and AEGERA. (Previously filed with the SEC as Exhibit 10.37 to the Annual Report on Form 10-K of Curis, Inc. for the period ended December 31, 2000 (File No. 0-30347), and incorporated herein by reference.)††
10.27	Warrant Agreement, dated as of October 1, 1997, between Curis, Inc. and Lighthouse Capital Partners, L.P. (Previously filed with the SEC as Exhibit 10.56 to the Joint Proxy Statement—Prospectus on Form S-4 of Curis, Inc. on March 14, 2000 (File No. 333-32446), and incorporated herein by reference.)

<u>Exhibit No.</u>	<u>Description</u>
10.28	Warrant Agreement, dated as of December 17, 1999, between Curis, Inc. and Lighthouse Capital III, L.P. (Previously filed with the SEC as Exhibit 10.61 to the Joint Proxy Statement—Prospectus on Form S-4 of Curis, Inc. on March 14, 2000 (File No. 333-32446), and incorporated herein by reference.)
10.29	Stock Subscription Warrant, dated as of November 21, 1997, between Curis, Inc. and MM Ventures. (Previously filed with the SEC as Exhibit 10.57 to the Joint Proxy Statement—Prospectus on Form S-4 of Curis, Inc. on March 14, 2000 (File No. 333-32446), and incorporated herein by reference.)
10.30	Warrant Agreement, dated as of September 1, 1999, between Curis, Inc. and Comdisco, Inc. (Previously filed with the SEC as Exhibit 10.59 to the Joint Proxy Statement—Prospectus on Form S-4 of Curis, Inc. on March 14, 2000 (File No. 333-32446), and incorporated herein by reference.)
10.31	Stock Subscription Warrant, dated as of November 21, 1997, between Curis, Inc. and Transamerica Business Credit Corp. (Previously filed with the SEC as Exhibit 10.57 to the Joint Proxy Statement—Prospectus on Form S-4 of Curis, Inc. on March 14, 2000 (File No. 333-32446), and incorporated herein by reference.)
10.32	Stock Subscription Warrant No. 2, dated as of November 15, 1999 between Curis, Inc. and Transamerica Business Credit Corp. (Previously filed with the SEC as Exhibit 10.60 to the Joint Proxy Statement—Prospectus on Form S-4 of Curis, Inc. on March 14, 2000 (File No. 333-32446), and incorporated herein by reference.)
10.33	Stock Subscription Warrant, dated July 2, 1998, between Curis, Inc. and TBCC Funding Trust II. (Previously filed with the SEC as Exhibit 10.39 to the Joint Proxy Statement—Prospectus on Form S-4 of Curis, Inc. on March 14, 2000 (File No. 333-32446), and incorporated herein by reference.)
10.34	Employment Agreement, dated June 17, 1996, between Ontogeny, Inc. and Dr. Platika. (Previously filed with the SEC as Exhibit 10.44 to the Annual Report on Form 10-K of Curis, Inc. for the period ended December 31, 2000 (File No. 0-30347), and incorporated herein by reference.)
10.35	Secured Promissory Note, dated June 17, 1996, between Ontogeny, Inc. and Dr. Platika in the original principal amount of \$500,000, as amended by that First Amendment to Secured Promissory Note, dated as of August 31, 1998, and that Second Amendment to Secured Promissory Note, dated as of December 15, 1999. (Previously filed with the SEC as Exhibit 10.63 to the Joint Proxy Statement—Prospectus on Form S-4 of Curis, Inc. on May 31, 2000 (File No. 333-32446), and incorporated herein by reference.)
10.36	Pledge Agreement, dated June 17, 1996, between Ontogeny, Inc. and Dr. Platika. (Previously filed with the SEC as Exhibit 10.64 to the Joint Proxy Statement—Prospectus on Form S-4 of Curis, Inc. on March 14, 2000 (File No. 333-32446), and incorporated herein by reference.)
10.37	Mortgage, dated December 15, 1999, between Ontogeny, Inc. and Dr. and Patricia C. Platika. (Previously filed with the SEC as Exhibit 10.70 to the Joint Proxy Statement—Prospectus on Form S-4 of Curis, Inc. on May 31, 2000 (File No. 333-32446), and incorporated herein by reference.)
10.38	Severance Agreement, effective November 20, 2000, between Curis, Inc. and Andrew C. G. Uprichard. (Previously filed with the SEC as Exhibit 10.1 to the Quarterly Report on Form 10-Q of Curis, Inc. for the period ended March 31, 2001 (File No. 0-30347), and incorporated herein by reference.)

<u>Exhibit No.</u>	<u>Description</u>
10.39	Severance Agreement, effective November 1, 2000, between Curis, Inc. and Daniel R. Passeri. (Previously filed with the SEC as Exhibit 10.2 to the Quarterly Report on Form 10-Q of Curis, Inc. for the period ended March 31, 2001 (File No. 0-30347), and incorporated herein by reference.)
10.40	Securities Purchase Agreement, dated as of July 18, 2001, among Curis, Inc., Elan International Services, Ltd. and Elan Pharma International Limited. (Previously filed with the SEC as Exhibit 10.1 to the Quarterly Report on Form 10-Q of Curis, Inc. for the period ended June 30, 2001 (File No. 0-30347), and incorporated herein by reference.)
10.41	Agreement for Purchase and Sale of Single-Chain Polypeptide Business, dated as of June 29, 2001, between Curis, Inc. and Micromet AG. (Previously filed with the SEC as an Exhibit to the Current Report on Form 8-K of Curis, Inc. (filed July 2, 2001 (File No. 0-30347)), and incorporated herein by reference.)
10.42	Secured Promissory Note, dated August 3, 2001, made by Dr. Platika in favor of Curis, Inc. (Previously filed with the SEC as Exhibit 10.2 to the Quarterly Report on Form 10-Q of Curis, Inc. for the period ended September 30, 2001 (File No. 0-30347), and incorporated herein by reference.)
10.43	Employment Agreement, dated September 20, 2001, between Curis, Inc. and Daniel R. Passeri. (Previously filed with the SEC as Exhibit 10.3 to the Quarterly Report on Form 10-Q of Curis, Inc. for the period ended September 30, 2001 (File No. 0-30347), and incorporated herein by reference.)
10.44	Revised Severance Agreement, effective November 5, 2001, between Curis, Inc. and Andrew C. G. Uprichard.*
10.45	First Amendment to the Secured Promissory Note, dated August 3, 2001, made by Dr. Platika in favor of Curis, Inc.*
10.46	Letter Agreement, dated January 28, 2002, between Dr. Platika and Curis, Inc.*
10.47	Letter Agreement, dated March 12, 2002, between Dr. Platika and Curis, Inc.*
10.48	Letter Agreement, dated March 6, 2002, between George A. Eldridge and Curis, Inc.*
21	Subsidiaries of Curis, Inc.*
23.1	Consent of Arthur Andersen LLP.*
23.2	Consent of Deloitte & Touche LLP.*
99.1	Letter to Commission Pursuant to Temporary Note 3T.*

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

\* filed herewith.

Curis, Inc. hereby agrees to furnish supplementally any schedules that have been omitted from this exhibit list to the SEC upon its request.