

ATRIX LABORATORIES INC

Form 10-K

March 25, 2003

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

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**FORM 10-K**

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

**For the Fiscal Year Ended December 31, 2002**

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

**For the transition period from            to**

Commission File Number 0-18231

**ATRIX LABORATORIES, INC.**

(Exact name of registrant as specified in its charter)

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

**84-1043826**  
(I.R.S. Employer  
Identification No.)

**2579 Midpoint Drive Fort Collins, Colorado**  
(Address of principal executive office)

**80525**  
(Zip Code)

Registrant's telephone number, including area code: (970) 482-5868

Securities registered pursuant to Section 12(b) of the Act: None

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

Common Stock \$.001 par value

(Title of Class)

Series A Preferred Stock Purchase Rights

(Title of Class)

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

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes  No

The aggregate market value of voting stock held by non-affiliates of the registrant as of June 28, 2002 was \$390,500,961, based upon the closing sale price on the Nasdaq National Market for that date. This calculation excludes shares of common stock held by registrant's officers and directors and each person known by the registrant to beneficially own more than 5% of the registrant's outstanding common stock, as such persons may be deemed to be affiliates. This determination of affiliate status should not be deemed conclusive for any other purpose.

The number of shares of the Registrant's common stock outstanding as of March 19, 2003 was 20,539,016.

### **DOCUMENTS INCORPORATED BY REFERENCE**

The information required by Part III of this report is incorporated by reference to the registrant's definitive Proxy Statement for the Annual Meeting of Stockholders scheduled to be held on April 27, 2003.

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**FORWARD-LOOKING INFORMATION**

*Statements in this Report that are not descriptions of historical facts are forward-looking statements provided under the safe harbor protection of the Private Securities Litigation Reform Act of 1995. These statements are made to enable a better understanding of our business, but because these forward-looking statements are subject to many risks, uncertainties, future developments and changes over time, actual results may differ materially from those expressed or implied by such forward-looking statements. Examples of forward-looking statements are statements about anticipated financial or operating results, financial projections, business prospects, future product performance, future research and development results, anticipated regulatory filings and approvals, and other matters that are not historical facts. Such statements often include words such as believes, expects, anticipates, intends, plans, estimates or similar expressions.*

*These forward-looking statements are based on the information that was currently available to us, and the expectations and assumptions that were deemed reasonable by us, at the time the statements were made. We do not undertake any obligation to update any forward-looking statements in this Report or in any of our other communications, except as required by law, and all such forward-looking statements should be read as of the time the statements were made, and with the recognition that these forward-looking statements may not be complete or accurate at a later date.*

*Many factors may cause or contribute to actual results or events being materially different from those expressed or implied by forward-looking statements. Although it is not possible to predict or identify all such factors, they include those set forth under Factors Affecting Our Business and Prospects below. These risk factors include, but are not limited to, the results of research and development efforts, the results of preclinical and clinical testing, the effect of regulation by the U.S. Food and Drug Administration, or FDA, and other agencies, the impact of competitive products, product development, commercialization and technology difficulties, the results of financing efforts, the effect of our accounting policies and other risks detailed in our filings with the Securities and Exchange Commission.*

**PART I**

**Item 1. Business.  
Overview**

We are an emerging specialty pharmaceutical company focused on advanced drug delivery. With five unique, patented, drug delivery technologies, we are currently developing a diverse portfolio of products, including proprietary oncology, dermatology, pain management and growth hormone releasing peptide-1, or GHRP-1. We also form strategic alliances with a variety of pharmaceutical and biotechnology companies to develop products utilizing our various drug delivery systems and/or to commercialize our products. These strategic alliances include collaborations with Pfizer Inc., Sanofi-Synthelabo Inc., MediGene AG, Fujisawa Healthcare, Inc., Geneva Pharmaceuticals, Inc., Sosei Co. Ltd. and CollaGenex Pharmaceuticals, Inc.

Our drug delivery systems deliver controlled amounts of drugs in time frames ranging from minutes to months to address a range of therapeutic and patient needs. Atrigel is our original proprietary sustained release biodegradable polymer drug delivery system. The Atrigel system may provide benefits over traditional methods of drug administration such as safety and effectiveness and ease of applications, site-specific or systemic delivery, customized release rates and biodegradability. With the acquisition of ViroTex Corporation in November 1998, we added four additional drug delivery systems: BEMA<sup>TM</sup>, SMP<sup>TM</sup>, MCA<sup>TM</sup> and BCP<sup>TM</sup>.

Atrix Laboratories, Inc. was incorporated in Delaware in August 1986. In November 1998, we acquired ViroTex Corporation. In June 1999, we organized our wholly owned registered subsidiary Atrix Laboratories Limited, which is based in London, England. In February 2000, we organized our wholly owned registered subsidiary Atrix Laboratories GmbH, which is based in Frankfurt, Germany, to conduct

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our European operations. In June 2000, we entered into a research joint venture, Transmucosal Technologies, Limited with Elan International, which is a wholly owned subsidiary of Elan Corporation, plc.

### **Our Strategy**

Our primary objective is to be a leading specialty pharmaceutical company focused on advanced drug delivery to improve the effectiveness of existing pharmaceuticals and new chemical entities, including proteins, peptides and small molecules. Key elements to our strategy include:

*Expanding our portfolio of products through internal development.* We intend to develop our own pharmaceutical product candidates and undertake late stage human clinical development ourselves. We are applying our drug delivery technologies to novel applications and formulations of approved pharmaceutical products to improve their delivery and effectiveness.

*Maximizing the value of products by entering into late stage collaborative relationships.* We believe that advancing our products through late-stage development before seeking commercialization partners allows us to license our products on more favorable terms than would be available earlier in the development cycle.

*Licensing our technologies to major pharmaceutical and biotechnology companies.* We are focused on developing partnerships with pharmaceutical and biotechnology companies to utilize our drug delivery systems for new chemical entities and life cycle management products. We also conduct preclinical feasibility studies with various companies.

*Pursuing acquisitions of complementary drug delivery technologies.* We are pursuing opportunities that further strengthen our delivery technologies. We believe that if we are able to increase the number of delivery systems in our portfolio, we can increase our attractiveness as a product development partner with other pharmaceutical and biotechnology companies. In addition, we believe that pursuit of this strategy will strengthen our internal product development efforts.

*Acquiring or in-licensing proprietary compounds.* To expand our pipeline, we seek to identify drug candidates that may benefit from the application of our drug delivery technologies. These compounds generally have entered or are about to enter human clinical trials.

*Forward integration.* To pursue a strategy of forward integration to include sales and marketing of our own products either through internal development or acquisition of late-stage products.

### **Recent Developments**

The following discussion highlights significant events during the year ended December 31, 2002 and thereafter:

#### *Eligard™ 7.5-mg One-Month Product*

In January 2002, we received approval from the FDA for our Eligard 7.5-mg one-month product, a subcutaneous injection for the treatment of advanced prostate cancer. In May 2002, we announced the U.S. marketing launch of our Eligard one-month product and we subsequently received a \$6.0 million milestone payment from Sanofi-Synthelabo in June 2002.

#### *Eligard 22.5-mg Three-Month Product*

In July 2002, we received approval from the FDA for our Eligard 22.5-mg three-month product. In September 2002, we announced the U.S. marketing launch of our Eligard three-month product and received a \$6.0 million milestone payment from Sanofi-Synthelabo.

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*Eligard 30-mg Four-Month Product*

We received a \$3.0 million milestone payment in June 2002 from Sanofi-Synthelabo for the April 2002 NDA filing of our Eligard 30-mg four-month product with the FDA. In February 2003, we received approval from the FDA for our Eligard 30.0-mg four-month product and we expect U.S. commercial launch in the first half of 2003.

*Eligard 45-mg Six-Month Formulation Product*

In January 2002, Sanofi-Synthelabo exercised its right to develop a 45-mg six-month formulation of Eligard for the treatment of prostate cancer. Under the terms of our agreement with Sanofi-Synthelabo, we will receive reimbursement for research and development expenses related to the six-month formulation of Eligard. In August 2002, we commenced enrollment of the Phase III clinical study for this unique dosage of our Eligard product formulation. Additionally, we may receive payments for certain regulatory and sales milestones, a royalty based on sales of the product and a manufacturing margin.

*Eligard International*

MediGene, our European marketing partner, submitted a Marketing Authorization Application, or MAA, in November 2001 for the Eligard 7.5-mg one-month product and in April 2002 for the Eligard 22.5-mg three-month product to the German regulatory authority, Bundesinstitut für Arzneimittel und Medizinprodukte, or BfArM, as the Reference Member State under a Mutual Recognition Procedure. The MAAs submitted by MediGene utilized data for the U.S. dosage strengths of Eligard, which is twice the strength of competing leuprolide acetate products used in Europe for the palliative treatment of hormone-sensitive advanced prostate cancer. The U.S. dosage strengths of the Eligard 7.5-mg one-month and 22.5-mg three-month products were approved by the FDA in January 2002 and July 2002, respectively. In June 2002, we received a \$1.0 million milestone payment from MediGene for the MAA submissions of the Eligard 7.5-mg one-month and 22.5-mg three-month products to BfArM.

In March 2002, we entered into an exclusive licensing agreement with Luxembourg Pharmaceuticals for the Israeli marketing rights of our four Eligard products. We also entered into exclusive licensing agreements in the third quarter of 2002 with the following marketing partners for our four Eligard products: Biosintetica in Brazil, Tecnofarma for the rest of Latin America including Mexico, and Key Oncologics in South Africa. Each company will be responsible for regulatory submissions necessary to gain approval in their respective territories and we will manufacture the products at our facility and will earn manufacturing margins and royalties on sales.

In October 2002, we received a \$0.5 million milestone payment from Mayne Pharma PTY Limited (formerly Faulding Pharmaceuticals) for the Australian governmental filing acceptance of our Eligard one-, three- and four-month products.

Sanofi-Synthelabo submitted New Drug Submissions, or NDSs, in Canada for our Eligard 7.5-mg one-month and the Eligard 22.5-mg three-month products in December 2001 and our Eligard 30-mg four-month product in November 2002.

In January 2003, we entered into an exclusive licensing agreement with Sosei Co., Ltd. to develop and commercialize our Eligard products in Japan. We received an up-front license fee of approximately \$1.0 million and may receive payments for research and development support and payments for specific clinical, regulatory and sales milestones. In addition to the milestone payments, we will receive royalty payments based on sales of the Eligard products upon approval for marketing by the Japanese Ministry of Health, Labor and Welfare, or MHLW. Sosei will be responsible for submission of the necessary documents to obtain marketing authorization from the MHLW. We will manufacture the Eligard products for Sosei at our facility and will earn manufacturing margins.

**Table of Contents***Other Products*

To date, we have submitted seven Abbreviated New Drug Applications, or ANDAs, to the FDA for approval of a generic equivalent to a topical dermatology product.

In March 2002, we announced that we received positive clinical data from the first Phase III clinical trial of Atrisone™ (5% dapsona topical gel) for the treatment of acne. Patients are currently completing additional Phase III clinical trials. In December 2002, Fujisawa Healthcare exercised their option to explore additional indications for topical Atrisone.

In April 2002, we submitted an Investigational New Drug Application, or IND, to the FDA to test sumatriptan, a migraine treatment drug, using our BEMA delivery system. A Phase I clinical safety study indicated that the BEMA-sumatriptan product was well tolerated by the subjects and provided measurable blood levels. Additional work is ongoing to determine the degree of differentiation from existing products.

In August 2002, Pfizer submitted an IND to the FDA for a novel bone growth product that uses our proprietary Atrigel drug delivery technology. This bone growth product is currently in Phase I clinical trials. Pfizer plans to conduct all clinical trials of the Atrigel formulation and we will continue to support this product through production of clinical supplies and consultation.

In November 2002, we entered into an exclusive North American marketing agreement with EmerGen Inc., for a one-month and a three-month leuprolide product for the treatment of endometriosis, a chronic painful gynecological condition that, if left untreated, can ultimately affect fertility.

**Our Marketed Products and Products under Development**

The following table details certain information about our marketed pharmaceutical products and products under development:

<b>Pharmaceutical Product Candidates</b>	<b>Delivery System</b>	<b>Indication</b>	<b>Status</b>	<b>Collaborative Partner(s)</b>
Eligard 7.5-mg one-month	Atrigel	Prostate cancer	Marketed U.S. launch, May 2002. New drug filings submitted in Germany, Canada and Australia.	Sanofi-Synthelabo, MediGene, Mayne, Tecnofarma, Biosintetica, Luxembourg, Key Oncologics and Sosei
Eligard 22.5-mg three-month	Atrigel	Prostate cancer	Marketed U.S. launch, Sept. 2002. New drug filings submitted in Germany, Canada and Australia.	Sanofi-Synthelabo, MediGene, Mayne, Tecnofarma, Biosintetica, Luxembourg, Key Oncologics and Sosei
Eligard 30-mg four-month	Atrigel	Prostate cancer	FDA approved Feb. 2003. New drug filings submitted in Canada and	Sanofi-Synthelabo, MediGene, Mayne, Tecnofarma, Biosintetica, Luxembourg, Key Oncologics and Sosei



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Australia.

Eligard 45-mg six-month formulation

Atrigel

Prostate cancer

Phase III

Sanofi-Synthelabo

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<b>Pharmaceutical Product Candidates</b>	<b>Delivery System</b>	<b>Indication</b>	<b>Status</b>	<b>Collaborative Partner(s)</b>
One- and three-month leuprolide products for endometriosis	Atrigel	Endometriosis	Preclinical	EmerGen
Atrisone	SMP™	Acne vulgaris Other indications (burn itch, atopic dermatitis, other)	Phase III Preclinical/ Phase I/ II	Fujisawa Healthcare Fujisawa Healthcare
Bone growth product	Atrigel	Bone regeneration	IND submitted	Pfizer
Growth hormone releasing peptide-1	Atrigel	HIV-associated lipodystrophy/cardio-myopathy	Phase I	Tulane University Health Science Center
BEMA-fentanyl	BEMA	Chronic and breakthrough cancer pain	Phase I	Elan
BEMA-sumatriptan	BEMA	Migraine	Phase I	None

We currently market four dental products, and one over-the-counter, or OTC, drug product. The following table provides a summary of our marketed dental and OTC products:

<b>Dental/OTC Products</b>	<b>Delivery System</b>	<b>Indication</b>	<b>Status</b>	<b>Collaborative Partner(s)</b>
Atridox	Atrigel	Antibiotic therapy for chronic periodontitis	Marketed Launched 1998	CollaGenex, PharmaScience, Genmedix
Atrisorb-Doxycycline FreeFlow GTR Barrier	Atrigel	Tissue regeneration and infection reduction following periodontal surgery	Marketed Launched 2002	CollaGenex, Pharmascience
Atrisorb FreeFlow GTR Barrier	Atrigel	Tissue regeneration following periodontal surgery	Marketed Launched 1998	CollaGenex, Pharmascience
Doxirobe® Gel	Atrigel	Periodontitis in companion animals	Marketed Launched 1997	Pharmacia & Upjohn Animal Health
Orajel-Ultra®	MCA™	Canker sores	Marketed OTC product	Del Laboratories

**Marketed Pharmaceutical Products and Product Candidates**  
*Eligard Products*

Our proprietary Eligard products for prostate cancer incorporate a leutinizing hormone-releasing hormone, or LHRH, agonist with our proprietary Atrigel drug delivery system. The Atrigel technology allows for sustained delivery of leuprolide acetate for periods ranging from one month to six months.

Clinical trials have demonstrated that the sustained release of a LHRH agonist decreases testosterone levels to suppress tumor growth in patients with hormone-responsive prostate cancer. The Phase III results for the Eligard 7.5-mg one-month, 22.5-mg three-month and 30-mg four-month products revealed low testosterone levels with 100% of completing patients achieving and maintaining castrate suppression by the conclusion of the studies.

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Our Eligard products are injected subcutaneously as a liquid with a small gauge needle. The polymers precipitate after injection, forming a solid implant in the body that slowly releases the leuprolide as the implant is bioabsorbed. We believe our Eligard products, which use a small needle and are injected subcutaneously, are safe and effective in treating prostate cancer.

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*Eligard 7.5-mg One-Month Product*

We received FDA approval of Eligard 7.5-mg one-month product in January 2002 and Sanofi-Synthelabo commenced U.S. marketing of this product in May 2002. In November 2001, MediGene submitted an MAA for our Eligard 7.5-mg one-month product to BfArM, as a Reference Member State under a Mutual Recognition Procedure. If approval is obtained in the Reference Member State, MediGene intends to submit a modified MAA to specific Concerned Member States in the European Union for marketing approval in other key countries. The filing is currently under review by BfArM.

Mayne Pharma submitted a General Marketing Authorization, or GMA, with the Australian regulatory authority in August 2002 and Sanofi-Synthelabo filed an NDS with the Canadian regulatory authority in December 2001 for our Eligard 7.5-mg one-month product. Both filings are currently under review by the respective country's regulatory authority.

*Eligard 22.5-mg Three-Month Product*

In July 2002, we received approval from the FDA for Eligard 22.5-mg three-month product and Sanofi-Synthelabo commenced marketing in the U.S. in September 2002.

In April 2002, MediGene submitted an MAA for our Eligard 22.5-mg three-month product to the German regulatory authority, BfArM, as a Reference Member State under a Mutual Recognition Procedure. If approval is obtained in the Reference Member State, MediGene intends to submit a modified MAA to specific Concerned Member States in the European Union for marketing approval in other key countries. The filing is currently under review by the BfArM.

Mayne Pharma submitted a GMA with the Australian regulatory authority in August 2002 and Sanofi-Synthelabo filed an NDS with the Canadian regulatory authority in December 2001 for our Eligard 22.5-mg three-month product. Both filings are currently under review by the respective countries' regulatory authority.

*Eligard 30-mg Four-Month Product*

In February 2003, we received FDA approval for Eligard 30-mg four-month product and the U.S. commercial launch commenced in March 2003.

Mayne Pharma submitted a GMA with the Australian regulatory authority in August 2002 and Sanofi-Synthelabo filed an NDS with the Canadian regulatory authority in November 2002 for our Eligard 30.0-mg three-month product. Both filings are currently under review by the respective country's regulatory authority.

*Eligard 45-mg Six-Month Product*

Our Eligard 45-mg six-month product for prostate cancer is currently in Phase III clinical trials. Enrollment for this clinical study commenced in August 2002. Sanofi-Synthelabo exercised its right to develop this product in December 2001.

*One- and Three-Month Leuprolide Products for Endometriosis*

In November 2002, we entered into an exclusive North American marketing agreement with EmerGen, Inc. for a one-month and a three-month leuprolide product for the treatment of endometriosis. The new leuprolide products for endometriosis involve the development and clinical testing of half-strength dose versions of Eligard 7.5-mg one-month and Eligard 22.5-mg three-month products. Currently, these products are in the preclinical stage of development.

*Atrisone*

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We are currently developing Atrisone, our proprietary product, for the treatment of acne, itching associated with healing burn wounds, atopic dermatitis and additional indications. Atrisone incorporates

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dapsone, an anti-inflammatory and antimicrobial drug, with our proprietary SMP drug delivery system. Dapsone is a potent antibiotic with a separate anti-inflammatory activity, which reduces inflammation associated with acne. The goal for Atrisone is topical application to the acne lesion so as to reduce any potential side effects, such as anemia. After topical application, the blood levels of dapsone are 500 to 1,000 times less than found when the compound is administered orally, thus significantly reducing the potential for systemic side effects.

Enrollment for the first Atrisone Phase III clinical trial was completed in October 2001. This clinical trial consisted of approximately 500 patients enrolled at 19 centers comparing 5% dapsone applied twice a day to a vehicle control. In March 2002, we received positive clinical data from the first Phase III clinical trial for Atrisone and we commenced additional Phase III clinical trials in December 2002. These Phase III trials consist of a total of approximately 2,900 patients to be enrolled in over 100 centers throughout the U.S. and Canada.

Additional potential indications for Atrisone include treatment of chronic itch associated with healed and healing burn wounds and atopic dermatitis. A pilot study for use in burn itch was completed in June 2002. In May 2001, we submitted an IND to the FDA for the use of Atrisone in the treatment of atopic dermatitis. Atopic dermatitis is a common chronic skin condition in children and adults and is characterized by dryness, redness and extreme itching.

### *Generic Dermatology Products*

We are also developing a targeted set of generic topical dermatology products with Geneva. We have completed several formulations and currently have seven ANDAs under review at the FDA.

### *Growth Hormone Releasing Peptide-1*

We are developing a sustained release GHRP-1 product utilizing our Atrigel drug delivery system. This proprietary compound promotes the pulsatile release of the body's own growth hormone from the pituitary gland. GHRP-1 represents the first of a new class of small synthetic peptides, and we believe the pulsatile delivery of growth hormone produced by GHRP-1 offers advantages over current methods of administration of growth hormone because pulsatile delivery more closely mirrors the natural physiological mechanism. Potential applications for human growth hormones and/or promoting compounds include inhibition of cachexia, or extensive muscle and tissue wasting, in patients whose immune systems are compromised, such as patients with AIDS or other immune system disorders, or patients receiving cancer treatments, treatment of HIV-lipodystrophy, improved cardiac function in patients with congestive heart failure, and possibly prevention of muscle wasting and frailty in aged individuals. We obtained an exclusive license to GHRP-1 from Tulane University Health Sciences Center in September 2001. We submitted an IND to the FDA for this product in August 2002 and commenced a Phase I clinical safety study in December 2002.

### *Bone Growth Product*

In August 2002, Pfizer submitted an IND to the FDA for a novel bone growth product, which uses our proprietary Atrigel drug delivery technology. Pfizer plans to conduct all clinical trials of the Atrigel formulation. We will continue to support this product through production of clinical supplies and consultation.

### *BEMA-Fentanyl*

Through our joint venture with Elan, we are developing BEMA-fentanyl, which uses our proprietary BEMA drug delivery system with fentanyl, an opiate analgesic, for breakthrough cancer pain and potentially the management of chronic pain. The BEMA delivery system is a polymer-based system designed to deliver systemic levels of drugs rapidly across oral or vaginal mucosal tissues. The system consists of a thin, semi-soft bioerodible multi-layer disc of various polymers which adheres readily to the mucosal tissues. The BEMA disc softens upon contact with moisture and erodes away over approximately

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10 to 20 minutes as it delivers the drug. In late 2001, we submitted an IND to the FDA and commenced a Phase I clinical safety study for BEMA-fentanyl.

*BEMA-Sumatriptan*

We are exploring the development of sumatriptan, a migraine product utilizing the BEMA drug delivery system, to provide relief for migraine headaches. In April 2002, we submitted an IND to the FDA to test sumatriptan using our BEMA delivery system. A Phase I clinical safety study indicated that the BEMA-sumatriptan product was well tolerated by the subjects and provided measurable blood levels. Additional work is ongoing to determine the degree of differentiation from existing products.

*Oral Interferon*

In March 2002, we commenced Phase II clinical trials for a proprietary formulation of a low-dose oral interferon-alpha product for the treatment of oral warts caused by human papilloma virus in HIV-infected patients. Based on many factors including changing market conditions and treatment options, we subsequently determined to eliminate this program.

***Marketed Dental and Over-The-Counter Products and Product Candidates***

*Dental Products*

We have a number of approved products that target the dental market. Atridox, which combines the Atrigel system and the antibiotic doxycycline, is a minimally invasive treatment intended to control the bacteria that causes periodontal disease. Atridox was awarded the American Dental Association Seal of Acceptance which is an important symbol to dentists and consumers that signifies a dental product's safety, effectiveness and the scientific validity of its health benefits.

Our Atrisorb-D product also uses the Atrigel system with the antibiotic doxycycline to address infections following periodontal surgery and thereby improve healing. Atrisorb-D is a biodegradable polymer that utilizes the Atrigel system to aid in the guided tissue regeneration of a tooth's support following osseous flap surgery or other periodontal procedures.

In addition to these dental products, Pharmacia & Upjohn Company currently has the worldwide marketing right of our Doxirobe Gel product, a periodontal disease treatment for companion animals, which is comprised of the antibiotic doxycycline and the Atrigel system.

Net sales and royalties for our dental products in the years ended December 31, 2002, 2001 and 2000 were approximately \$2.6 million, \$2.4 million and \$4.7 million, respectively.

*Over-the-Counter Products*

Orajel-Ultra Mouth Sore Medicine is an over-the-counter product, which utilizes our proprietary MCA drug delivery system and is currently marketed by Del Laboratories. We receive royalties on the net sales of this product.

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The following chart provides a brief description of our drug delivery systems:

<b>Technology</b>	<b>Description</b>	<b>Application</b>
Atrigel System	Biodegradable sustained release implant for local or systemic delivery	Delivery of drugs from days to months
Bioerodible Mucoadhesive Disc System (BEMA)	Bioerodible disc for local or systemic delivery	Delivery of drugs through mucosal membranes
Solvent Microparticle System (SMP)	Topical gel providing two-stage delivery through the skin	Delivery of water insoluble drugs through the skin
Mucocutaneous Absorption System (MCA)	Water resistant topical gel providing sustained delivery	Film for either wet or dry surfaces
Biocompatible Polymer System (BCP)	Non-cytotoxic gel/liquid for topical delivery ( non-cytotoxic means the material does not kill cells or tissue in the body)	Protective gel film for wound healing and liquid formulation for wound washing

***Atrigel System***

The Atrigel drug delivery system consists of biodegradable polymers, similar to those used in biodegradable sutures, dissolved in biocompatible carriers. Pharmaceuticals may be blended into this liquid delivery system at the time of manufacturing or, depending upon the product, may be added later by the physician at the time of use. When the liquid product is injected subcutaneously or intramuscularly through a small gauge needle or placed into accessible tissue sites through a cannula, displacement of the carrier with water in the tissue fluids causes the polymer to precipitate, forming a solid film or implant. The drug encapsulated within the implant is then released in a controlled manner as the polymer matrix biodegrades with time. Depending upon the patient's medical needs, the Atrigel system can deliver small molecules, peptides or proteins over a period ranging from days to months.

We believe that the Atrigel system addresses many of the limitations associated with traditional drug delivery technologies. Most drugs are administered orally or by injection at intermittent and frequent doses. These routes of administration are not optimal for several reasons, including:

destruction of the compound in the gastrointestinal system,

difficulty in maintaining uniform drug levels over time,

problems with toxicity and side effects,

high costs due to frequent administration, and

poor patient compliance.

Furthermore, innovations in biotechnology have led to an increase in the number of protein and peptide drugs under development. These therapeutics, because of their larger molecular size and susceptibility to degradation in the gastrointestinal tract, often are required to be administered by multiple injections, usually in a hospital or other clinical setting.

We believe that the Atrigel system may provide benefits over traditional methods of drug administration such as tablets or capsules, injections and continuous infusion as a result of the following properties:



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*Broad Applicability* The Atrigel system is compatible with a broad range of pharmaceutical compounds, including water soluble and insoluble compounds and high and low molecular weight compounds, including peptides and proteins.

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*Site Specific Drug Delivery* The Atrigel system can be delivered directly to a target area, thus potentially achieving higher drug concentrations at the desired site of action to minimize systemic side effects.

*Systemic Drug Delivery* The Atrigel system can also be used to provide sustained drug release into the systemic circulation.

*Customized Continuous Release and Degradation Rates* The Atrigel system can be designed to provide continuous release of incorporated pharmaceuticals over a targeted time period thereby reducing the frequency of drug administration.

*Biodegradability* The Atrigel system will biodegrade and does not require removal when the drug is depleted.

*Ease of Application* The Atrigel system can be injected or inserted as flowable compositions, such as solutions, gels, pastes, and putties, by means of ordinary needles and syringes, or can be sprayed or painted onto tissues.

*Safety* All current components of the Atrigel system are biocompatible and have independently established safety and toxicity profiles. The polymers used in the system are members of a class of polymers, some of which have previously been approved by the FDA for human use in other applications.

### ***Bioerodible Mucoadhesive System***

The Bioerodible Mucoadhesive, or BEMA, system is a proprietary polymer-based system designed to deliver systemic levels of drugs across oral or vaginal mucosal tissues. The semi-soft BEMA disc adheres readily to the mucosa, where it softens further on contact with moisture, becoming unnoticeable as it delivers the drug and erodes away. The BEMA system is versatile and can incorporate a wide variety of drugs, including proteins and peptides. The compound can be loaded into the mucoadhesive layer for delivery into the mucosal tissue, while minimizing drug release into surrounding tissues or cavities. The drug may also be loaded into the backing layer to provide more controlled release into the oral or vaginal cavity.

Various properties of the BEMA products, such as residence time, bioerosion kinetics, taste, shape and thickness can be modified to the desired level to customize drug delivery to the medical need and patient needs. The BEMA technology has potential applications in pain management, anti-migraine compounds and anti-emetics.

### ***Solvent/ Microparticle System***

The Solvent/ Microparticle, or SMP, technology consists of a two-stage system designed to provide topical delivery of highly water-insoluble drugs to the skin. The combination of dissolved drug with a microparticle suspension of the drug in a single formulation allows a controlled amount of the dissolved drug to permeate into the epidermal layer of the skin, while a high level of the microparticle drug is maintained just above the outermost layer of the skin for later delivery. The consistent microparticle size and distribution maximize drug delivery while minimizing crystal growth over the shelf life of the product.

### ***Mucocutaneous Absorption System***

The Mucocutaneous Absorption, or MCA, delivery system can be formulated as either alcohol-based gels or as aerosols for the localized delivery of drugs to the skin or mucosal tissues. The MCA formulations can be applied to dry, damp or even wet skin or mucosal surfaces. Because of the novel blend of cellulose polymers dissolved in alcohol, they quickly dry to form moisture-resistant films that can deliver drugs and/or promote healing. Depending on the desired application, the MCA products can be formulated to form opaque films to highlight the area of treatment, or to transparent films that are more

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cosmetically acceptable. The MCA formulations can be easily flavored to mask the taste of active ingredients for oral products and are compatible with liquid spray applicators.

### ***Biocompatible Polymer System***

The Biocompatible Polymer, or BCP system, composed of polymers, solvents and actives carefully selected for their low toxicity to skin cells, can be formulated as either film-forming gels or liquids for topical applications. The BCP gels are non-greasy, non-staining formulations that can be applied to wounded or denuded skin to deliver a drug, such as an antibiotic, and then dry to form a non-constricting, protective film over the wound. We believe the gels have the unique property of maintaining an ideal wound-healing environment by removing excess moisture from exudative wounds and transferring moisture from the gel into wounds that are too dry. The liquid BCP formulations are designed to provide effective cleansing of topical wounds or denuded skin without causing further trauma to the skin, thereby promoting faster healing with minimal scarring.

### **Research and Development**

Our strategic goal is to devote substantial resources to our medical research and development efforts with the expectation of quickly moving products from the development stage to commercialization. During the year ended December 31, 2002, we continued to devote significant resources to the research and development of our Eligard and Atrisine products. Currently, we have multiple compounds in various stages of preclinical development, a number of which are being developed through partnerships with a variety of external companies. Most of these projects are preliminary in nature and we cannot predict whether any of them will be commercialized.

Our research and development expenses were \$32.7 million, \$28.6 million and \$16.7 million for the years ended December 31, 2002, 2001 and 2000, respectively.

### **Collaborative Arrangements**

Our business strategy includes forming collaborations to provide technological, financial, marketing and other resources. We have entered into a number of such collaborative arrangements with a variety of pharmaceutical and biotechnology companies utilizing our various drug delivery systems and/or to commercialize our products. Our significant strategic alliances include Pfizer, Sanofi-Synthelabo, MediGene, Fujisawa Healthcare, Geneva, Elan and CollaGenex.

#### ***Pfizer, Inc.***

In August 2000, we executed a non-exclusive comprehensive research and worldwide licensing agreement with Pfizer to provide broad-based access to our proprietary drug delivery systems in the development of new products. Pfizer will provide funding to develop and commercialize selected compounds developed by Pfizer using our patented drug delivery technologies. We retained co-manufacturing rights and will receive royalties on the sales of products that are successfully developed and commercialized under this agreement. Pfizer purchased 447,550 shares of our common stock for \$5.0 million as part of the agreement. Pfizer submitted an IND for a novel bone growth product in August 2002 and Pfizer will conduct all clinical trials of the Atrigel formulation. This bone growth product is currently in Phase I clinical trials. As of December 31, 2002, all other products under the Pfizer agreement were in preclinical stages of development.

#### ***Sanofi-Synthelabo, Inc.***

In December 2000, we entered into an exclusive North American marketing agreement with Sanofi-Synthelabo, for our Eligard one-, three-, and four-month prostate cancer treatment products. Under the terms of the agreement, we will manufacture the Eligard products and receive an agreed upon transfer price from Sanofi-Synthelabo as well as royalties from sales. In addition, we received an up-front license fee of \$8.0 million. As part of the agreement, Sanofi purchased 824,572 shares of our common stock for

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\$15.0 million. The Sanofi agreement provides for payments of up to \$60.0 million, including the purchase of our common stock, licensing fees and payments for clinical, regulatory and sales milestones for the Eligard products upon approval for marketing by the FDA. In January 2002, Sanofi exercised its right to develop a six-month formulation of Eligard. Under the terms of the agreement, we will receive reimbursement for research and development expenses related to the development of this six-month formulation. Additionally, we will receive payments for certain regulatory and sales milestones, a royalty based on sales of the product and will manufacture the six-month product at our facility. We commenced a Phase III clinical study for Eligard 45-mg six-month product in September 2002. For the year ended December 31, 2002, we received the following milestone payments from Sanofi:

\$3.0 million milestone payment for the April 2002 NDA submission of Eligard 30-mg four-month product;

\$6.0 million milestone payment for the May 2002 U.S. commercial launch of Eligard 7.5-mg one-month product; and

\$6.0 million milestone payment for the September 2002 commercial launch of Eligard 22.5-mg three-month product.

***MediGene AG***

In April 2001, we entered into an exclusive European marketing agreement with MediGene AG, a German biotechnology company, to market our Eligard one-, three- and four-month products. MediGene also has the right to develop the Eligard 45-mg six-month product. Under the terms of the agreement, we will manufacture the Eligard products and we will receive additional payments for certain clinical, regulatory and sales milestones and royalties from sales. Pursuant to the agreement, we received an up-front license fee of \$2.0 million. MediGene purchased 233,918 shares of our common stock for \$3.8 million. Additionally, MediGene will provide funding to conduct clinical, research and regulatory activities associated with seeking European marketing approvals. The MediGene agreement provides for payments of up to \$16.0 million including MediGene's purchase of our common stock, the license fee and payments for certain clinical, regulatory and sales milestones. In November 2001, MediGene submitted an MAA for our Eligard 7.5-mg one-month product to the German regulatory authority, BfArM, as a Reference Member State under a Mutual Recognition Procedure. In April 2002, MediGene submitted an MAA for our Eligard 22.5-mg three-month product to BfArM, as a Reference Member State under a Mutual Recognition Procedure. The MAAs submitted by MediGene utilized data for the U.S. dosage strengths of Eligard, which is twice the strength of competing leuprolide acetate products used in Europe for the palliative treatment of hormone-sensitive advanced prostate cancer. The U.S. dosage strengths of the Eligard 7.5-mg one-month and 22.5-mg three-month products were approved by the FDA in January 2002 and July 2002, respectively. In June 2002, we received a \$1.0 million milestone payment from MediGene for the Eligard one- and three-month MAA submissions.

***Fujisawa Healthcare, Inc.***

In October 2001, we entered into a collaboration, license and supply agreement with Fujisawa, for the exclusive North American marketing and distribution rights of our Atrisone acne treatment product. The Fujisawa agreement provides for payments of up to \$25.0 million for an up-front license fee, research and development support and certain milestone payments. Additionally, we will receive a royalty on net sales of the Atrisone product and a manufacturing margin. In October 2001, we received a \$2.0 million license fee upon signing of the agreement. In December 2002, Fujisawa exercised its option to explore additional indications for topical Atrisone. Similar to the original agreement, Fujisawa will be responsible for a significant portion of any research and development costs that arise for development of Atrisone for these additional indications. We received no milestone payments or license fees from Fujisawa for the year ended December 31, 2002.

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***Geneva Pharmaceuticals, Inc.***

In August 2000, we entered into a collaboration, development and supply agreement with Geneva Pharmaceuticals, Inc., a subsidiary of Novartis, to conduct research and development activities on a collaborative basis to develop designated generic topical prescription dermatology products. Under the terms of the agreement, we will be responsible for validation, formulation, development and required clinical studies of selected products. This collaboration extends to the United States, although additional territories may be added at a later date. Geneva will be responsible for market research and commercialization of the products. Geneva will reimburse us for 50% of the research and development expenses we incur and both parties will share equally in the net profits from the sale of the products. We have completed several formulations and have submitted seven ANDAs to the FDA for approvals for seven separate generic dermatology products.

***Elan International Services, Ltd.***

In July 2000, we formed a joint venture with Elan International Services, Ltd., a wholly owned subsidiary of Elan Corporation, plc, for the purpose of developing and commercializing oncology and pain management products. This joint venture, Transmucosal Technologies, Ltd., will use our patented BEMA and Atrigel drug delivery systems to deliver compounds targeted for major unmet medical needs in oncology and pain management. As a part of this agreement, we granted the joint venture an exclusive license to use our BEMA technology in these fields. The first compound selected was the opiate analgesic, fentanyl, using our BEMA drug delivery system for breakthrough cancer pain and management of chronic pain. BEMA-fentanyl completed a Phase I clinical evaluation that indicated good tolerance and rapid delivery of product. In March 2001, BEMA-ondansetron was selected as the second compound for development in the joint venture. The BEMA-ondansetron product is intended for the prevention of nausea and vomiting associated with cancer chemotherapy and is currently in preclinical studies. As part of our agreement, Elan may provide funding to develop this and any future selected compounds. Initially, we are the majority-owner of this joint venture. As of December 31, 2002, the two joint venture projects are currently under review for further development.

In connection with the formation of the joint venture, Elan purchased 12,015 shares of our Series A Convertible Exchangeable Preferred Stock for \$12.0 million and 442,478 shares of our common stock for \$5.0 million, and received a five-year warrant to purchase up to one million shares of our common stock at an exercise price of \$18 per share. The Series A Convertible Exchangeable Preferred Stock is convertible at any time after July 2002, at Elan's option, into shares of our common stock at a price equivalent to \$18 per share. In the event of a merger or the sale of our common stock in an underwritten public offering, we have the option to convert the Series A Convertible Exchangeable Preferred Stock into shares of our common stock. Alternatively, Elan has the option to exchange this preferred stock for a 30.1% interest in the joint venture. This exchange option will terminate if the preferred stock is converted into our common stock unless we cause the conversion. We must redeem this preferred stock in July 2006 for either cash or shares of our common stock, at our option, in an amount or value equal to the liquidation preference of the preferred stock.

As part of our agreement, Elan may loan us up to \$8.0 million to support our share of the joint venture's research and development costs pursuant to a convertible promissory note we issued to Elan. The convertible promissory note has a maximum principal amount of \$8.0 million and is due in July 2006. The note is convertible into shares of our common stock at a conversion price of \$14.60 per share, subject to adjustment as provided in the note agreement. As of December 31, 2002, we have not drawn any amounts under the convertible promissory note and we do not expect to draw down any amounts under this note.

Our revenues from the joint venture were \$1.2 million, \$4.1 million and \$0.3 million for the years ended December 31, 2002, 2001 and 2000, respectively.

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### ***CollaGenex Pharmaceuticals, Inc.***

In August 2001, we licensed the exclusive U.S. marketing rights of our dental products to CollaGenex, following the reacquisition of the sales and marketing rights from Block. Under the terms of the CollaGenex agreement, we received \$1.0 million for an up-front license fee. Additionally, we receive a royalty on product sales and a manufacturing margin. As part of the transaction, we purchased 330,556 shares of CollaGenex's common stock for \$3.0 million. CollaGenex commenced U.S. marketing of Atridox and Atrisorb FreeFlow in November 2001 and of Atrisorb-D in January 2002.

### **International Operations**

In February 2000, our wholly owned registered subsidiary, Atrix Laboratories GmbH, based in Frankfurt, Germany, commenced operations. Atrix Laboratories GmbH was organized to conduct our European dental operations. Atrix Laboratories GmbH manages our business relationships with European distributors for the dental products and in 2002 commenced promoting Atridox directly to dentists in Germany. Atrix Laboratories Limited and Atrix Laboratories GmbH, both wholly-owned subsidiaries, currently hold the marketing authorizations for international sales of Atridox. To date, we have received individual marketing authorizations in sixteen European countries.

In addition to our agreement with MediGene, in March 2002, we entered into an exclusive licensing agreement with Luxembourg Pharmaceuticals for the Israeli marketing rights of our four Eligard products. We also entered into exclusive licensing agreements in the third quarter of 2002 with the following marketing partners for our four Eligard products: Biosintetica in Brazil, Tecnofarma for the rest of Latin America including Mexico, and Key Oncologics in South Africa. Each company will be responsible for regulatory submissions necessary to gain approval in their respective territories and we will manufacture the products at our facility and will earn manufacturing margins and royalties on sales.

In August 2002, Mayne Pharma submitted General Marketing Applications with the Australian government for our Eligard one-, three-, and four-month products. The applications are currently under review.

Sanofi-Synthelabo submitted New Drug Submissions, or NDS, in Canada for our Eligard 7.5-mg one- and the Eligard 22.5-mg three-month products in December 2001 and an NDS was filed in Canada for our Eligard 30.0-mg four-month product in November 2002. The submissions are currently under review by the Canadian regulatory authority.

In January 2003, we entered into an exclusive licensing agreement with Sosei Co., Ltd. to develop and commercialize our Eligard products in Japan. Sosei will be responsible for submission of the necessary documents to obtain marketing authorization from the Japanese Ministry of Health, Labor and Welfare. We received \$0.9 million in January 2003 for an up-front license fee.

Our revenues from foreign sources, including the joint venture with Elan, were \$3.1 million, \$5.5 million and \$1.2 million for the fiscal years ended December 31, 2002, 2001 and 2000, respectively.

### **Patents and Trademarks**

We consider patent protection and proprietary position to be significant to our business. As of December 31, 2002, we hold 51 United States patents and 87 foreign patents, and 18 United States and 141 foreign patent applications are pending. A number of the claims contained in these patents and pending patent applications cover certain aspects of our drug delivery technologies, including the Atrigel, BEMA, SMP, MCA and BCP drug delivery technologies, and products based upon these technologies, including the Eligard, Atrisone, Atridox, Atrisorb-D, Atrisorb FreeFlow and Atrisorb GTR Barrier products.

Notwithstanding our pursuit of patent protection, others may develop delivery systems, compositions and/or methods that infringe our patent rights resulting from outright ownership or non-revocable exclusive licensure of patents which relate to our delivery systems, composition and/or methods. In that

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event, such delivery systems, compositions and methods may compete with our systems, compositions and methods and may adversely affect our operations. Furthermore, patent protection may not afford adequate protection against competitors with similar systems, composition or methods, and our patents may be infringed or circumvented by others. Moreover, it may be costly to pursue and to prosecute patent infringement actions against others, and such actions could hamper our business. We also rely on our unpatented proprietary knowledge. Others may be able to develop substantially equivalent proprietary knowledge or otherwise obtain access to our knowledge, and our rights under any patents may not afford sufficient protection.

Our patents expire at various times between 2008 and 2020. The following table sets forth the number of patents expiring in each year:

<b>Year Expiring</b>	<b>U.S. Patents</b>	<b>Foreign Patents</b>	<b>Total Patents</b>
2008	7		7
2009	2	24	26
2010		17	17
2011	7	1	8
2012		14	14
2013	4		4
2014	9	3	12
2015	7	4	11
2016	7	3	10
2017	1	18	19
2018	3		3
2019	3	3	6
2020	1		1
Total	51	87	138

In addition to patents, we also maintain several United States and numerous foreign trademark and service mark applications for registrations of our company name, logo, and names for drug delivery systems and products. These include 9 U.S. and 56 foreign issued trademarks, with 2 U.S. and 9 foreign trademark applications pending.

**Drug Delivery Industry**

Drug delivery companies apply proprietary technologies for the improved administration of therapeutic compounds. These products could potentially provide various benefits, including better control of drug concentration in the blood, improved safety and efficacy, improved patient compliance and ease of use. Additionally, alternative drug delivery technologies can be utilized to extend existing patent franchises, to expand markets for existing products, as well as to develop new products. The increasing need to deliver medication to patients efficiently and with fewer side effects has accelerated the pace of competition within the drug delivery industry.

We believe focusing on drug delivery for existing drugs is less costly than attempting to discover new drugs. Drug discovery is more costly and more time consuming in comparison with drug delivery of existing drugs. For instance, our clinical trials need only to demonstrate that our carrier technology delivers the drug without harming the patient or changing the clinical attributes of the drug.

In addition, focusing on drug delivery compared to drug discovery allows us to form a number of collaborations to deliver a wide variety of medicines without limiting our proprietary technology rights.

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### **Customers**

Our customers include such companies as Pfizer, Sanofi, Fujisawa, Geneva, and CollaGenex. During 2002, these five customers accounted for 67% of our total revenues. The distribution network for pharmaceutical products is subject to increasing consolidation. As a result, a few large distributors control a significant share of the market. In addition, the number of independent drug stores and small chains has decreased as retail consolidation has occurred. Further consolidation or financial difficulties of distributors or retailers could result in the combination or elimination of warehouses, which may result in reductions in purchases of our products or cause a reduction in the inventory levels of distributors and retailers.

### **Competition**

The biotechnology and pharmaceutical industries are subject to rapid and substantial technological change. We face, and will continue to face, intense competition in the development, manufacturing, marketing and commercialization of our products and product candidates. Products utilizing our proprietary drug delivery systems are expected to compete with other products for specified indications, including drugs marketed in conventional and alternative dosage forms. New drugs or further developments in alternative drug delivery methods may provide greater therapeutic benefits for a specific drug or indication, or may offer comparable performance at lower cost, than those offered by our drug delivery systems. We expect proprietary products approved for sale to compete primarily on the basis of product safety, efficacy, patient convenience, reliability, availability and price.

Our competitors include academic institutions, government agencies, research institutions, biotechnology and pharmaceutical companies, including our collaborators, and drug delivery companies. Several companies have drug delivery technologies that compete with our technologies, including Alkermes, Inc., ALZA Corporation, Cima Labs, Inc., Durect Corp., Noven Pharmaceuticals, Inc., and SkyePharma, plc. Competitors of our Eligard prostate cancer treatment products include, AstraZeneca's Zoladex™ product, Bayer's Viadur™ product, Pharmacia & Upjohn Co.'s Trelstar™ product and TAP Pharmaceuticals, Inc.'s Lupron™ product. Competitors of our dental products include OraPharma, Inc., whose Arestin™ product is used for the treatment of periodontal disease.

Many specialized biotechnology companies have formed collaborative arrangements with large, established pharmaceutical companies to support research, development and commercialization of products that may be competitive with our products. Developments by others may render our products, product candidates or technologies obsolete or noncompetitive, and our collaborators may choose to use competing drug delivery methods.

Many of our competitors and potential competitors have substantially greater capital resources, manufacturing and marketing experience, research and development resources and production facilities than we do. Many of these competitors also have significantly greater experience than we do in undertaking preclinical testing and clinical trials of new pharmaceutical products and obtaining FDA and other regulatory approvals.

### **Government Regulation**

The research and development, preclinical studies and clinical trials, and ultimately, the manufacturing, marketing and labeling of our products, are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries. The United States Food, Drug and Cosmetic Act and the regulations promulgated thereunder govern, among other things, the testing, manufacturing, safety, efficacy, labeling, storage, record keeping, approval, clearance, advertising and promotion of our products. Preclinical studies, clinical trials and the regulatory approval process typically take years and require the expenditure of substantial resources. If regulatory approval or clearance of a product is granted, the approval or clearance may include significant limitations on the indicated uses for which the product may be marketed.



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***FDA Regulation Approval of Therapeutic Products***

Our Eligard, Atrisone, generic dermatology products, bone growth product, BEMA-fentanyl, BEMA-sumatriptan, GHRP-1, Atridox and Doxirobe Gel products are regulated in the United States as drugs. The steps ordinarily required before a drug may be marketed in the United States include:

preclinical studies,

the submission to the FDA of an IND, which must become effective before human clinical trials may commence,

adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug,

the submission of an NDA to the FDA, and

FDA approval of the application, including approval of all labeling.

Preclinical tests include laboratory evaluation of product chemistry and formulation, as well as animal studies to assess the potential safety and efficacy of the product. Preclinical tests must be conducted in compliance with good laboratory practice regulations. The results of preclinical testing are submitted as part of an IND to the FDA. A 30-day waiting period after the filing of each IND is required prior to the commencement of clinical testing in humans. In addition, the FDA may, at any time during this 30-day period, or anytime thereafter, impose a clinical hold on proposed or ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials cannot commence or recommence without FDA authorization.

Clinical trials to support NDAs are typically conducted in three sequential phases, but the phases may overlap. In Phase I, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics and pharmacology and safety, including side effects associated with increasing doses. Phase II usually involves studies in a limited patient population to:

assess the efficacy of the drug in specific, targeted indications,

assess dosage tolerance and optimal dosage, and

identify possible adverse effects and safety risks.

If a compound is found to be potentially effective and to have an acceptable safety profile in Phase II evaluations, Phase III trials are undertaken to further demonstrate clinical efficacy and to further test for safety within an expanded patient population at multiple study sites. Phase I, Phase II or Phase III clinical studies may not be completed successfully within any specified time period, if at all, with respect to any of our products subject to such testing.

After successful completion of the required clinical testing, generally an NDA is submitted. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the Food, Drug and Cosmetic Act, and User Fee legislation, the FDA has up to twelve months in which to review the NDA and respond to the applicant. The FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee. If the FDA evaluations of the NDA and the manufacturing facilities are favorable, the FDA may issue either an approval letter or an approvable letter. The approvable letter usually contains a number of conditions that must be met to secure final FDA approval of the NDA. When, and if, those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter. If the FDA's evaluation of the NDA or manufacturing facility is not favorable, the FDA may refuse to approve the NDA or issue a non-approvable letter which often requires additional testing or information. Even if regulatory approval is obtained, a marketed product and its manufacturing facilities are subject to continual review and periodic inspections. In addition, identification of certain side effects after a drug is on the market or the occurrence of manufacturing problems could cause subsequent withdrawal of approval, reformulation of the drug, additional preclinical testing or clinical trials and changes in labeling.

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Failure to comply with the FDA or other applicable regulatory requirements may subject a company to administrative sanctions or judicially imposed sanctions such as civil penalties, criminal prosecution, injunctions, product seizure or detention, product recalls, or total or partial suspension of production. In addition, noncompliance may result in the FDA's refusal to approve pending NDAs or supplements to approved NDAs, pre-market approval application, or PMA, or PMA supplements and the FDA's refusal to clear 510(k)s.

### ***FDA Regulation Approval of Medical Devices***

Our Atrisorb GTR Barrier products are regulated in the United States as medical devices. New medical devices are generally introduced to the market based on a pre-market notification or 510(k) submission to the FDA. Under a 510(k) submission, the sponsor establishes that the proposed device is substantially equivalent to a legally marketed Class I or Class II medical device or to a Class III device for which the FDA has not required pre-market approval. If the sponsor cannot demonstrate substantial equivalence, the sponsor will be required to submit a PMA, which generally requires preclinical and clinical trial data, to prove the safety and effectiveness of the device.

### ***FDA Regulation Post-Approval Requirements***

Even if regulatory clearances or approvals for our products are obtained, our products and the facilities manufacturing our products are subject to continued review and periodic inspections by the FDA. Each United States drug and device-manufacturing establishment must be registered with the FDA. Domestic manufacturing establishments are subject to biennial inspections by the FDA and must comply with the FDA's current good manufacturing practices, or cGMP, if the facility manufactures drugs, and quality system regulations, or QSRs, if the facility manufactures devices. In complying with cGMP and QSRs, manufacturers must expend funds, time and effort in the area of production and quality control to ensure full technical compliance. The FDA stringently applies regulatory standards for manufacturing.

The FDA also regulates labeling and promotional activities. Further, we must report certain adverse events involving our drugs and devices to the FDA under regulations issued by the FDA.

### ***European Regulation Approval of Medicinal Products***

Our Eligard and Atridox products are regulated in Europe as medicinal products. In 1993, legislation was adopted which established a new and amended system for the registration of medicinal products in the European Union, or EU. The objective of this system is to prevent the existence of separate national approval systems that have been a major obstacle to harmonization. One of the most significant features of this new system is the establishment of a new European Agency for the Evaluation of Medicinal Products. Under this new system, marketing authorization may be submitted at either a centralized or decentralized level.

The Centralized Procedure is administered by the European Agency for the Evaluation of Medicinal Products. This procedure is mandatory for the approval of biotechnology products and is available at the applicant's option for other innovative products. The Centralized Procedure provides, for the first time in the EU, for the granting of a single marketing authorization that is valid in all EU member states.

A Mutual Recognition Procedure is available at the request of the applicant for all medicinal products that are not subject to the Centralized Procedure, under a Decentralized Procedure. The Decentralized Procedure creates a new system for mutual recognition of national approvals and establishes procedures for coordinated EU action on product suspensions and withdrawals. Under this procedure, the holder of a national marketing authorization for which mutual recognition is sought may submit an application to one or more Concerned Member States, certifying that identical dossiers are being submitted to all Concerned Member States for which recognition is sought. Within 90 days of receiving the application and assessment report, each Concerned Member State must decide whether or not to recognize the approval. The procedure encourages Concerned Member States to work with applicants and other regulatory authorities to resolve disputes concerning mutual recognition. If such disputes cannot be resolved within the 90-day

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period provided for review, the application will be subject to a binding arbitration procedure at the request of the applicant. Alternatively, the application may be withdrawn.

***European Regulation Approval of Medical Devices***

Our Atrisorb GTR Barrier products are regulated in Europe as medical devices. The EU has promulgated rules that require medical devices to affix the CE Mark, an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. Failure to receive the right to affix the CE Mark prohibits a company from selling products in Concerned Member States of the EU.

***Regulatory Considerations for Orphan Drug Products***

If a developer obtains designation by the FDA of a drug as an orphan drug for a particular use, the developer may request small grants from the federal government to help defray the costs of qualified testing expenses in connection with the development of such drug. Orphan drug designation may be granted to drugs for rare diseases, typically defined as a disease or condition that affects populations of fewer than 200,000 individuals in the United States, and includes many genetic diseases. The first applicant who has obtained designation of a drug for a particular use as an orphan drug and then obtains approval of a marketing application for such drug for the particular use is entitled to marketing exclusivity for a period of seven years, subject to certain limitations.

Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory approval process. Although obtaining FDA approval to market a product with an orphan drug designation can be advantageous, there can be no assurance that the scope of protection or the level of marketing exclusivity that is currently afforded by orphan drug designation will remain in effect in the future.

***Regulatory Considerations for OTC Drug Products***

An OTC drug may be lawfully marketed in one of three ways:

the drug is generally recognized as safe and effective, or GRAS/ E,

the drug is the subject of an approved NDA, or

the drug complies with a tentative final or final monograph published by the FDA as part of the OTC review.

Prior FDA approval is required only if an NDA is submitted. A company makes the determination as to which route to market is the most appropriate. If a company determines that the drug product is GRAS/ E or is covered in a monograph, it is the company's responsibility to substantiate the safety and efficacy of the formulation and that the dosage form and claims are applicable under GRAS/ E or monograph status. Most OTC drug products are marketed pursuant to an FDA monograph.

There are several other regulatory requirements applicable to all OTC drug products. These requirements pertain to labeling, drug registration and listing, and manufacturing. With regard to labeling, the regulations require certain language for statement of identity, net contents, adequate directions for use, and name and address of the manufacturer, and their placement on the finished package, as well as additional warning statements when relevant to the product. All OTC manufacturers must register their establishments with the FDA and submit to the FDA a list of products made within five days after beginning operations, as well as submit a list of products in commercial distribution. All registered establishments must be inspected by the FDA at least every two years and OTC drug products must be manufactured in accordance with cGMP regulations. If the FDA finds a violation of cGMPs, it may enjoin a company's operations, seize product, or criminally prosecute the manufacturer.

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***Abbreviated New Drug Applications***

Any products emanating from our generic topical dermatological business are subject to the ANDA approval process. The Food, Drug and Cosmetic Act, as amended in 1984, established a statutory procedure to permit the marketing approval for duplicate and related versions of previously approved pioneer drug products. The procedure provides for approval of these duplicate or generic drugs through the ANDA. The process provides for approval for duplicate or related versions of approved drugs whose patents have expired, and that have been shown through the ANDA requirements to be as safe and effective as their brand name counterparts, but without the submission of duplicative safety and efficacy data. Therefore, the process is intended to encourage competition by decreasing the time and expense of bringing generic drugs to market.

Generic drug products are required to be shown as bioequivalent to the pioneer drug product via an in vivo bioavailability study. In addition, the ANDA must contain information on the production, analytical testing of the drug product, and a certification regarding patent status of the pioneer drug. To obtain approval, the ANDA must verify that the generic drug product is bioequivalent to the pioneer drug product, that the necessary procedures and controls are in place to produce the generic product under cGMPs, and that the applicant has complied with the patent requirements of the Act.

The innovator company holding patents for the pioneer drug product may challenge an ANDA on the basis of alleged patent infringement. Such a legal challenge can delay the approval of an ANDA for up to 30 months. Post approval, generic drug products are subject to labeling, promotional, and cGMP compliance requirements.

**Additional Regulatory Issues**

Under the Drug Price Competition and Patent Term Restoration Act of 1984, a patent which claims a product, use or method of manufacture covering drugs and certain other products may be extended for up to five years to compensate the patent holder for a portion of the time required for research and FDA review of the product. This law also establishes a period of time following approval of a drug during which the FDA may not accept or approve applications for certain similar or identical drugs from other sponsors unless those sponsors provide their own safety and effectiveness data. We cannot provide assurance that we will be able to take advantage of either the patent term extension or marketing exclusivity provisions of this law.

The Department of Health and Human Services requested the National Institute of Health to submit proposals for addressing potential conflicts of interest in the biomedical research sector. Although the proposal request is aimed at establishing rules to treat potential abuses in the system without imposing unnecessary burdens and disincentives, we cannot assure that any rules adopted will not adversely affect our ability to obtain research grants. Various aspects of our business and operations are regulated by a number of other governmental agencies including the Occupational Safety and Health Administration and the Securities and Exchange Commission.

**Third-Party Reimbursement**

Government and private insurance programs, such as Medicare, Medicaid, health maintenance organizations and private insurers, fund the cost of a significant portion of medical care in the United States. Governmental imposed limits on reimbursement of hospitals and other health care providers, including dental practitioners, have significantly impacted their spending budgets. Under certain government insurance programs, a health care provider is reimbursed a fixed sum for services rendered in treating a patient, regardless of the actual charge for such treatment. Private third-party reimbursement plans are also developing increasingly sophisticated methods of controlling health care costs through redesign of benefits and exploration of more cost-effective methods of delivering health care. In general, these government and private measures have caused health care providers to be more selective in the purchase of medical products.

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Significant uncertainty exists as to the reimbursement status of newly approved health care products, and we cannot provide assurance that adequate third-party coverage will be available. Limitations imposed by government and private insurance programs and the failure of certain third-party payers to fully, or substantially reimburse health care providers for the use of the products could seriously harm our business.

### **Employees**

As of February 14, 2003, we employed 167 employees on a full-time basis. Of the 167 full-time employees, 144 are engaged in production, research and clinical testing and the remaining 23 are in administrative capacities. A total of 40 employees have earned doctorate or advanced degrees. None of our employees are represented by a union or collective bargaining unit and management considers relations with employees to be good.

### **Additional Information**

#### ***Environmental***

Compliance with federal, state and local laws regarding the discharge of materials into the environment or otherwise relating to the protection of the environment has not had, and is not expected to have, any adverse effect upon our capital expenditures, earnings or our competitive position. We are not presently a party to any litigation or administrative proceeding with respect to our compliance with such environmental standards. In addition, we do not anticipate being required to expend any funds in the near future for environmental protection in connection with our operations.

#### ***Supply of Raw Materials***

We currently obtain supplies of the polymer used in our polymer delivery systems from Birmingham Polymers in Alabama, Absorbable Polymer Technology Inc. in Alabama, Boehringer Ingelheim in Germany and Purac in Holland. Supplies of doxycycline, used in our Atridox, Atrisorb-D and Doxirobe Gel periodontal disease treatment products, are obtained from Hovione in Portugal and Macau. Supplies of leuprolide acetate, used in our Eligard prostate cancer products, are primarily obtained from Bachem in Switzerland, Mallinckrodt in Missouri, and, to a lesser extent, PolyPeptide Laboratories in California. A solvent used in the Eligard products is obtained from International Specialty Products in Texas. We currently obtain supplies of dapsone for our Atrisone™ product from Lundbeck in Germany. We have qualified multiple vendors for the majority of our raw materials. These alternative vendors were used in our clinical trials, filed in our FDA applications and are in an approved status. If we should lose any of our suppliers of raw materials, we believe that we could locate and obtain such raw materials from other available sources without substantial adverse delay or increased expense. We did not experience any serious shortages or delays in obtaining raw materials in 2002 and we do not anticipate any significant shortages or delays in the foreseeable future.

#### ***Available Information***

Our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, are available on our website at [www.atrirlabs.com](http://www.atrirlabs.com), the same day the reports are available on the Securities and Exchange Commission website.

### **Factors Affecting Our Business and Prospects**

There are many factors that affect our business and results of operations, some of which are beyond our control. The following is a description of some of the important factors that may cause the actual results of our operations in future periods to differ materially from those currently expected or desired.

*We have a history of operating losses.* Since our inception, we have invested a significant amount of time and money in research and development of new products. Our research and development expenses,

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including research and development licensing fees, were \$32.7 million, \$28.6 million and \$16.7 million for the years ended December 31, 2002, 2001 and 2000, respectively, exceeded our total revenue of \$26.4 million, \$15.8 million, \$10.0 million, respectively, in such years. Because of our time and financial commitments to our new products, we have operated at a loss for the previous five years under revenue recognition policies as currently applied. Our accumulated deficit at December 31, 2002 was \$151.3 million. We anticipate approaching profitability in 2003. If we do not ultimately achieve and maintain profitability, our stock price may decline.

*We must obtain domestic and foreign regulatory marketing approval of our product candidates, which requires a significant amount of time and money.* The research and development, preclinical studies and clinical trials, and ultimately, the manufacturing, marketing and labeling of our products, are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries. We currently have ten products for which we have submitted a marketing application to the FDA or appropriate foreign governmental authority and are involved in the regulatory approval process. These products include three Eligard products and seven generic formulations of dermatology products. FDA approval can be delayed, limited or denied for many reasons, including:

a product candidate may be found to be unsafe or ineffective,

the FDA may interpret data from preclinical testing and clinical trials differently and less favorably than the way we interpret it,

the FDA might not approve our manufacturing processes or facilities,

the FDA may change its approval policies or adopt new regulations that may negatively affect or delay our ability to bring a product to market, and

a product candidate may not be approved for all the indications we requested and thus our markets may be limited.

The process of obtaining approvals in foreign countries is also subject to delay and failure for similar reasons. Delays in obtaining approval may result in our needing to make significant expenditures of additional time and money to bring a new product to market. If we do not obtain approval for any particular product, we will have spent a significant amount of time and money in the approval process and will be unable to market the product to generate revenue.

We are also required to comply with the FDA's cGMPs with respect to the manufacturing of our drugs, and QSRs with respect to the manufacturing of our medical devices. These cGMPs and QSRs include requirements relating to quality control, quality assurance and maintenance of records and documentation. Manufacturing facilities are subject to biennial inspections by the FDA and must be approved before we can use them in the commercial manufacturing of our products. If our contract manufacturers, or we are unable to comply with the applicable cGMPs, QSRs and other regulatory requirements, the FDA may seek sanctions and/or remedies against us, including suspension of our manufacturing operations, issue us warning letters, force us to recall or withdraw our product(s) from the market and possibly issue civil and/or criminal penalties in extreme cases.

*Clinical trials are expensive and their outcome is uncertain.* Before obtaining regulatory approvals for the commercial sale of any products, we or our partners must demonstrate through preclinical testing and clinical trials that our product candidates are safe and effective for use in humans. We have multiple compounds in various stages of preclinical development, a number of which are being developed through partnerships with a variety of other pharmaceutical companies. We spend and will continue to spend a significant amount of financial resources conducting preclinical testing and clinical trials.

Clinical trials are expensive and may take several years or more and the length of time can vary substantially. Expenses associated with clinical trials and other aspects of the FDA approval process have typically exceeded \$5 million for each of the products we are marketing in the United States. The FDA

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approval process has taken a minimum of 10 months and as long as two years for these products. Our initiation and rate of completion of clinical trials may be delayed by many factors, including:

- our inability to recruit patients at a sufficient rate,
- the failure of clinical trials to demonstrate a product candidate's safety and efficacy,
- our inability to follow patients adequately after treatment,
- our inability to predict unforeseen safety issues,
- our inability to manufacture sufficient quantities of materials for clinical trials,
- the potential for unforeseen governmental or regulatory delays,
- the potential lack of sufficient financial resources, and
- our inability to satisfy FDA requirements which may result in the clinical trials being repeated.

We have not experienced any significant delays in our clinical trials or received notice by the FDA to halt any of our clinical trials.

In addition, the results from preclinical testing and early clinical trials do not always predict results of later clinical trials. Within the pharmaceutical industry, a number of new drugs have shown encouraging results in early clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. For example, in 1993 our 5% sanguinarine product failed to establish efficacy in Phase III clinical trials. We reformulated the active ingredient in the product and conducted additional Phase III clinical trials. The trials were ultimately successful and the product is now marketed as our Atridox product, which did not receive regulatory approval until 1998.

If a product candidate fails to demonstrate safety and efficacy in clinical trials, this failure may delay development of other product candidates and hinder our ability to conduct related preclinical testing and clinical trials. Such potential failures may also make it more difficult to find additional collaborators or to obtain additional financing. Delays in our clinical trials may require us to expend significant additional amounts of time and money, and termination of our clinical trials may prevent us from generating any revenue from the product candidate at issue.

Furthermore, to market our products outside the United States, our products may be subject to additional clinical trials and approvals even though the products have been approved in the United States. To meet any additional requirements that might be imposed by foreign governments, we may incur additional costs that may impact our profitability. If the approvals are not obtained or will be too expensive to obtain, foreign distribution may not be feasible, which could harm our business.

*As our product and product candidates, if and when approved, are used commercially, unintended side effects, adverse reactions or incidence of misuse may appear.* We cannot predict whether the commercial use of products (or product candidates in development if and when they are approved for commercial use) will produce undesirable or unintended side effects that have not been evident in the use of or clinical trials conducted for such products (and product candidates) to date. Additionally, incidents of product misuse may occur. These events, among others, could result in product recalls or withdrawals or additional regulatory controls.

*Our future profitability depends on the development of new products.* We currently have a variety of new products in various stages of research and development and are working on possible improvements, extensions or reformulations of some existing products. These research and development activities, as well as the clinical testing and regulatory approval process, which must be completed before commercial quantities of these products can be sold, will require significant commitments of personnel and financial resources. Delays in the research, development, testing and approval processes will cause a corresponding delay in revenue generation from those products. Regardless of whether they are ever released to the market, the expense of such processes will have already been incurred.

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We reevaluate our research and development efforts regularly to assess whether our efforts to develop a particular product or technology are progressing at the rate that justifies our continued expenditures. On the basis of these reevaluations, we have abandoned in the past, and may abandon in the future, our efforts on a particular product or technology. If we fail to take a product or technology from the development stage to market on a timely basis, we may incur significant expenses without a near-term financial return.

*We market our products through arrangements with third parties, and if we fail to maintain such arrangements our business could be harmed.* We form strategic relationships with collaborators to help us commercialize and market our products. These relationships are critical to the success of our products on the market. We expect that most of our future revenue will be obtained from royalty payments from sales or a percentage of profits of products licensed to our collaborators. Failure to make or maintain these arrangements, failure to form new arrangements or a delay in a collaborator's performance could reduce our revenue and may require us to expend significant amounts of time and money to find new collaborators and structure alternative arrangements. For example, MediGene is the current holder to the European marketing rights of our Eligard products. MediGene is currently searching for a marketing partner for our Eligard products. If MediGene is unsuccessful in their efforts in obtaining a marketing partner, European sales of our Eligard products would be negatively impacted, assuming we receive regulatory approval to market our Eligard products in European countries.

Disputes with a collaborator could delay the program on which we are working with the collaborator and could result in expensive arbitration or litigation, which may not be resolved in our favor. For example, prior to 2002, Block had exclusive rights to market and distribute our Atridox, Atrisorb-FreeFlow GTR Barrier and Atrisorb-D GTR Barrier products in North America. We had disputes with Block relating to product pricing and the payments due to us upon achievement of milestones under our commercialization agreement with Block and were involved in arbitration and litigation proceedings with them until final settlement of all disputes in September 2001. We then entered into a new arrangement for the marketing and distribution of these products in the United States with CollaGenex. Our legal dispute with Block and the transition to CollaGenex as our new marketing partner for these products were the primary factors causing our 39% decrease in product net sales and royalty revenue between our 2000 and 2001 fiscal years and part of the reason for our 28% increase in administrative and marketing expenses between such years.

In addition, our collaborators could merge with or be acquired by another company or experience financial or other setbacks unrelated to our collaboration that could impair their ability to market and sell our products and cause a decrease in our revenue. For example, GlaxoSmithKline acquired our North American dental products' marketing partner, Block, and subsequently discontinued marketing our dental products under the terms of our August 2001 termination agreement.

Finally, we cannot control our collaborative partners' performance or the resources they devote to our programs. If a collaborative partner fails to perform, or perform on a timely basis, the research, development or commercialization program on which it is working will be delayed. If this happens, we may have to use funds, personnel, laboratories and other resources that we have not budgeted, and consequently, we may not be able to continue the program.

*We have limited experience in marketing and selling our products.* Our Eligard 7.5-mg one-month and Eligard 22.5-mg three-month products, sales of which accounted for 36% of our net sales and royalty revenue in the fiscal year ended December 31, 2002, have been marketed in the United States by Sanofi-Synthelabo since May 2002 and September 2002, respectively. Our Atridox, Doxirobe and Atrisorb-FreeFlow GTR Barrier products, sales of which accounted for approximately 46% of our net sales and royalty revenue in the fiscal year ended December 31, 2002, have been marketed by our partners and have been on the market for only four and a half years. To achieve commercial success for any of our products, we must either develop a marketing and sales force or contract with another party to perform these services for us. In either case, we are competing with companies that have experienced and well-funded marketing and sales operations. We have historically relied upon arrangements with third parties to market and sell our products. If we do not maintain good relationships with these third parties, we may not be able to make alternative arrangements on acceptable terms and our product sales may decline. To the



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extent we undertake to market or co-market our own products, however, we would require additional expenditures and management resources. In particular, factors that may inhibit our efforts to commercialize our products without collaborative partners include:

The inability of either a contract sales organization or us to recruit and retain adequate numbers of effective sales personnel,

The inability of sales personnel working on our behalf to obtain access to or persuade adequate numbers of physicians to prescribe our products,

The lack of complementary products to be offered by sales personnel working on our behalf, which may put us at a competitive disadvantage against companies with broader product lines, and

Unforeseen costs associated with creating an independent sales force and marketing organization.

*If our products do not achieve market acceptance, our revenue will be reduced.* Our products may not gain market acceptance among physicians, patients, third-party payors and the medical community. Under Block's and CollaGenex's marketing of our dental products in North America, our dental products have been slow in achieving market acceptance within the dental community. We expect an increase in market acceptance for our dental products in foreign countries as we establish marketing authorizations and commence marketing within these countries by our Germany-based subsidiary, Atrix GmbH. In the fiscal year ended December 31, 2002, we generated \$5.7 million, or 22% of our \$26.4 million total revenue, from net sales and royalties. Sanofi-Synthelabo commenced marketing in the United States of our Eligard 7.5-mg one-month and Eligard 22.5-mg three-month products in May 2002 and September 2002, respectively. We anticipate market acceptance to increase for our Eligard products as Sanofi's marketing and product awareness efforts continue, and with the launch of the Eligard 30.0-mg four-month product in 2003. However, if Sanofi's efforts are not successful in marketing our Eligard products, our Eligard U.S. sales revenue would decline.

The degree of market acceptance of any of our products and product candidates depends on a number of factors, including:

demonstration of their clinical efficacy and safety,

their cost-effectiveness,

their potential advantage over alternative existing and newly developed treatment methods,

the marketing and distribution support they receive, and

reimbursement policies of government and third-party payors.

Our products and product candidates, if successfully developed, will compete with a number of drugs and therapies currently manufactured and marketed by major pharmaceutical and other biotechnology companies. Our products may also compete with new products currently under development by others or with products which may cost less than our products. Physicians, patients, third-party payors and the medical community may not accept or utilize our products. If our products do not achieve significant market acceptance, we may not generate enough revenue to offset our research and development expenses incurred in obtaining the required regulatory approvals and, therefore, we may not realize profitability.

*We have limited experience in manufacturing products on a commercial scale, and if we are unable to produce enough of our products to meet market demands, this could cause a decrease in our revenue.* We currently are in the process of expanding our manufacturing facility and expect to complete construction during the second quarter of 2003, however, the expanded facility and the new equipment must be approved by the FDA prior to production activities commencing in this expanding facility. We anticipate FDA approval of the expanded facility within five months of completion, however the FDA may not approve our facility and equipment resulting in a delay of manufacturing our products in the expanded facility. Additionally, there is a risk that we may fail to manufacture present and future products in compliance with applicable regulations and at an acceptable cost.

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*We have a dependence on one contract manufacturer involved in the production of our Eligard products. We currently outsource the lyophilization, or sterilization, process of our Eligard products to an approved contract manufacturer and rely on this manufacturer for this highly specialized service. If the vendor was unable to meet our needs for this manufacturing process, or if our relationship with this vendor was to deteriorate or terminate, production of our Eligard products may be temporarily discontinued for several months. We currently have one other contract manufacturer as a back-up source for the lyophilization process should there be a disruption in our Eligard product supply chain. However, the FDA would need to approve the change in the manufacturer of the lyophilization process for our Eligard products, which could take several months. Additionally, we have at least six months of inventory safety stock of Eligard products to meet near term future demands, should a disruption in the lyophilization process occur.*

*We generate a majority of our revenue from our contract research and development activities and any adverse effect on our relationships with these customers could cause a decrease in our revenue. To support our research and development of certain product candidates, we rely on agreements with collaborators, licensors and others that provide financial and clinical support. Our contract research and development revenue of \$14.2 million for the fiscal year ended December 31, 2002 represented 54% of our \$26.4 million total revenue.*

If any of our research and development agreements were terminated or substantially modified, or if our relationships with any of these collaborators deteriorated, our contract research and development revenue may decrease and our ability to develop and commercialize our technologies may be hindered. Contract research and development revenue recognized under our agreements with Fujisawa, Geneva, Sanofi, Pfizer and our joint venture with Elan was 91% of our 2002 total contract research and development revenue, and 49% of our 2002 total revenue. If any of these agreements were terminated or if our relationship with these collaborators deteriorated, our revenue would likely decrease significantly.

*We conduct operations in foreign countries, which are subject to risks, and our plans for international expansion may not succeed, which could harm our revenue and profitability. We conduct our European operations through our wholly owned subsidiaries, Atrix Laboratories GmbH, in Frankfurt, Germany, and Atrix Laboratories Limited, in London, England. Revenue from product sales to customers outside of the U.S. amounted to \$1.1 million, or 19% of our net sales and royalties revenue and 4% of our total revenue, for the fiscal year ended December 31, 2002.*

We face foreign exchange rate fluctuations, primarily with respect to the Euro and the British Pound, because we translate the financial results of our foreign subsidiaries into U.S. dollars for consolidation and because we translate the financial results of our transactions with our foreign marketing partners. As exchange rates vary, our results, when translated, may vary from expectations and may result in a decrease in our revenue.

One of our strategies for increasing our revenue depends on expansion into international markets. Our international operations may not succeed for a number of reasons, including:

- difficulties in managing foreign operations or obtaining the required regulatory approvals from foreign governmental authorities,
- fluctuations in currency exchange rates or imposition of currency exchange controls,
- competition from local and foreign-based companies,
- issues relating to uncertainties of laws and enforcement relating to the protection of intellectual property,
- unexpected changes in trading policies and regulatory requirements,
- duties and taxation issues,
- language and cultural differences,

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general political and economic trends, and

expropriation of assets, including bank accounts, intellectual property and physical assets by foreign governments.

Accordingly, we may not be able to successfully execute our business plan in foreign markets. If we are unable to achieve anticipated levels of revenue from our international operations, our revenue and profitability may decline.

*Our inability to protect our intellectual property and defend ourselves from intellectual property suits could harm our competitive position and our financial performance.* We rely heavily on our proprietary information in developing and manufacturing our products. Notwithstanding our pursuit of patent protection, other companies may develop delivery systems, compositions and methods that infringe our patent rights resulting from outright ownership or non-revocable exclusive licensure of patents that relate to our delivery systems, composition and methods. In that event, such delivery systems, compositions and methods may compete with our systems, compositions and methods and may reduce sales of our products. Our patents may not afford adequate protection against competitors with similar systems, composition and methods, and other companies may circumvent our patents.

In addition to patents, we also maintain several U.S. and numerous foreign trademark and service mark applications for registrations of our name, logo, drug delivery systems and products. If other companies infringe on our trademarks and service marks, we may not be able to market our products as effectively and our brand recognition may decline.

We also rely on our unpatented proprietary knowledge. Despite our efforts to protect our proprietary rights from unauthorized use or disclosure, parties, including former employees or our consultants, may attempt to disclose, obtain or use our proprietary information or technologies. Other companies may also develop substantially equivalent proprietary knowledge. The steps we have taken may not prevent misappropriation of our proprietary information and technologies, particularly in foreign countries where laws or law enforcement practices may not protect our proprietary rights as fully as in the United States. If other companies obtain our proprietary knowledge or develop substantially equivalent knowledge, they may develop products that compete against ours and adversely affect our product sales.

Intellectual property claims brought against us, regardless of their merit, could result in costly litigation and the diversion of our financial resources and technical and management personnel. Further, if such claims are proven valid, through litigation or otherwise, we may be required to change our trademarks and service marks, stop using our technologies and pay financial damages, which could harm our profitability and financial performance.

*If we engage in acquisitions, we will incur a variety of costs, and we may not be able to realize the anticipated benefits.* From time to time, we engage in preliminary discussions with third parties concerning potential acquisitions of products, technologies and businesses. Acquisitions involve a number of risks, including:

difficulties in and costs associated with the assimilation of the operations, technologies, personnel and products of the acquired companies,

assumption of known or unknown liabilities or other unanticipated events or circumstances,

risks of entering markets in which we have limited or no experience, and

potential loss of key employees.

Any of these risks could harm our ability to achieve levels of profitability of acquired operations or to realize other anticipated benefits of an acquisition.

*We may seek to raise additional funds, and additional funding may be dilutive to stockholders or impose operational restrictions.* Any additional equity financing may be dilutive to our stockholders and debt financing, if available, may involve restrictive covenants, which may limit our operating flexibility with

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respect to certain business matters. If additional funds are raised through the issuance of equity securities, the percentage ownership of our stockholders will be reduced. These stockholders may experience additional dilution in net book value per share and any additional equity securities may have rights, preferences and privileges senior to those of the holders of our common stock.

*Our future performance depends on our ability to attract and retain key personnel.* Our success depends in part on our ability to attract and retain highly qualified management and scientific personnel. If key employees terminate their employment with us, our business relationships may be adversely affected, and management's attention may be diverted from our operations to focusing on transition matters and identifying suitable replacements. If any of our key research and development employees terminate their employment, our research and development efforts may be hindered, adversely affecting our ability to bring new products to market. Because competition for personnel in our industry is intense, we may not be able to locate suitable replacements for any key employees that leave the company, and we may not be able to offer employment to them on reasonable terms.

*We are subject to environmental compliance risks.* Our research, development and manufacturing areas involve the controlled use of hazardous chemicals, primarily flammable solvents, corrosives, and toxins. The biologic materials include microbiological cultures, animal tissue and serum samples. Some experimental and clinical materials include human source tissue or fluid samples. We are not licensed to receive or handle radioactive materials. We are also subject to federal, state and local government regulation in the conduct of our business, including regulations on employee safety and our handling and disposal of hazardous and radioactive materials. Any new regulation or change to an existing regulation could require us to implement costly capital or operating improvements for which we have not budgeted. If we do not comply with these regulations, we may be subject to fines and other liabilities.

*Our industry is characterized by intense competition and rapid technological change, which may limit our commercial opportunities, render our products obsolete and reduce our revenue.* The pharmaceutical and biotechnology industries are highly competitive. We face intense competition from academic institutions, government agencies, research institutions and other biotechnology and pharmaceutical companies, including other drug delivery companies. Some of these competitors are also our collaborators. Our competitors are working to develop and market other drug delivery systems, vaccines, antibody therapies and other methods of preventing or reducing disease, and new small-molecule and other classes of drugs that can be used without a drug delivery system.

Many of our competitors have much greater capital resources, manufacturing and marketing experience, research and development resources and production facilities than we do. Many of them also have much more experience than we do in preclinical testing and clinical trials of new drugs and in obtaining FDA and foreign approvals. In addition, they may succeed in obtaining patents that would make it difficult or impossible for us to compete with their products.

Because major technological changes can happen quickly in the biotechnology and pharmaceutical industries, the development by competitors of technologically improved or different products may make our products or product candidates obsolete or noncompetitive.

*If third-party payors will not provide coverage or reimburse patients for the use of our products, our revenue will suffer.* The commercial success of our products is substantially dependent on whether third-party reimbursement is available for the use of our products by the medical and dental professions. Medicare, Medicaid, health maintenance organizations and other third-party payors may not authorize or otherwise budget for the reimbursement of our products. In addition, they may not view our products as cost-effective and reimbursement may not be available to consumers or may not be sufficient to allow our products to be marketed on a competitive basis. Likewise, legislative proposals to reform health care or reduce government programs could result in lower prices or rejection of our products. Changes in reimbursement policies or health care cost containment initiatives that limit or restrict reimbursement for our products may cause our revenue to decline.

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*If product liability lawsuits are brought against us, we may incur substantial costs.* Our industry faces an inherent risk of product liability claims from allegations that our products resulted in adverse effects to the patient and others. These risks exist even with respect to those products that are approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA. We maintain worldwide product liability insurance in the amount of \$10.0 million with a \$25,000 deductible per occurrence and an aggregate deductible of \$250,000. Our insurance may not provide adequate coverage against potential product liability claims or losses. In the future we may not be able to obtain adequate insurance coverage on reasonable terms and insurance premiums and deductibles may increase. Even if we were ultimately successful in product liability litigation, the litigation could consume substantial amounts of our financial and managerial resources and may create adverse publicity, all of which would impair our ability to generate sales. If we were found liable for any product liability claims in excess of our insurance coverage or outside our coverage, the cost and expense of such liability could severely damage our business and profitability.

Additionally, product recalls may be issued at our discretion or at the direction of the FDA, other government agencies or other companies having regulatory control for pharmaceutical product sales. If product recalls occur, such recalls are generally expensive and often have an adverse affect on the image of the product being recalled.

*Our stock price is volatile and the value of a stockholder's investment may be subject to sudden decreases.* The price of our stock has been and may continue to be volatile. The price of our stock during the last two years has ranged from a low of \$9.62 on April 3, 2001 per share to a high of \$29.18 per share on October 25, 2001. Our stock price may fluctuate due to a variety of factors, including:

announcements of developments related to our business or our competitors' businesses,

fluctuations in our operating results,

sales of our common stock in the marketplace,

failure to meet, or changes in, analysts' expectations,

general conditions in the biotechnology and pharmaceutical industries or the worldwide economy,

announcements of innovations, new products or product enhancements by us or by our competitors,

developments in patents or other intellectual property rights or any litigation relating to these rights, and

developments in our relationships with our customers, suppliers and collaborators.

Decreases in our stock price may adversely affect the trading market for our stock and may cause stockholders to lose all or a portion of their investments.

**Item 2. Properties.**

We lease a total of 43,109 square feet of office and research laboratory space located in Fort Collins, Colorado, pursuant to a lease that expires in June 2006. In October 2001, we entered into an agreement to extend the lease for our office and research laboratory space from June 2003 to June 2006. Additionally, we increased our lease space from 24,580 square feet to 30,092 square feet as part of the October 2001 lease extension agreement. In February 2002, we amended our lease agreement to increase our lease space from 30,092 square feet to 43,109 square feet. In April 2001, we entered into a two-year lease agreement for 4,800 square feet warehouse space, located in Fort Collins.

We own a 26,437 square foot manufacturing facility in Fort Collins that we acquired in July 1996. As part of the building acquisition, we acquired two acres of vacant land, directly adjacent to the building. In August 1997, we acquired an additional 2.7 acres for possible future development or expansion. In April 2002, construction commenced to expand our manufacturing facility from 26,437 square feet to a two-story, 58,000 square foot building. In the expanded facility we intend to produce the full line of our

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Eligard prostate cancer products, Atrisone topical dermatological products, generic dermatology products, dental products and clinical supplies for products currently in development. We anticipate construction on this expansion to be completed in the second quarter of 2003. Approximately 40% of the new building expansion will be devoted to production with the remainder allotted for warehousing, quality assurance and laboratory work. Once the building is complete, an extensive FDA certification of the plant and equipment is required, which could take up to five months.

We also lease 367 square feet of office space located in Frankfurt, Germany, pursuant to a month-to-month lease that will expire in June 2004 unless terminated earlier. This office space is used for the operation of our wholly owned subsidiary Atrix Laboratories GmbH.

We own substantially all of our laboratory and manufacturing equipment, which we consider to be adequate for our research, development and testing requirements for the foreseeable future.

**Item 3. Legal Proceedings.**

We are involved in certain litigation arising in the ordinary course of business. Although we believe that these matters will not have a material adverse effect on our consolidated financial position or results of operations, the ultimate outcome of these matters cannot, at this time, be predicted, in light of the uncertainties inherent in litigation.

**Item 4. Submission of Matters to a Vote of Security Holders.**

No matter was submitted to a vote of our security holders, through the solicitation of proxies or otherwise, during the fourth quarter of our 2002 fiscal year.

**PART II****Item 5. Market for the Registrant's Common Equity and Related Stockholder Matters.  
Market Information**

Our common stock is traded on The Nasdaq National Market under the symbol **ATRX**. The following table sets forth, for the fiscal periods indicated, the range of high and low sales price per share of our common stock, as reported on The Nasdaq National Market:

	<u>High</u>	<u>Low</u>
2002:		
Fourth Quarter	\$ 19.670	\$ 14.510
Third Quarter	22.900	11.040
Second Quarter	25.250	20.820
First Quarter	19.670	14.510
2001:		
Fourth Quarter	\$ 29.180	\$ 18.580
Third Quarter	28.400	17.350
Second Quarter	24.760	9.625
First Quarter	25.000	13.375

**Holder**

As of March 19, 2003, there were 2,288 holders of record of our common stock.

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**Dividends**

To date, we have not declared or paid cash dividends to shareholders. We currently anticipate that we will retain all available funds for use in the operation of our business and do not anticipate paying any cash dividends in the foreseeable future. For the year ended December 31, 2002, we issued 916 shares of Series A Convertible Exchangeable Preferred Stock to Elan for accrued preferred stock dividends. Additionally, 487 shares of Series A Convertible Exchangeable Preferred Stock were issued to Elan in the first quarter of 2003 for accrued preferred stock dividends for the period of July 19, 2002 through January 18, 2003.

**Issued Unregistered Securities**

In March 2002, we called for redemption our outstanding 7% Convertible Subordinated Notes. Subsequently, \$2.9 million in principal amount of the outstanding notes were converted into 151,300 shares of our common stock valued at a \$19.00 per share conversion price. The conversion of the outstanding notes occurred prior to the redemption date of May 15, 2002. For the year ended December 31, 2002, we exchanged a total of \$5.2 million in principal amount of our 7% Convertible Subordinated Notes for 279,931 shares of our common stock. These transactions were made in reliance on the exemption from the registration requirements of the Securities Act of 1933 provided by Section 3(a)(9) of the Securities Act.

**Table of Contents****Item 6. Selected Financial Data.**

The selected consolidated financial data presented below is derived from our consolidated financial statements, which have been audited and reported upon by Deloitte & Touche LLP, our independent auditors. The selected consolidated financial data set forth in the table below is not necessarily indicative of our results of future operations and should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations and the consolidated financial statements and related notes included herein.

	Years Ended December 31,				
	2002	2001	2000	1999	1998
(In thousands, except per share data)					
<b>Summary of Consolidated Operations:</b>					
Total revenue	\$ 26,384	\$ 15,811	\$ 10,043	\$ 5,635	\$ 21,073
Total expense	(47,094)	(37,880)	(23,766)	(21,830)	(19,996)
Other income (expense)	2,512	(3,145)	(12,773)	(350)	404
Income tax expense					(48)
Income (loss) before extraordinary item and cumulative effect of change in accounting principle	(18,198)	(25,214)	(26,496)	(16,545)	1,433
Extraordinary gain (loss) on extinguished debt	30	(319)	80	3,275	257
Cumulative effect of change in accounting principle			(20,612)		
Net income (loss) before preferred stock dividends	(18,168)	(25,533)	(47,028)	(13,270)	1,690
Accretion of dividends on preferred stock	(946)	(1,171)	(383)		
Net income (loss) applicable to common stock	\$ (19,114)	\$ (26,704)	\$ (47,411)	\$ (13,270)	\$ 1,690
Basic and diluted earnings per common share:					
Income (loss) before extraordinary item and cumulative effect of change in accounting principle	\$ (.90)	\$ (1.54)	\$ (2.23)	\$ (1.46)	\$ 0.13
Extraordinary gain (loss) on extinguished debt		(0.02)		0.29	0.02
Cumulative effect of change in accounting principle			(1.73)		
Net income (loss) before preferred stock dividends	(.90)	(1.56)	(3.96)	(1.17)	0.15
Accretion of dividends on preferred stock	(.05)	(0.07)	(0.03)		
Net income (loss) applicable to common stock	\$ (.95)	\$ (1.63)	\$ (3.99)	\$ (1.17)	\$ 0.15
Basic and diluted weighted average shares outstanding	20,077	16,348	11,884	11,327	11,270
<b>Consolidated Balance Sheet Data:</b>					



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Working capital	\$ 114,039	\$ 135,219	\$ 56,549	\$ 38,646	\$ 63,121
Total assets	150,025	157,493	74,172	54,659	79,480
Long-term obligations	37,064	33,579	60,408	36,690	48,500
Series A Convertible Exchangeable Preferred Stock	14,514	13,568	12,397		
Shareholders' equity (deficit)	82,255	99,160	(4,588)	14,670	28,422

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Notes: In 2000, we changed the accounting method for licensing, marketing rights and milestone revenue to conform to Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements. See further discussion in Note 1 to the consolidated financial statements.

Included in long-term obligations are the non-current amounts of deferred revenue. These amounts are not subject to future repayment.

Our Series A Convertible Exchangeable Preferred Stock, or the Series A Stock, which was issued in connection with the formation of our joint venture with Elan International, has an exchange feature that allows the holder to convert it into an additional holding in Transmucosal Technologies, which is a redemption feature that is outside our control. As a result, our Series A Convertible Exchangeable Preferred Stock is presented outside of permanent shareholders' equity until such time as the exchange feature is exercised or expires.

**Table of Contents****Item 7. Management's Discussion and Analysis of Consolidated Financial Condition and Results of Operations.**

*The following Management's Discussion and Analysis of Financial Condition and Results of Operations, as well as information contained elsewhere in this Report, contain statements that constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, and Section 21E of the Securities Exchange Act of 1934. These include statements regarding the intent, belief or current expectations of us, our directors or our officers with respect to, among other things: (1) whether we will receive, and the timing of, regulatory approvals or clearances to market potential products; (2) the results of current and future clinical trials; (3) the time and expenses associated with the regulatory approval process for products; (4) the safety and effectiveness of our products and technologies; (5) our expectation that our marketing partners will be able to successfully market our products; (6) our expectation of receiving royalties on sales of our products and our plans to manufacture certain of our products at our facility in Fort Collins, Colorado; (7) the timing of new product launches; and (8) expected future additional equity losses for Transmucosal Technologies, Ltd. Forward-looking statements are not guarantees of future performance and involve risks and uncertainties. Actual results may differ materially from those projected in the forward-looking statements as a result of various factors, including those described under Item 1. Business Factors Affecting Our Business and Prospects.*

**Overview**

We are an emerging specialty pharmaceutical company focused on advanced drug delivery. With five unique patented drug delivery technologies, we are currently developing a diverse portfolio of products, including proprietary oncology, dermatology, pain management and growth hormone releasing peptide-1, or GHRP-1. We also form strategic alliances with a variety of pharmaceutical and biotechnology companies to develop products utilizing our various drug delivery systems and/or to commercialize our products. These strategic alliances include collaborations with Pfizer, Inc., Sanofi-Synthelabo, Inc., MediGene AG, Fujisawa Healthcare, Inc., Geneva Pharmaceuticals, Inc., Elan International Services, Ltd., Sosei Co. Ltd., and CollaGenex Pharmaceuticals, Inc.

Our drug delivery systems deliver controlled amounts of drugs in time frames ranging from minutes to months to address a range of therapeutic and patient needs. Atrigel is our original proprietary sustained release biodegradable polymer drug delivery system. The Atrigel system may provide benefits over traditional methods of drug administration such as safety and effectiveness, wide array and ease of applications, site-specific or systemic delivery, customized release rates and biodegradability. With the acquisition of ViroTex in November 1998, we added four additional drug delivery systems: BEMA, SMP, MCA and BCP.

Our Eligard 7.5-mg one-month and Eligard 22.5-mg three-month prostate cancer treatment products are currently marketed in the U.S. and our four dental products are currently marketed worldwide. In February 2003, the FDA approved our Eligard 30.0-mg four-month product and we launched this product in March 2003. Additional Marketing Authorization Applications, or MAAs, for our Eligard one- and three-month products were submitted in Germany, and New Drug Submissions, or NDSs, for the Eligard one-, three- and four-month products were submitted in Canada and General Marketing Applications, or GMAs, were submitted in Australia for the three Eligard products.

**Critical Accounting Policies**

Our established accounting policies are outlined in the notes to the Consolidated Financial Statements entitled Organization and Summary of Significant Accounting Policies. As part of its oversight responsibilities, our management continually evaluates the propriety of our accounting methods as new events occur. We have chosen to highlight certain policies that we consider critical to the operations of the business and understanding of our consolidated financial statements.

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### ***Principles of Consolidation***

The consolidated financial statements include the accounts of Atrix Laboratories, Inc. and our wholly owned subsidiaries Atrix Laboratories, GmbH and Atrix Laboratories, Ltd. All significant intercompany transactions and balances have been eliminated. While we initially own 80.1% of Transmucosal Technologies outstanding common stock, Elan and its subsidiaries have retained significant minority investor rights that are considered participating rights as defined in Emerging Issues Task Force Consensus 96-16, Investor's Accounting for an Investee When the Investor Has a Majority of the Voting Interest, but the Minority Shareholder or Shareholders Have Certain Approval or Veto Rights. Elan's significant rights in Transmucosal Technologies that are considered participating rights include equal representation in the management of the joint venture and development of its business plan and approval rights on the board of directors as it relates to the business plan. Accordingly, we account for our investment in Transmucosal Technologies under the equity method of accounting.

### ***Revenue Recognition***

We recognize revenue on product sales and contract manufacturing at the time of shipment when title to the product transfers and the customer bears the risk of loss. Product sales revenue is recorded net of estimated returns and allowances. The estimation process is based upon the professional knowledge and experience of our management.

All contract research and development is performed on a best effort basis under signed contracts. Revenue under contracts with a fixed price is recognized over the term of the agreement on a straight-line basis, which is consistent with the pattern of work performed. Billings are made in accordance with schedules as specified in each agreement, which generally include an up-front payment as well as periodic payments. Advance payments are recorded as deferred revenue. Revenue under other contracts is recognized based on terms as specified in the contracts, including billings for time incurred at rates as specified in the contracts and as reimbursable expenses are incurred. Such arrangements are regularly evaluated on an individual basis.

Nonrefundable licensing fees, marketing rights and milestone payments received under contractual arrangements are deferred and recognized over the remaining contractual term using the straight-line method.

### ***Research and Development***

Costs incurred in connection with research and development activities are expensed as incurred. These costs consist of direct and indirect costs associated with specific projects, as well as fees paid to various entities that perform certain research on our behalf. Additionally, licensing fees paid by us to acquire technology are expensed as incurred if no alternative future use exists. A portion of overhead costs is allocated to research and development costs on a weighted-average percentage basis among all projects under development. We consider that regulatory and other uncertainties inherent in the development of new products preclude us from capitalizing development costs. This treatment includes upfront and milestone payments made to third parties in connection with research and development activities.

With respect to the previously described critical accounting policies, our management believes that the application of judgments and assessments is consistently applied and produces financial information which fairly depicts the results of operations for all years presented.

## **Results of Operations**

### ***Years Ended December 31, 2002 and 2001***

Total revenue for the year ended December 31, 2002 was \$26.4 million compared to \$15.8 million for the year ended December 31, 2001, representing a 67% increase.

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Net sales and royalties were \$5.7 million for the year ended December 31, 2002 compared to \$3.8 million for the year ended December 31, 2001, representing a 50% increase. The increase of \$1.9 million was primarily related to net sales and royalties from our marketing partner Sanofi-Synthelabo on our Eligard 7.5-mg one-month and Eligard 22.5-mg three-month products launched in May 2002 and September 2002, respectively. Eligard product sales and royalties to us totaled \$2.1 million in 2002. We expect net sales and royalty revenues to increase in 2003 as a result of a full year of product sales of our Eligard 7.5-mg one-month and Eligard 22.5-mg three-month products. Additionally, the FDA approved our Eligard 30-mg four-month product in February 2003 and we anticipate U.S. commercial launch in the first half of 2003.

Contract research and development revenue represents revenue we earned from unaffiliated third parties and from our joint venture with Elan for performing contract research and development activities using our various patented drug delivery technologies. Contract research and development revenue was \$14.2 million for the year ended December 31, 2002 compared to \$8.2 million for the year ended December 31, 2001, representing a 73% increase. This increase is primarily related to the increase of \$3.4 million in revenue from Fujisawa for partial funding of Atrisone research costs, \$2.5 million for funding of an Eligard 45-mg six-month product by Sanofi-Synthelabo, \$2.9 million increase in revenue from Geneva for efforts under the generic dermatology program, and \$0.1 million increase in revenue from research activities funded by other parties. These increases were offset by a \$2.9 million decrease in revenue recognized in conjunction with our joint venture as a result of the completion of feasibility work performed by us. The two joint venture projects are currently under review for further development. We expect that contract revenue from our partner-funded research and development expenses will increase in 2003 as we continue to develop products under those collaborative agreements, as new products are developed and as new agreements are entered into.

Licensing, marketing rights and milestone revenue for the year ended December 31, 2002 was \$6.5 million compared to \$3.8 million for the year ended December 31, 2001, representing a 71% increase. This increase is primarily related to the recognition of \$1.1 million in additional revenue for the net effects of our 2001 amendment to our agreement with Block and the subsequent agreement with CollaGenex, the recognition of \$1.4 million in additional licensing fee and milestone revenue for our Eligard products under the Sanofi-Synthelabo, MediGene and other Eligard marketing agreements, and the recognition of \$0.1 million additional milestone revenue for our Atrisone product under the Fujisawa agreement. We expect licensing, marketing and milestone revenue to increase in 2003 as a result of a full year of revenue recognition from licensing and milestone payments received from our marketing partners in 2002 and any revenue recognition from potential licensing and milestone payments that we may receive from our current or future partners in 2003. With the approval of Eligard 30-mg four-month product in February 2003, we anticipate a milestone payment of \$6.0 million from Sanofi upon first commercial sales of this product. All milestone and licensing payments received are deferred and recognized over the remaining term of the related agreement.

Cost of sales was \$3.3 million for the year ended December 31, 2002 compared to \$1.7 million for the year ended December 31, 2001, representing a 94% increase. The increase in cost of sales primarily relates to the increase in product sales as a result of our Eligard 7.5-mg one-month and Eligard 22.5-mg three-month products. We expect that cost of sales will increase in 2003 with the expected increase in sales of our Eligard one- and three-month products and the anticipated commercial launch of our Eligard 30-mg four-month product in the first half of 2003.

Research and development expenses, excluding research and development licensing fees, for the year ended December 31, 2002 were \$32.7 million compared to \$25.6 million for the year ended December 31, 2001 representing a 28% increase. An increase of \$4.4 million was related to progress in the development of our generic dermatology products under the Geneva agreement. An increase of \$1.9 million was related to progress in the development of our Atrisone acne product under the Fujisawa agreement. GHRP-1 research and development activities increased \$1.5 million for 2002. Increases of \$1.3 million, \$1.1 million and \$0.8 million were related to research activities for our sumatriptan, octreotide, and various partner-funded projects, respectively. Additionally, an increase of \$1.1 million was directed to development

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activities to identify potential pipeline projects using our Atrigel and BEMA technologies. These increases were offset by a decrease of \$2.6 million as a result of the completion of clinical studies on our one-, three- and four-month Eligard products and to a decrease in research and development of \$1.6 million on joint venture activities. The two projects under this joint venture arrangement are currently under review for further development. Further, dental product and other research and development activities decreased \$0.8 million. While future research and development expense recognized in conjunction with our joint venture is uncertain at this time, we expect that partner-funded research and development expenses will increase for 2003 as we continue to develop products under collaborative agreements, as new products are developed and as new agreements are entered into. However, we expect that research and development expenses for internally funded activities will decrease in 2003 due to our current focus on completion of Atrisone clinical studies and development of generic dermatology products. Following completion of these programs, we expect internal product development expenses to increase again in the foreseeable future.

Research and development licensing fees for the year ended December 31, 2002 were \$0 compared to \$3.0 million for the year ended December 31, 2001, which represents licensing fees paid by us of \$2.5 million to Tulane University for GHRP-1 and \$0.5 million to Amarillo BioSciences for rights to an oral low-dose interferon product. These fees were expensed as incurred, as the technology licensed was for research and development purposes with no future alternative uses. We did not incur any licensing fees during the year ended, December 31, 2002. We may, in the future, incur additional costs for the acquisition of licenses; however, we cannot predict if or when that may happen or what the cost may be.

Administrative and marketing expenses, excluding stock option compensation, for the year ended December 31, 2002 were \$9.8 million compared to \$5.5 million for the year ended December 31, 2001, representing a 78% increase. This increase was primarily related to the addition of administrative personnel of \$0.5 million, performance-based compensation to key executive personnel of \$0.6 million, costs associated with potential acquisitions of \$0.5 million, increased public relations expense of \$0.2 million, increased European sales and marketing efforts of \$1.9 million, and write-downs of accounts receivable balances of \$0.6 million. We expect that our administrative and marketing expenses may increase for the foreseeable future as we continue to grow and additional support is required.

Administrative stock option compensation for the year ended December 31, 2002 was \$1.3 million, as compared to \$2.1 million for the year ended December 31, 2001, representing a 38% decrease. A charge of \$1.3 million for the year ended December 31, 2002 was recognized in connection with the retirement of an executive officer. For the year ended December 30, 2001, we granted a \$2.0 million non-qualified stock option grant to our Chief Executive Officer. The options were fully vested on the date of the grant and expire on August 6, 2011. We may, in the future, incur additional costs for stock compensation and performance-based compensation activities; however, we cannot predict if or when that may happen or what the cost may be.

We recognized a loss of \$1.0 million for our 80.1% equity share in the loss of Transmucosal Technologies, or joint venture with Elan, for the year ended December 31, 2002, compared to a loss of \$3.3 million for the year ended December 31, 2001, representing a 70% decrease. The decrease was primarily related to the completion of feasibility work performed through the joint venture. The two joint venture projects are currently under review for further development, and as a result, the amount of future recognition of equity in loss of our joint venture is uncertain at this time.

Investment income for the year ended December 31, 2002 was \$4.8 million compared to \$4.0 million for the year ended December 31, 2001, representing a 20% increase. The increase was primarily the result of an increase in our average cash and cash equivalents and our marketable securities for the year ended December 31, 2002 compared to the average balances for the year ended December 31, 2001. This increase was offset partially by lower interest rates on investments in 2002 as compared to 2001. In 2002, the average rate earned on our portfolio was 3.4% compared to 4.1% in 2001. We expect net investment income to decrease in 2003 as a result of expected lower average cash and cash equivalents and marketable securities balances, and expected lower interest rates for marketable securities in 2003 compared to 2002.

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Loss on sale and write-down of marketable securities for the year ended December 31, 2002 was \$1.1 million compared to \$0.8 million for the year ended December 31, 2001. This increase was primarily due to the sale of our \$0.8 million principal amount of WorldCom, Inc. Senior Corporate Notes in May 2002 for proceeds of \$0.4 million which resulted in a loss on sale of marketable securities of \$0.4 million. In June 2002, we incurred a \$0.7 million charge for a write-down of our remaining position in WorldCom Senior Corporate Notes, principal value of \$0.8 million, upon WorldCom's bankruptcy filing. The market value of our WorldCom Senior Notes as of December 31, 2002 was \$0.2 million. For the year ended December 31, 2001, we recorded an impairment charge of \$0.8 million on our \$1.0 million Enron corporate notes, upon Enron's bankruptcy filing. The market value of our Enron notes as of December 31, 2002 was \$0.1 million. We may incur losses on the sale or writedown of our marketable securities in the future; however, we cannot predict when, or if, that will occur, nor can we predict amounts. At December 31, 2002, we had a net unrecognized gain of \$1.5 million in our investment portfolio consisting of \$1.7 million in aggregate unrecognized gains offset by \$0.2 million in the aggregate unrealized losses.

Interest expense for the year ended December 31, 2002 was \$79,000 compared to \$0.8 million for the year ended December 31, 2001. This decrease was due to the exchange of 279,931 shares of our common stock for \$5.2 million in principal amount of our 7% Convertible Subordinated Notes since the period ended December 31, 2001. Interest expense is expected to decrease in 2003 due to the full conversion of our 7% Convertible Subordinated Notes as of May 2002.

During the year ended December 31, 2002, we exchanged 279,931 shares of our common stock to extinguish \$5.2 million in outstanding principal amount of our 7% Convertible Subordinated Notes. Of the 279,931 shares of our common stock issued, 274,014 shares were valued at the conversion price of \$19.00 per share and the remaining 5,917 shares were valued at \$21.09 per share, the closing market price of our common stock on the date of exchange. As a result of the conversions, we recognized an extraordinary gain of \$30,000, for the write-off of \$80,000 of pro rata deferred finance charges net of \$110,000 interest expense payable eliminated as a result of these exchanges. Debt conversion expense of approximately \$125,000 was recognized for the year ended December 31, 2002 related to the additional 5,917 shares valued at \$21.09 per share. As of December 31, 2002 and December 31, 2001, the outstanding principal amount of the 7% Convertible Subordinated Notes was \$0 and \$5.2 million, respectively. In comparison, during the year ended December 31, 2001, we exchanged 1,725,735 shares of our common stock for \$31.0 million of our 7% Convertible Subordinated Notes. As a result of these exchanges, we recognized non-cash charges for debt conversion expense of \$2.2 million for extraordinary loss on extinguished debt in 2001. As a result of converting the remaining outstanding principal balance on the 7% Convertible Subordinated Notes in 2002, no interest expense or payments, no debt conversion expense and no extraordinary gain or loss will be recognized in 2003 for these notes.

We issued shares of our Series A Convertible Exchangeable Preferred Stock to Elan in July 2000 in connection with the formation of Transmucosal Technologies Ltd. Related to this issuance, we recognized \$0.9 million for accretion of dividends on the Series A Preferred Stock for the year ended December 31, 2002 compared to \$0.9 million for accretion of dividends for the year ended December 31, 2001. Additionally, a beneficial conversion charge of \$0.3 million for the year ended December 31, 2001 was recognized as a result of our common stock price being in excess of the preferred stock conversion price of \$19.00 at the time the preferred shares were issued in 2001. We expect that the charge for accretion of dividends on the Series A Preferred Stock will increase in the future as the amount of the preferred stock increases as a result of issuing preferred stock for accretion of dividends. However, we cannot predict if we will incur any future beneficial conversion charges, since the charges are dependent on the price of our common stock being in excess of the \$19.00 Series A Preferred Stock conversion price at the time the preferred stock is issued for the accretion of dividends.

For the reasons described above, we recorded a consolidated net loss applicable to common stock of \$19.1 million, or \$0.95 per share, for the year ended December 31, 2002 compared to a consolidated net loss applicable to common stock of \$26.7 million, or \$1.63 per share, for the year ended December 31, 2001.

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***Years Ended December 31, 2001 and 2000***

Total revenue for the year ended December 31, 2001 were \$15.8 million compared to \$10.0 million for the year ended December 31, 2000, representing a 58% increase.

Net sales and royalty revenue were \$3.8 million for the year ended December 31, 2001 compared to \$6.2 million for the year ended December 31, 2000, representing a 39% decrease. The decrease of \$2.4 million was primarily related to our legal dispute with Block that was settled in August, 2001 and the transition of dental product licensing rights to CollaGenex as our new U.S. marketing partner. As a result of the legal settlement, we paid Block \$0.7 million for the return of dental products. We subsequently licensed the U.S. marketing rights of our dental products to CollaGenex in August 2001. CollaGenex commenced U.S. marketing of Atridox and Atrisorb FreeFlow in November 2001. In 2001, \$0.8 million of net sales were to Block and \$0.5 million of net sales were to CollaGenex, compared to \$2.8 million of net sales to Block in 2000. Additionally, sales of our Doxirobe Gel periodontal disease treatment product for companion animals decreased by \$0.7 million as a result of a large product shipment to Pharmacia in late 2000, resulting in an inventory level to sustain Pharmacia's 2001 Doxirobe sales.

Contract research and development revenue represents revenue we earned from unaffiliated third parties and from our joint venture with Elan for performing contract research and development activities using our various patented drug delivery technologies. Contract research and development revenue was \$8.2 million for the year ended December 31, 2001 compared to \$2.0 million for the year ended December 31, 2000, representing a 310% increase. This increase is primarily related to the recognition of \$4.1 million in revenue for the year ended December 31, 2001 compared to \$0.3 million in revenue for the comparable period for oncology and pain management research activities associated with our joint venture, Transmucosal Technologies. We commenced research and development activities for Transmucosal Technologies in October 2000. Additionally, research activities funded by our collaborative partners, including Pfizer, Fujisawa and Geneva, increased by \$2.3 million.

Licensing, marketing rights and milestone revenue for the year ended December 31, 2001 was \$3.8 million compared to \$1.9 million for the year ended December 31, 2000, representing a 100% increase. This increase is primarily related to the recognition of \$1.2 million in licensing fee and milestone revenue for our Eligard products under the Sanofi-Synthelabo and MediGene agreements for the year ended December 31, 2001. Recognition of licensing revenue commenced in January 2001 for Sanofi and in April 2001 for MediGene. Additionally, milestone revenue recognition from Sanofi for FDA acceptance of our NDA filings of Eligard 7.5-mg one-month and Eligard 22.5-mg three-month commenced in May 2001 and in November 2001, respectively. Additional revenue of \$0.7 million was recognized for the year ended December 31, 2001 due to the net effects related to the amendment of the Block agreement and the subsequent CollaGenex agreement. The net effects of the amendment of the Block agreement will be recognized as revenue over the term of the amended agreement and the transfer of marketing rights to CollaGenex will be recognized as revenue over the term of the agreement using the straight-line method.

Cost of sales was \$1.7 million for the year ended December 31, 2001 compared to \$2.6 million for the year ended December 31, 2000, representing a 35% decrease. This decrease in cost of sales correlates to the decline in product sales.

Research and development expenses for the year ended December 31, 2001 were \$25.6 million compared to \$16.7 million for the year ended December 31, 2000, representing a 53% increase. An increase of \$3.0 million was due to the rapid progress in the development of our Eligard for prostate cancer treatment products and the NDA filings of our Eligard 7.5-mg one-month and 22.5-mg three-month products. An increase of \$2.0 million was related to oncology and pain management research activities with our joint venture, Transmucosal Technologies, which commenced research and development activities in October 2000. Additionally, \$3.9 million of the increase was related to our research and development activities for Atrisorb, various dermatology products under the Geneva Pharmaceuticals agreement and GHRP-1.

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Research and development licensing fees for the year ended December 31, 2001 was \$3.0 million. This expense represents licensing fees paid by us of \$2.5 million to Tulane University for GHRP-1 and \$0.5 million to Amarillo BioSciences for oral low-dose interferon. These fees were expensed as incurred, as the technology licensed was for research and development purposes with no future alternative uses. We did not incur any licensing fees in 2000.

Administrative and marketing expenses for the year ended December 31, 2001 were \$5.5 million compared to \$4.3 million for the year ended December 31, 2000, representing a 28% increase. The increase was primarily related to an increase in legal expenses associated with general business planning and activities, including fees for patent/trademark searches and the dispute with Block. The increase also represents personnel additions in business development and accounting.

Administrative stock option compensation for the year ended December 31, 2001 was \$2.1 million, as compared to \$0.1 million for the year ended December 31, 2000. The increase was primarily due to a \$2.0 million non-qualified stock option grant to our Chief Executive Officer in August 2001. The non-qualified stock options were fully vested on the date of the grant and expire in August 2011. The remaining increase was for non-qualified stock options granted to non-employees for services rendered.

We recognized a loss of \$3.3 million for our 80.1% equity share in the loss of Transmucosal Technologies during 2001 as compared to \$12.2 million in 2000, representing a 73% decrease. The joint venture was established in July 2000 and recorded a one-time, non-cash charge of \$15.0 million in July 2000, for an exclusive license to use Elan's nanoparticulate drug delivery technology. This licensing fee was recorded as a charge to research and development expense by Transmucosal Technologies as it was acquired for research and development with no future alternative use. We do not expect that Transmucosal Technologies will incur additional licensing fees in the future. The loss in 2001 represents our share of the joint venture's net loss, which was generated primarily through research and development activities.

Investment income for the year ended December 31, 2001 was \$4.0 million compared to \$2.1 million for the year ended December 31, 2000, representing a 90% increase. The increase was primarily the result of an increase in our average cash and cash equivalents and our marketable securities for the year ended December 31, 2001 compared to the average balances for the year ended December 31, 2000. The increase in our average cash and investment balances in 2001 was primarily due to two underwritten public common stock offerings, licensing fees and milestone payments under our agreements with Sanofi, MediGene and Fujisawa. The increase was offset partially by lower interest rates on investments in 2001 as compared to 2000. In 2001, the average rate earned on our portfolio was 4.1% compared to 5.8% in 2000.

Loss on sale and write-down of marketable securities for the year ended December 31, 2001 was \$0.8 million compared to \$0.2 million for the year ended December 31, 2000. This increase was primarily due to an impairment charge in the fourth quarter of 2001 of \$0.8 million on our \$1.0 million Enron corporate notes. The market value of our Enron notes as of December 31, 2001 was \$0.2 million, which represents the approximate market value of the notes after the bankruptcy filing by Enron.

Interest expense for the year ended December 31, 2001 was \$0.8 million compared to \$2.6 million for the year ended December 31, 2000, representing a 69% decrease. The reduction in interest expense was primarily the result of a series of private transactions involving the exchange of shares of our common stock for \$31.0 million in principal amount of our 7% Convertible Subordinated Notes throughout the year ended December 31, 2001.

During the year ended December 31, 2001, we exchanged 1,725,735 shares of our common stock to extinguish \$31.0 million of our 7% Convertible Subordinated Notes. As a result of these exchanges, we recognized non-cash charges for debt conversion expense of \$2.2 million and \$0.3 million for extraordinary loss on extinguished debt in 2001.

Effective in the fiscal fourth quarter of 2000, we changed our method of accounting for nonrefundable technology access fees and milestone payments to recognize such payments as revenue over the term of the related agreements. The change in accounting principle is based on guidance provided in SAB No. 101.



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Prior to the year 2000, we recognized \$24.1 million for nonrefundable technology access fees and milestone payments as revenue when received and when we fulfilled all contractual obligations relating to the fees and milestone payments. We recorded \$20.6 million cumulative effect for this change in accounting principle that was reported as a charge in the first quarter of 2000.

We issued shares of our Series A Convertible Exchangeable Preferred Stock to Elan in July 2000 in connection with the formation of Transmucosal Technologies. Related to this issuance, we recognized \$0.9 million for accretion of dividends on the Series A Preferred Stock and a beneficial conversion charge of \$0.3 million for the year ended December 31, 2001 compared to \$0.4 million for accretion of dividends for the year ended December 31, 2000.

For the reasons described above, we recorded a consolidated net loss applicable to common stock of \$26.7 million, or \$1.63 per share, for the year ended December 31, 2001 compared to a consolidated net loss applicable to common stock of \$47.4 million, or \$3.99 per share, for the year ended December 31, 2000. The \$12.2 million equity in loss of our joint venture and the \$20.6 million cumulative effect from a change in accounting principle during 2000 were the primary factors attributable to the change in consolidated net loss applicable to common stock between periods.

## **Liquidity and Capital Resources**

As of December 31, 2002, we had cash and cash equivalents of \$30.7 million, marketable securities (at fair value) of \$81.8 million, net accounts receivable of \$6.1 million, inventories of \$8.7 million and other current assets of \$2.9 million, for total current assets of \$130.2 million. We had accounts payable of \$7.3 million, short-term deferred revenue of \$7.9 million and other current liabilities of \$1.0 million, for total current liabilities of \$16.2 million, which resulted in working capital of approximately \$114.0 million.

During the year ended December 31, 2002, net cash used in operating activities was \$7.2 million. This was primarily the result of the net loss for the year ended December 31, 2002 of \$18.2 million, adjusted for certain non-cash expenses, and changes in operating assets and liabilities as set forth in the consolidated statements of cash flows. We recognized a non-cash charge of \$1.3 million for the vesting of incentive stock options in conjunction with the retirement of an executive officer in the first quarter of 2002. Additionally, we recorded a loss on sale and write-down of marketable securities of \$1.1 million, primarily as a result of the sale of half of our \$1.5 million principal amount of WorldCom Senior Notes and the subsequent write-down of \$0.7 million on the remaining half of the WorldCom Senior Notes upon WorldCom's bankruptcy filing in July 2002. Further, we recognized non-cash charges of \$3.2 million of depreciation and amortization expense and \$1.0 million for our equity in the loss of Transmucosal Technologies. We recognized a cash inflow from the advanced receipt of milestone payments, licensing fees and certain contract research and development payments of \$18.1 million, partially offset by amortization of deferred revenue of \$9.4 million. Cash flow increased with the increase of our accounts payable of \$3.7 million primarily related to our plant expansion costs and related equipment purchases. Significant uses of cash included: (1) \$5.3 million of increased inventories primarily related to the build up of inventory of the Eligard and generic dermatology products, and the anticipated commercial launch of our Eligard 30-mg four-month product, (2) \$1.9 million of increased accounts receivable primarily related to other commercial accounts and (3) \$1.7 million of increased prepaid expenses and deposits primarily related to prepayments on certain research and development projects, insurance and various operating agreements.

Net cash used in investing activities was \$6.9 million during the year ended December 31, 2002. This was primarily due to \$6.1 million used for our plant expansion and the purchase of equipment related to the expansion. Additionally, \$3.5 million was used for the acquisition of equipment and leasehold improvements. Cash used in investing activities also included payments for patents and trademarks of \$0.8 million, \$0.9 million for deposits primarily related to manufacturing equipment to be acquired in connection with our plant expansion, and \$1.5 million for the funding of our 80.1% portion of the joint venture expenditures. Partially offsetting the use of cash for the above investing activities included the net effects of \$69.1 million for proceeds received from the maturity and sale of marketable securities

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available-for-sale less \$63.3 million used to fund the purchases of various marketable securities available-for-sale.

During the third quarter of 2002, we sold various corporate note securities and subsequently reinvested the proceeds in high rated corporate notes, U.S. government securities, and diversified bond mutual funds to minimize our exposure to credit risk.

Net cash used in financing activities was \$6.0 million during the year ended December 31, 2002. This was primarily the result of the repurchase of \$9.2 million of our common stock in the open market, offset by proceeds of \$3.2 million from the issuance of common stock. In September 2001, our Board of Directors approved a stock repurchase program to acquire up to \$5.0 million of our common stock. On July 23, 2002, our Board of Directors approved an amendment to the program to increase the total amount of common stock that can be purchased under the program from a maximum of \$5.0 million to a maximum of \$15.0 million. In November 2002, our Board of Directors amended our stock repurchase program to provide that we may acquire up to a maximum of \$20.0 million of our common stock in the open market or in privately negotiated transactions under this program. The program terminates on the earlier of the date that we have repurchased \$20.0 million of our common stock or December 31, 2003. Since the inception of the stock repurchase program on September 17, 2001 through December 31, 2002, we have repurchased a total of 657,700 shares of our common stock in the open market for \$10.7 million, or an average price per share of \$16.33. During the year ended December 31, 2002, we repurchased 580,200 shares of our common stock in the open market for \$9.2 million, or an average price per share of \$15.82 under the program. As of December 31, 2002, \$9.3 million remains available to repurchase our common stock under the stock repurchase program.

In November 1997, we issued \$50.0 million in principal amount of our 7% Convertible Subordinated Notes. Interest was payable semi-annually and the notes were due to mature on December 1, 2004. The notes were convertible, at the option of the holder, into common stock at a conversion price of \$19.00 a share, subject to adjustment in certain events. The notes were redeemable, in whole or in part, at our option at any time on or after December 5, 2000. In March 2002, we announced the redemption date of May 15, 2002 for the remaining outstanding notes. Prior to the redemption date, the remaining notes were converted into our common stock valued at a price of \$19.00 per share. During the year ended December 31, 2002 we exchanged 279,931 shares of our common stock for \$5.2 million in principal amount of our 7% Convertible Subordinated Notes. Of the 279,931 shares of our common stock issued, 274,014 shares were valued at the conversion price of \$19.00 per share and the remaining 5,917 shares were valued at the conversion price of \$21.09 per share, the closing market price of our common stock on date of exchange. As a result, we recognized an extraordinary gain of \$30,000, for the write-off of \$80,000 of pro rata deferred finance charges net of \$110,000 interest expense payable eliminated as a result of these exchanges. Debt conversion expense of approximately \$125,000 was recognized for the year ended December 31, 2002 related to the additional 5,917 shares valued at \$21.09 per share. As of December 31, 2002 and December 31, 2001, the outstanding principal amount of the 7% Convertible Subordinated Notes was \$0 and \$5.2 million, respectively.

In July 2000, we formed Transmucosal Technologies Ltd., a joint venture, with Elan to develop and commercialize oncology and pain management products. Subject to the satisfaction of certain conditions, Elan has agreed to loan us up to \$8.0 million under a convertible promissory note agreement in support of our 80.1% share of the joint venture's research and development costs. The note has a six-year term, will accrue interest at 7% per annum, compounded semi-annually and added to principal, and is convertible at Elan's option into our common stock at a \$14.60 conversion price. As of December 31, 2002, we had not drawn any amounts under the note. We are required to fund our 80.1% share of the joint venture's obligations, and this cash funding totaled \$1.5 million for the year ended December 31, 2002 and \$2.7 million for the year ended December 31, 2001. The two joint venture projects are currently under review for further development and the outcome of the review may effect future funding obligations.

We have a revolving line of credit with a bank that expires on May 20, 2003. Under the terms of the line of credit, we may borrow up to \$1.0 million. Borrowings under the line bear interest at the prime rate

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and are subject to financial covenants requiring us to maintain certain levels of net worth and liquidity. Additionally, in June 2002, we established a second \$1.0 million bank line of credit that expires on June 15, 2003. Borrowings under the line bear interest at a rate of 5.25%. As of December 31, 2002, there was no obligation outstanding under either of these credit agreements.

We have historically funded our operations through debt and equity offerings, payments received for licenses, milestones and research and development support under contractual arrangements and, to a lesser extent, product sales and royalties. We anticipate future funding of our operations to be achieved through continued licensing fees, milestone payments and net sales and royalties of our products. At December 31, 2002, we had \$30.7 million of cash and cash equivalent investments and \$81.8 million of marketable securities available-for-sale (at fair value) to fund future operations and capital requirements. Our marketable securities available-for-sale includes primarily U.S. government bonds, diversified bond mutual funds and investment grade corporate notes. Our portfolio of corporate notes is diversified and, under our policy, we only invest in investment grade corporate notes. We believe the quality of the notes we hold and the diversity of our portfolio significantly mitigates our credit and market risks; however from time to time we have experienced investment losses as some of the issuers of our investment grade corporate notes have declared bankruptcy, such as Enron and WorldCom. We believe that we have adequate liquidity and capital resources to fund our operations and capital requirements for the foreseeable future. However, we may have to raise additional funds to complete the development of our technologies as discussed below.

At December 31, 2002 we had available for Federal income tax purposes, net operating loss carryforwards of \$92.4 million and \$3.8 million in research and development tax credits, which expire through 2022. Our ability to utilize our purchased net operating loss acquired with the acquisition of ViroTex, alternative minimum tax, and research and development credit carryforwards is subject to an annual limitation in future periods. This is pursuant to the change in ownership rules under Section 382 of the Internal Revenue Code of 1986, as amended.

We do not have any financial partnerships with unconsolidated entities, such as entities often referred to as structured finance or special purpose entities, which are often established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. Accordingly, we are not exposed to any financing, liquidity, market or credit risk that could arise if we had such relationships.

## **Future Capital Requirements**

Our long-term capital expenditure requirements will depend on numerous factors, including:

- the progress of our research and development programs,
- the time required to file and process regulatory approval and applications,
- the development of our commercial manufacturing facilities,
- the potential for expenses related to the implementation of a specialty sales force,
- our ability to obtain additional licensing arrangements, and
- the demand for our products.

We expect to continue to incur substantial expenditures for research and development, testing, regulatory compliance, market development in European and other foreign countries, possible repurchases of our common stock and to hire additional management, scientific, manufacturing and administrative personnel. We will also continue to expend a significant amount of funds for our ongoing clinical studies. Depending on the results of our research and development activities, we may determine to accelerate or expand our efforts in one or more proposed areas and may, therefore, require additional funds earlier than previously anticipated. We believe that the existing cash and cash equivalent assets, in addition to our marketable security resources will be sufficient to fund our operations for the foreseeable future. However, underlying assumed levels of revenue and expense may not prove to be accurate.

**Table of Contents***Research and Development*

The following table summarizes research and development activities funded by our collaborators, as well as, research and development activities funded by us for the years ended December 31, 2000, 2001 and 2002, including research and development costs inception-to-date and estimated completion dates and costs (in thousands):

<b>Technology</b>	<b>Expenses 2000</b>	<b>Expenses 2001</b>	<b>Expenses 2002</b>	<b>Expenses Inception-to-Date</b>	<b>Funded Expenses Inception-to-Date</b>	<b>Anticipated Completion (to market)</b>		<b>Anticipated Costs to Completion (to market)</b>
Atrigel	\$ 10,845	\$ 13,727	\$ 13,011	\$ 110,521	\$ 9,001	2003	2009	\$ 70,000
SMP	3,090	4,604	6,547	16,568	5,314		2005	25,000
BEMA	259	2,397	2,252	5,461	1,020	2006	2007	10,000
Other	2,541	4,907	10,929	33,898	10,928	2003	2007	30,000
<b>Total</b>	<b>\$ 16,735</b>	<b>\$ 25,635</b>	<b>\$ 32,739</b>	<b>\$ 166,448</b>	<b>\$ 26,263</b>	<b>2003</b>	<b>2009</b>	<b>\$ 135,000</b>
Funded	\$ 1,921	\$ 10,626	\$ 18,721					
Not Funded	14,814	15,009	14,018					
<b>Total</b>	<b>\$ 16,735</b>	<b>\$ 25,635</b>	<b>\$ 32,739</b>					

The predominate product lines included under the Atrigel technology are the Eligard and dental products which comprise 30% and 61%, respectively, of the expenses incurred to date. Recently, however, the Eligard products comprised more of the research and development effort with 68%, 64% and 59% of the 2000, 2001, and 2002 Atrigel expenses, respectively. As dental products have moved into market, expenses to support them have stabilized and comprised 25%, 10% and 7% of the 2000, 2001, and 2002 Atrigel expenses, respectively. Of the expenses funded by third parties, 18% of funds received were to support the dental products, 39% of funds have come recently to support the Eligard products domestically as well as internationally, and 43% of funds have come from direct support of research contracts with various companies.

The Atrisine acne product represents 100% of expenses and funding under the SMP technology.

Under the BEMA technology, approximately 52% of expenses incurred to date relate to the development of two products through our joint venture with Elan and approximately 100% of funding for BEMA research and development has come from the joint venture.

Other research and development expenses incurred to date represent efforts to introduce additional products into our pipeline. Expenses related to develop generic dermatology products are also included in this category and represents 31% of expenses incurred to date and 44% of funding.

*Series A Preferred Stock*

The Series A Convertible Exchangeable Preferred Stock is convertible at any time after July 2002, at Elan's option, into shares of our common stock at a price equivalent to \$18 per share. Elan has the option to exchange this preferred stock for a 30.1% interest in the joint venture. This exchange option will terminate if the preferred stock is converted into our common stock unless we cause the conversion. We must redeem this preferred stock in July 2006 for either cash or shares of our common stock, at our option, in an amount or value equal to the liquidation preference of the preferred stock. We cannot predict if the preferred stock will be exchanged for common stock or cash.

*Plant Expansion*

## Edgar Filing: ATRIX LABORATORIES INC - Form 10-K

In April 2002, we announced our plans to expand our manufacturing and laboratory facilities to support current and future projects. The current 26,000 square foot facility will be expanded to 58,000 square feet. Construction costs are estimated to be approximately \$5.9 million with additional expenditures to be incurred as needed for equipment. As of December 31, 2002, approximately

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\$5.6 million has been spent on construction costs and \$1.3 million has been spent on related equipment and equipment deposits.

*Operating Leases*

The following table summarizes our future contractual commitments, which consist of operating leases. At December 31, 2002, our future payments under our non-cancelable operating leases are as follows (amounts in thousands):

Years Ended December 31,	Minimum Rental Commitments
2003	\$ 581
2004	484
2005	449
2006	190
2007	7
	—
Total	\$1,711

*Common Stock Repurchases*

As of December 31, 2002, \$9.3 million remains available to repurchase our common stock under the stock repurchase program. We will repurchase stock under this program at times and prices as management determines are most advantageous to us. We cannot predict if, or when, we will repurchase the remaining amounts available under the stock repurchase program.

*Other Future Capital Requirements*

We believe that it is advisable to augment our cash to fund all of our activities, including potential product acquisitions. Therefore, we will consider raising cash whenever market conditions are favorable. Such capital may be raised through additional public or private financing, as well as collaborative relationships, borrowings and other available sources. In addition, in the course of our business, we evaluate products and technologies held by third parties which, if acquired, could result in our development of product candidates or which complement technologies that we are currently developing. We expect, from time to time, to be involved in discussions with other entities concerning our potential acquisition of rights to additional pharmaceutical and/or biotechnology products. If we acquire such products or third-party technologies, we may find it necessary or advisable to obtain additional funding.

**Impact of Inflation**

Although it is difficult to predict the impact of inflation on our costs and revenues in connection with our products, we do not anticipate that inflation will materially impact our costs of operation or the profitability of our products when marketed.

**Recent Accounting Pronouncements**

In June 2001, SFAS No. 143, *Accounting for Asset Retirement Obligations* was issued by the Financial Accounting Standards Board (FASB). SFAS No. 143 addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs and applies to all entities. It applies to legal obligations associated with the retirement of long-lived assets that result from the acquisition, construction, development and (or) the normal operation of a long-lived asset, except for certain obligations of lessees. We will adopt SFAS No. 143 on January 1, 2003. The adoption of this statement is not expected to have a material impact on our consolidated financial position or results of operations.

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In April 2002, SFAS No. 145, *Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections* was issued by the FASB. SFAS No. 145 rescinds FASB Statement No. 4, *Reporting Gains and Losses from Extinguishment of Debt*, and an amendment of that Statement, FASB Statement No. 64, *Extinguishments of Debt Made to Satisfy Sinking-Fund Requirements*. This Statement also rescinds FASB Statement No. 44, *Accounting for Intangible Assets of Motor Carriers*. This Statement amends FASB Statement No. 13, *Accounting for Leases*, to eliminate an inconsistency between the required accounting for sale-leaseback transactions and the required accounting for certain lease modifications that have economic effects that are similar to sale-leaseback transactions. This Statement also amends other existing authoritative pronouncements to make various technical corrections, clarify meanings, or describe their applicability under changed conditions. We will adopt SFAS No. 145 in the first quarter of 2003, at which time the comparative financial statements will be restated to reclassify the extraordinary gain or loss on extinguishment of debt to be included in loss from continuing operations.

In August 2002, SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* was issued by the FASB. SFAS No. 146 addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force Issue No. 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in Restructuring)*. SFAS No. 146 requires that a liability for a cost associated with an exit or disposal activity is to be recognized when the liability is incurred. The provisions of SFAS No. 146 are effective for exit or disposal activities that are initiated after December 31, 2002. The adoption of this statement is not expected to have a material impact on our consolidated financial position or results of operations.

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*. This statement amends SFAS No. 123, *Accounting for Stock-Based Compensation*, to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based compensation. It also amends the disclosure provisions of that statement and requires disclosure of the pro forma effect in interim financial statements. SFAS No. 148 is effective for our fiscal year ended December 31, 2002. We do not currently plan to change to the fair value method of accounting for its stock-based compensation; therefore, we anticipate that the adoption of this statement will not have a material impact on our consolidated financial position or results of operations.

In November 2002, the FASB issued Interpretation No. 45 (FIN 45), *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*. FIN 45 requires that a liability be recorded in the guarantor's balance sheet upon issuance of a guarantee. FIN 45 also requires additional disclosures about the guarantees an entity has issued, including a rollforward of the entity's product warranty liabilities. We will apply the recognition provisions of FIN 45 prospectively to guarantees issued or modified after December 31, 2002. The disclosure requirements are effective for our financial statements for the year ended December 31, 2002. The adoption of FIN 45 is not expected to have a material impact on our consolidated financial position or results of operations.

In January 2003, the FASB issued Interpretation No. 46 (FIN 46), *Consolidation of Variable Interest Entities*. FIN 46 provides guidance on how to identify a variable interest entity (VIE) and determine when the assets, liabilities, and results of operations of a VIE need to be included in a company's consolidated financial statements. FIN 46 also requires additional disclosures by primary beneficiaries and other significant variable interest holders in a VIE. The provisions of FIN 46 are effective immediately for all VIEs created after January 31, 2003. For VIEs created before February 1, 2003, the provisions of FIN 46 must be adopted at the beginning of the first interim or annual reporting period beginning after June 15, 2003. The adoption of FIN 46 is not expected to have a material impact on our consolidated financial position or results of operations.

In November 2002, the Emerging Issues Task Force (EITF) issued EITF Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*. EITF Issue No. 00-21 addresses how

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to determine whether a revenue arrangement involving multiple deliverables contains more than one unit of accounting for the purposes of revenue recognition and how the revenue arrangement consideration should be measured and allocated to the separate units of accounting. EITF Issue No. 00-21 applies to all revenue arrangements that we enter into after June 30, 2003. We have not yet determined the impact, if any, that EITF Issue No. 00-21 will have on our consolidated financial position and results of operations.

**Item 7A. Quantitative and Qualitative Disclosures Concerning Market Risks.**

We own financial instruments that are sensitive to market risks as part of our investment portfolio of cash equivalents and marketable securities. The investment portfolio is primarily used to preserve our capital until it is required to fund operations, including our research and development activities. None of these market-risk sensitive instruments are held for trading purposes and we do not own derivative financial instruments in our portfolio. Our investment portfolio contains instruments that are primarily subject to interest rate risk and our equity investment in CollaGenex is subject to equity price risks.

As of December 31, 2002, our investment in cash, cash equivalents and marketable securities available-for-sale was approximately \$112 million. These current assets are invested primarily in cash funds, high rated commercial paper, U.S. government and agency investments, U.S. corporate bonds and notes, and mutual funds. The mutual funds may invest in foreign securities, which may be unfavorably affected by interest-rate and currency-exchange-rate changes as well as by market, economic and political conditions of the countries where investments are made. The funds may invest in mortgage-backed securities, which are subject to unique interest and maturity risks. When interest rates fall, mortgages may be paid early through refinancing, which may shorten the expected maturity of these securities. Alternatively, when interest rates rise, mortgages are not likely to be paid early, which may lengthen the expected maturity of these securities. Therefore, during times of fluctuating interest rates, these factors may cause the value of mortgage-backed securities to increase or decrease more than those of other fixed-income securities.

**Interest Rate Risk**

Our investment portfolio includes fixed rate debt instruments that are primarily U.S. government and agency bonds and notes and corporate bonds and notes with maturity dates ranging from one to fifteen years. To mitigate the impact of fluctuations in cash flow, we maintain the majority of our debt instruments at fixed rates. The market value of these bonds and notes are subject to interest rate risk and could decline in value if interest rates increase. The portion maintained as fixed rate is dependent on many factors including judgments as to future trends in interest rates.

Our investment portfolio also includes mutual funds that invest in U.S. government and agency bonds, corporate bonds, mortgage-backed and asset-backed securities, and possibly foreign securities. The value of these mutual fund investments is also subject to interest rate risk, as well as maturity risks on mortgage-backed securities and possibly foreign market risks.

We regularly assess the above described market risks and have established policies and business practices to protect against the adverse effects of these and other potential exposures. Our investment policy restricts investments to U.S. government or government-backed securities, high-rated commercial paper and other high-rated investments only. By restricting our investments, management substantially mitigates losses due to the market and other factors. As a result, we do not anticipate any material losses in these investments, however, losses may still occur due to market, political and economic conditions.

For disclosure purposes, we use sensitivity analysis to determine the impacts that market risk exposures may have on the fair values of our debt and financial instruments. The financial instruments included in the sensitivity analysis consist of our cash equivalents, short-term and long-term debt instruments.

To perform a sensitivity analysis, we assess the fair values loss risk from the impact of hypothetical interest rate changes on market sensitive instruments. The fair values are computed based on the present



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value of future cash flows as impacted by the changes in the rates attributable to the market risk being measured. The discount rates used for the present value computations were selected based on market interest rates in effect at December 31, 2002. The fair values that result from these computations are compared with the fair values of these financial instruments at December 31, 2002. The differences in this comparison are the hypothetical gains or losses associated with each type of risk. The results of the sensitivity analysis at December 31, 2002 are as follows:

Interest Rate Sensitivity: A 10% decrease in the levels of interest rates, with all other variables held constant would result in an increase in the fair value of our financial instruments by \$0.4 million. A 10% increase in the levels of interest rates, with all other variables held constant would result in a decrease in the fair value of our financial instruments by \$0.4 million per year. We maintain a portion of our financial instruments, including long-term debt instruments of \$27.2 million at December 31, 2002, at variable interest rates.

The use of a 10% estimate is strictly for estimation and evaluation purposes only. The value of our assets may rise or fall by a greater amount depending on actual general market performances and the value of the individual securities we own.

## **Exchange Rate Risk**

We face foreign exchange rate fluctuations, primarily with respect to the British Pound and the Euro foreign currencies, as the financial results of our foreign subsidiaries are translated into United States dollars for consolidation. As exchange rates vary, these results, when translated may vary from expectations and adversely impact net income (loss) and overall profitability. The effect of foreign exchange rate fluctuation for the year ended December 31, 2002 was not material. Based on our overall foreign currency rate exposure at December 31, 2002, we do not believe that a hypothetical 10% change in foreign currency rates would materially affect our financial position.

## **Item 8. Financial Statements and Supplementary Data.**

Our consolidated financial statements required by Regulation S-X are attached to this Report. Reference is made to Item 15(a) and Page F-1 of this Report for an index to the consolidated financial statements.

## **Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.**

None.

## **PART III**

## **Item 10. Directors and Executive Officers of the Registrant.**

The information required by this item regarding our directors and officers and compliance with Section 16(a) of the Exchange Act is incorporated herein by reference to the sections entitled Election of Directors and Section 16(a) Beneficial Ownership Reporting in our definitive proxy statement for our annual stockholders meeting scheduled to be held on April 27, 2003.

## **Item 11. Executive Compensation.**

The information required by this item regarding executive compensation is incorporated herein by reference to the section entitled Executive Compensation in our definitive proxy statement for our annual stockholders meeting scheduled to be held on April 27, 2003.

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**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

The information required by this item regarding security ownership of certain beneficial owners and management and equity compensation plan information is incorporated herein by reference to the sections entitled Security Ownership of Certain Beneficial Owners and Management and Equity Compensation Plan Information in our definitive proxy statement for our annual stockholders meeting scheduled to be held on April 27, 2003.

**Item 13. Certain Relationships and Related Transactions.**

The information required by this item regarding certain relationships and related transactions is incorporated herein by reference to the section entitled Certain Relationships and Related Transactions in our definitive proxy statement for our annual stockholders meeting scheduled to be held on April 27, 2003.

**Item 14. Controls and Procedures.**

Within the 90 days prior to the filing of this report, we carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Our disclosure controls and procedures are designed with the objective of ensuring that information required to be disclosed in our reports filed under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures are effective in timely alerting them to material information required to be included in our periodic SEC reports. It should be noted that the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

There have been no significant changes in our internal controls or in other factors, which could significantly affect internal controls subsequent to the date of this evaluation.

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**PART IV**

**Item 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K.**

(a) Our following documents are filed as part of this Report:

1. Consolidated Financial Statements

Independent Auditors Report

Consolidated Balance Sheets December 31, 2002 and 2001

Consolidated Statements of Operations

Years Ended December 31, 2002, 2001, and 2000

Consolidated Statements of Changes in Shareholders Equity (Deficit)

Years Ended December 31, 2002, 2001, and 2000

Consolidated Statements of Cash Flows

Years Ended December 31, 2002, 2001, and 2000

Notes to the Consolidated Financial Statements

2. Consolidated Financial Statement Schedules

Schedules for which provision is made in the applicable regulations of the Securities and Exchange Commission have been omitted because they are not required under the related instructions or the information related is contained elsewhere in the consolidated financial statements.

3. Exhibits

The exhibits are set forth in the Exhibit Index.

(b) Reports on Form 8-K: We did not file any Current Reports on Form 8-K during the quarter ended December 31, 2002.

**Table of Contents****SIGNATURES**

Pursuant to the requirements of Section 13 and 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.

ATRIX LABORATORIES, INC.  
(Registrant)

Date: March 25, 2003

By: /s/ David R. Bethune

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David R. Bethune  
Chairman of the Board of Directors and  
Chief Executive Officer

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/ David R. Bethune</u> David R. Bethune	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)	March 25, 2003
<u>/s/ Brian G. Richmond</u> Brian G. Richmond	Chief Financial Officer and Secretary (Principal Financial and Accounting Officer)	March 25, 2003
<u>/s/ Nicolas G. Bazan</u> Nicolas G. Bazan	Director	March 25, 2003
<u>/s/ H. Stuart Campbell</u> H. Stuart Campbell	Director	March 25, 2003
<u>/s/ Dr. D. Walter Cohen</u> Dr. D. Walter Cohen	Director	March 25, 2003
<u>/s/ Sander A. Flaum</u> Sander A. Flaum	Director	March 25, 2003
<u>/s/ C. Rodney O Connor</u> C. Rodney O Connor	Director	March 25, 2003
<u>/s/ Peter J. Schied</u> Peter J. Schied	Director	March 25, 2003
<u>/s/ George J. Vuturo</u>	Director	March 25, 2003



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**CERTIFICATIONS**

I, David R. Bethune, Chairman and Chief Executive Officer of Atrix Laboratories, Inc., certify that:

1. I have reviewed this annual report on Form 10-K of Atrix Laboratories, Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

(a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

(b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the Evaluation Date); and

(c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

/s/ David R. Bethune

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David R. Bethune  
Chairman and Chief Executive Officer

Date: March 25, 2003

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I, Brian G. Richmond, Chief Financial Officer of Atrix Laboratories, Inc., certify that:

1. I have reviewed this annual report on Form 10-K of Atrix Laboratories, Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

(a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

(b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

(c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

/s/ Brian G. Richmond

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Brian G. Richmond  
Chief Financial Officer

Date: March 25, 2003

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**INDEPENDENT AUDITORS REPORT**

To the Board of Directors and Shareholders

Atrix Laboratories, Inc. and Subsidiaries  
Fort Collins, Colorado

We have audited the accompanying consolidated balance sheets of Atrix Laboratories, Inc. and subsidiaries (the Company) as of December 31, 2002 and 2001, and the related consolidated statements of operations, changes in shareholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2002. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. 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 consolidated 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, such consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2002 and 2001, and the results of its operations and cash flows for each of the three years in the period ended December 31, 2002 in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 1 to the consolidated financial statements, the Company changed its method of accounting for revenue recognition in 2000.

DELOITTE & TOUCHE LLP

Denver, Colorado

March 12, 2003

**Table of Contents****ATRIX LABORATORIES, INC. AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS  
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)**

	December 31, 2002	December 31, 2001
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 30,698	\$ 50,058
Marketable securities available-for-sale, at fair value	81,767	87,910
Accounts receivable, net of allowance for doubtful accounts of \$623 and \$5	6,140	3,522
Interest receivable	679	995
Inventories	8,694	3,314
Prepaid expenses and deposits	2,253	606
	<hr/>	<hr/>
Total current assets	130,231	146,405
	<hr/>	<hr/>
PROPERTY, PLANT AND EQUIPMENT, NET	15,431	7,557
	<hr/>	<hr/>
<b>OTHER ASSETS:</b>		
Goodwill	399	399
Intangible and other assets, net of accumulated amortization of \$3,116 and \$3,008	3,964	3,132
	<hr/>	<hr/>
Other assets, net	4,363	3,531
	<hr/>	<hr/>
<b>TOTAL ASSETS</b>	<b>\$ 150,025</b>	<b>\$ 157,493</b>
	<hr/>	<hr/>
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable trade	\$ 7,261	\$ 3,108
Accrued expenses and other	1,042	611
Deferred revenue	7,889	7,467
	<hr/>	<hr/>
Total current liabilities	16,192	11,186
	<hr/>	<hr/>
DEFERRED REVENUE	37,064	28,373
CONVERTIBLE SUBORDINATED NOTES PAYABLE		5,206
<b>COMMITMENTS AND CONTINGENCIES (SEE NOTES 4 AND 9)</b>		
<b>SERIES A CONVERTIBLE EXCHANGEABLE PREFERRED STOCK,</b> \$.001 par value, 20,000 shares authorized; 13,787 and 12,871 shares issued and outstanding. Liquidation preference \$14,227 and \$13,281	14,514	13,568
<b>SHAREHOLDERS EQUITY:</b>		
Preferred stock, \$.001 par value; 5,000,000 shares authorized		
Series A preferred stock, \$.001 par value, 200,000 shares authorized, none issued or outstanding		
Common stock, \$.001 par value; 45,000,000 shares authorized; 20,516,069 and 19,859,807 shares issued; 19,858,369 and 19,782,307 shares outstanding	21	20
Additional paid-in capital	242,699	232,903
Treasury stock, 657,700 and 77,500 shares, at cost	(10,740)	(1,558)

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Accumulated other comprehensive income (loss)	1,590	(4)
Accumulated deficit	(151,315)	(132,201)
	<u>          </u>	<u>          </u>
Total shareholders' equity	82,255	99,160
	<u>          </u>	<u>          </u>
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 150,025	\$ 157,493
	<u>          </u>	<u>          </u>

See notes to the consolidated financial statements.

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**Table of Contents****ATRIX LABORATORIES, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF OPERATIONS  
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)**

	Year Ended December 31, 2002	Year Ended December 31, 2001	Year Ended December 31, 2000
<b>REVENUE:</b>			
Net sales and royalties	\$ 5,749	\$ 3,818	\$ 6,156
Contract research and development revenue	14,170	8,178	2,009
Licensing, marketing rights and milestone revenue	6,465	3,815	1,878
<b>Total revenue</b>	<b>26,384</b>	<b>15,811</b>	<b>10,043</b>
<b>OPERATING EXPENSE:</b>			
Cost of sales	3,251	1,693	2,644
Research and development	32,739	25,635	16,735
Research and development licensing fees		2,985	
Administrative and marketing	9,847	5,450	4,262
Administrative stock option compensation	1,257	2,117	125
<b>Total operating expense</b>	<b>47,094</b>	<b>37,880</b>	<b>23,766</b>
<b>LOSS FROM OPERATIONS</b>	<b>(20,710)</b>	<b>(22,069)</b>	<b>(13,723)</b>
<b>OTHER INCOME (EXPENSE):</b>			
Equity in loss of joint venture	(972)	(3,285)	(12,239)
Investment income	4,795	3,965	2,131
Loss on sale and write-down of marketable securities	(1,071)	(831)	(172)
Interest expense	(79)	(780)	(2,582)
Debt conversion expense	(125)	(2,194)	
Other	(36)	(20)	89
<b>Net other income (expense)</b>	<b>2,512</b>	<b>(3,145)</b>	<b>(12,773)</b>
<b>LOSS BEFORE EXTRAORDINARY ITEM AND CUMULATIVE EFFECT OF CHANGE IN ACCOUNTING PRINCIPLE</b>			
CHANGE IN ACCOUNTING PRINCIPLE	(18,198)	(25,214)	(26,496)
Extraordinary gain (loss) on extinguished debt	30	(319)	80
Cumulative effect of change in accounting principle			(20,612)
<b>NET LOSS</b>	<b>(18,168)</b>	<b>(25,533)</b>	<b>(47,028)</b>
Accretion of dividends on preferred stock	(946)	(1,171)	(383)
<b>NET LOSS APPLICABLE TO COMMON STOCK</b>	<b>\$ (19,114)</b>	<b>\$ (26,704)</b>	<b>\$ (47,411)</b>
<b>Basic and diluted loss per common share:</b>			
Loss before extraordinary item and cumulative effect of change in accounting principle	\$ (.90)	\$ (1.54)	\$ (2.23)
Extraordinary gain (loss) on extinguished debt		(.02)	

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Cumulative effect of change in accounting principle			(1.73)
Net loss	(.90)	(1.56)	(3.96)
Accretion of dividends on preferred stock	(.05)	(.07)	(.03)
Net loss applicable to common stock	\$ (.95)	\$ (1.63)	\$ (3.99)
Basic and diluted weighted average common shares outstanding	20,076,999	16,348,365	11,883,712
Pro forma amounts assuming the change in revenue recognition method is applied retroactively:			
Net loss before extraordinary item	\$ (18,198)	\$ (25,214)	\$ (26,496)
Net loss applicable to common stock	\$ (19,114)	\$ (26,704)	\$ (26,799)
Basic and diluted earnings per common share:			
Loss before extraordinary item	\$ (.90)	\$ (1.54)	\$ (2.23)
Net loss applicable to common stock	\$ (.95)	\$ (1.63)	\$ (2.26)

See notes to the consolidated financial statements.

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**Table of Contents****ATRIX LABORATORIES, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS EQUITY (DEFICIT)**

(IN THOUSANDS, EXCEPT SHARE DATA)

	Common Stock		Additional Paid-In Capital	Treasury Stock	Accumulated Other Comprehensive	Accumulated Deficit	Total Shareholders Equity (Deficit)
	Shares	Amount			Income (Loss)		
<b>BALANCE, December 31, 1999</b>	11,427,554	\$ 11	\$ 74,496	\$ (81)	\$ (1,696)	\$ (58,060)	\$ 14,670
Comprehensive loss:							
Net loss						(47,028)	(47,028)
Accretion of dividend on preferred stock						(383)	(383)
Other comprehensive income (loss):							
Foreign currency translation adjustments					14		14
Unrealized gain on investments					1,211		1,211
Net comprehensive loss							(46,186)
Issuance of common stock and warrants to Elan	442,478		5,000				5,000
Issuance of common stock to Pfizer	447,550	1	4,999				5,000
Issuance of common stock to Sanofi-Synthelabo	824,572	1	14,999				15,000
Exercise of stock options and issuance for employee stock purchase plan shares	148,539		1,248	81		(26)	1,303
Issuance of restricted stock	42,702		500				500
Issuance for earn-out distribution	8,286		125				125
<b>BALANCE, December 31, 2000</b>	13,341,681	13	101,367		(471)	(105,497)	(4,588)
Comprehensive loss:							
Net loss						(25,533)	(25,533)
Accretion of dividend on preferred stock						(1,171)	(1,171)
Other comprehensive income (loss):							
Foreign currency translation adjustments					(29)		(29)
Unrealized gain on investments					496		496
Net comprehensive loss							(26,237)
Issuance of common stock to extinguish debt	1,725,735	2	33,177				33,179
Issuance of common stock to MediGene	233,918		3,780				3,780
Non-qualified stock option compensation			2,117				2,117
Exercise of stock options and issuance of employee stock purchase plan shares	419,692	1	4,181				4,182
Issuance of restricted stock	39,031		565				565
Purchase of treasury stock	(77,500)			(1,558)			(1,558)
Offering of common stock, net of offering costs of \$6,574	4,099,750	4	87,716				87,720
<b>BALANCE, December 31, 2001</b>	19,782,307	20	232,903	(1,558)	(4)	(132,201)	99,160
Net loss						(18,168)	(18,168)
Accretion of dividend on preferred stock						(946)	(946)
Other comprehensive income (loss):							
Foreign currency translation adjustments					102		102

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Unrealized gain on investments				1,492			1,492
Net comprehensive loss							(17,520)
Issuance of common stock to extinguish debt	279,931		5,330				5,330
Non-qualified stock option compensation			1,257				1,257
Exercise of stock options and issuance of employee stock purchase plan shares	350,259	1	2,921				2,922
Issuance of non-qualified stock	6,000		37				37
Issuance of restricted stock	20,072		290				290
Purchase of treasury stock	(580,200)			(9,182)			(9,182)
Stock offering costs			(39)				(39)
<b>BALANCE, December 31, 2002</b>	<b>19,858,369</b>	<b>\$ 21</b>	<b>\$242,699</b>	<b>\$ (10,740)</b>	<b>\$ 1,590</b>	<b>\$ (151,315)</b>	<b>\$ 82,255</b>

See notes to the consolidated financial statements.

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**Table of Contents****ATRIX LABORATORIES, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF CASH FLOWS  
(IN THOUSANDS)**

	Year Ended December 31, 2002	Year Ended December 31, 2001	Year Ended December 31, 2000
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$(18,168)	\$ (25,533)	\$(47,028)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization	3,188	2,480	2,189
Amortization of deferred revenue	(9,445)	(4,332)	(2,217)
Equity in loss of joint venture	972	3,285	12,239
Loss on sale and write-down of marketable securities	1,071	831	172
Stock option compensation	1,257	2,117	125
Debt conversion expense	125	2,194	
Interest expense converted to equity	110	345	
Extraordinary (gain) loss on extinguished debt	(30)	319	(80)
Cumulative effect of change in accounting principle			20,612
Other non-cash items	71	25	(5)
Net changes in operating assets and liabilities:			
Accounts receivable	(1,904)	(925)	(1,397)
Note receivable - licensing fee		8,000	
Interest receivable	316	(523)	90
Inventories	(5,281)	(1,387)	(75)
Prepaid expenses and deposits	(1,725)	479	(666)
Accounts payable	3,732	481	(424)
Accrued expenses and other	417	(144)	75
Deferred revenue	18,058	12,957	660
Net cash provided by (used in) operating activities	(7,236)	669	(15,730)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Acquisition of property, plant and equipment	(9,589)	(2,069)	(775)
Investment in intangible and other assets	(1,666)	(419)	(246)
Proceeds from maturity and sale of marketable securities	69,119	23,245	7,402
Investment in marketable securities	(63,259)	(82,683)	(422)
Investment in joint venture	(1,500)	(2,746)	
Net cash provided by (used in) investing activities	(6,895)	(64,672)	5,959
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from issuance of equity securities, net of issuance costs	3,211	96,247	11,678
Payments to acquire treasury stock	(9,182)	(1,558)	
Note receivable - stock subscription		15,000	
Extinguished convertible long-term debt			(408)
Net cash provided by (used in) financing activities	(5,971)	109,689	11,270
NET EFFECT OF EXCHANGE RATE ON CASH	742	(112)	(37)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(19,360)	45,574	1,462
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	50,058	4,484	3,022



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CASH AND CASH EQUIVALENTS, END OF YEAR	<u>\$ 30,698</u>	<u>\$ 50,058</u>	<u>\$ 4,484</u>
Supplemental cash flow information:			
Cash paid for interest	<u>\$</u>	<u>\$ 614</u>	<u>\$ 2,568</u>

See notes to the consolidated financial statements.

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**ATRIX LABORATORIES, INC. AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF CASH FLOWS (Continued)**

Non-cash investing and financing activities:	<b>2002</b>
	Issued common stock valued at \$5,330,000 in exchange for \$5,206,000 of the 7% Convertible Subordinated Notes.
	Issued preferred stock valued at \$917,000 to Elan for accreted dividends.
	<b>2001</b>
	Issued preferred stock valued at \$883,000 to Elan for accreted dividends.
	Issued common stock valued at \$33,177,000 in exchange for \$30,984,000 of 7% Convertible Subordinated Notes.
	<b>2000</b>
	Issued common stock valued at \$15,000,000 in exchange for a note receivable to Sanofi-Synthelabo in connection with the marketing agreement.
	Issued preferred stock valued at \$12,015,000 in exchange for an 80.1% initial interest in the joint venture with Elan.
	Issued common stock valued at \$125,000 in connection with the November 2000 earn-out payments relating to the ViroTex acquisition.

See notes to the consolidated financial statements.

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**ATRIX LABORATORIES, INC. AND SUBSIDIARIES**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**Years Ended December 31, 2002, 2001 and 2000**

**1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

Atrix Laboratories, Inc. ( Atrix ) was formed in August 1986 as a Delaware corporation. In November 1998, Atrix acquired ViroTex Corporation. In June 1999, Atrix organized its wholly owned subsidiary Atrix Laboratories Limited, which is based in London, England. In February 2000, Atrix organized its wholly owned subsidiary Atrix Laboratories GmbH, which is based in Frankfurt, Germany, to conduct its European operations. Collectively, Atrix and its subsidiaries are referred to as Atrix or the Company. In June 2000, the Company entered into a research joint venture, Transmucosal Technologies Ltd., with Elan International Services, Ltd., a wholly owned subsidiary of Elan Corporation, plc.

The Company is an emerging specialty pharmaceutical company focused on advanced drug delivery. With five unique patented drug delivery technologies, the Company is currently developing a diverse portfolio of products, including proprietary oncology, dermatology products, pain management, and growth hormone releasing peptide-1. The Company also forms strategic alliances with a variety of pharmaceutical and biotechnology companies to develop products utilizing various drug delivery systems and/or to commercialize products. These strategic alliances include collaborations with Pfizer Inc., Sanofi-Synthelabo Inc., MediGene AG, Fujisawa Healthcare, Inc., Geneva Pharmaceuticals, Inc., Elan International Services, Ltd., Sosei Co. Ltd., and CollaGenex Pharmaceuticals, Inc.

**Principles of consolidation**

The accompanying consolidated financial statements include the accounts of Atrix Laboratories, Inc. and its wholly owned subsidiaries Atrix Laboratories Limited and Atrix Laboratories, GmbH. All significant intercompany transactions and balances have been eliminated. While the Company initially owns 80.1% of Transmucosal Technologies' outstanding common stock, Elan and its subsidiaries have retained significant minority investor rights that are considered participating rights as defined in Emerging Issues Task Force Consensus 96-16, *Investor's Accounting for an Investee When the Investor Has a Majority of the Voting Interest, but the Minority Shareholder or Shareholders Have Certain Approval or Veto Rights*. Elan's significant rights in Transmucosal Technologies that are considered participating rights include equal representation in the management of the joint venture and development of its business plan and approval rights on the board of directors as it relates to the business plan. Accordingly, the Company accounts for its investment in Transmucosal Technologies under the equity method of accounting. Additionally, the joint venture contracts with Atrix to perform certain research and development activities. See Note 5.

**Use of estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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 revenues and expenses during the reporting period. Significant estimates include allowances for doubtful accounts and the term over which deferred revenues are recognized. Actual results could differ from those estimates and the differences could be material.

**Table of Contents****ATRIX LABORATORIES, INC. AND SUBSIDIARIES****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Cash and cash equivalents**

Cash equivalents include highly liquid investments with an original maturity of three months or less.

**Marketable securities**

Marketable securities are classified as available-for-sale and are carried at fair value with the unrealized holding income or loss included in shareholders' equity as a component of other comprehensive income or loss. Fair value is based on quoted market prices or dealer quotes. Premiums and discounts associated with bonds and notes are amortized using the effective interest rate method. The investment portfolio includes fixed rate debt instruments that are primarily U.S. government and agency bonds and notes, diversified bond mutual funds, and corporate bonds and notes. The maturity dates for the individual securities range from one to fifteen years and there is no maturity date on the bond mutual funds. If a decline in market value is determined to be other than temporary, a charge is taken to operations.

**Inventories**

Inventories are stated at the lower of cost, determined by the first-in, first-out (FIFO) method, or market. Inventories include the cost of materials, direct labor and overhead. The components of inventories are as follows as of December 31 (amounts in thousands):

	<u>2002</u>	<u>2001</u>
Raw materials	\$6,590	\$2,399
Work in progress	1,035	201
Finished goods	1,069	714
	<u>          </u>	<u>          </u>
Total inventories	\$8,694	\$3,314
	<u>          </u>	<u>          </u>

**Property, plant and equipment**

Property, plant and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, which range from three to forty years. Leasehold improvements and capital additions to the Company's building are amortized over the remaining term of the related lease and estimated useful life respectively. The components of net property, plant and equipment are as follows as of December 31 (amounts in thousands):

	<u>2002</u>	<u>2001</u>
Land	\$ 1,071	\$ 1,071
Building	3,921	3,868
Construction in progress	6,072	
Leasehold improvements	731	618
Furniture and fixtures	733	615
Machinery	8,306	6,004
Office equipment	2,075	1,243
	<u>          </u>	<u>          </u>
Total property, plant and equipment	22,909	13,419
Accumulated depreciation and amortization	(7,478)	(5,862)
	<u>          </u>	<u>          </u>
Property, plant and equipment, net	\$ 15,431	\$ 7,557



**Table of Contents****ATRIX LABORATORIES, INC. AND SUBSIDIARIES****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Goodwill**

The Company adopted Statement of Financial Accounting Standards (SFAS) No. 142, Goodwill and Other Intangible Assets, on January 1, 2002. Goodwill is no longer amortized, but instead is tested for impairment on an annual basis or as circumstances change. In the first quarter of 2002, the Company completed the initial goodwill impairment test. No accounting charge resulted from the completion of this initial impairment test.

The following table presents the adjusted net income and loss per share had SFAS No. 142 been in effect for all periods presented (in thousands, except per share amounts):

	<u>2002</u>	<u>2001</u>	<u>2000</u>
Reported net loss applicable to common stock	\$(19,114)	\$(26,704)	\$(47,411)
Add back: Goodwill amortization		208	170
Adjusted net loss applicable to common stock	<u>\$(19,114)</u>	<u>\$(26,496)</u>	<u>\$(47,241)</u>
Basic and diluted loss per common share:			
As reported	\$ (.95)	\$ (1.63)	\$ (3.99)
Goodwill amortization		.01	.01
Basic and diluted, as adjusted	<u>\$ (.95)</u>	<u>\$ (1.62)</u>	<u>\$ (3.98)</u>

**Intangible and other assets**

Intangible assets consist of patents and trademarks, purchased technology and purchased royalty rights. Patents and trademarks are stated at the legal cost incurred to obtain the patents. Upon approval, patent and trademark costs are amortized, using the straight-line method, over their estimated useful life ranging from ten to twenty years. The values assigned to the purchased technology, and royalty rights are being amortized using the straight-line method over the period of expected benefit of four to five years.

The Company reviews the carrying values of its other intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset might not be recoverable. In performing its review for recoverability, the Company estimates the future cash flows expected to result from the use of the asset and its eventual disposition. If the sum of the expected future cash flows is less than the carrying amount of the asset, an impairment loss is recognized. Measurement of impairment losses is based on the excess of the carrying amount of the asset over the fair value calculated using discounted expected future cash flows.

Costs associated with the issuance of the Company's 7% Convertible Subordinated Notes were deferred and were being amortized on a straight-line basis, which approximated the effective interest method, over the seven-year term of the notes. As convertible notes were repurchased and subsequently extinguished or exchanged for the Company's common stock, the pro-rata portion of deferred finance costs was written off. In March 2002, the Company called for redemption of the remaining outstanding 7% Convertible Subordinated Notes. As a result of the full conversion of the Company's 7% Convertible Subordinated Notes, the remaining balance of the Company's deferred finance costs was written off in May 2002. Deferred financing costs were \$85,000, net of accumulated amortization of \$121,000, at December 31, 2001.

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**ATRIX LABORATORIES, INC. AND SUBSIDIARIES**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Fair value of financial instruments**

Unless otherwise stated herein, the fair value of the Company's financial instruments approximate their carrying value due to the relatively short periods to maturity of the instruments and/or variable rates of the instruments, which approximate current interest rates.

**Concentrations of credit risk**

Financial instruments, which possibly expose the Company to concentration of credit risk, consist primarily of cash equivalents, marketable securities and accounts receivable. The Company's cash equivalents are placed with major financial institutions and are primarily invested in investment grade commercial paper with an average original maturity of three months or less and in money market accounts, which, at times, may exceed federally insured limits. The Company has not experienced any losses on such accounts. The Company's marketable securities consist primarily of U.S. government or U.S. government-backed securities, diversified bond mutual funds, investment grade corporate securities, and various equity securities. During the year ended December 31, 2001, the Company recorded a write-down of \$0.8 million on its \$1.0 million investment in Enron corporate notes. In 2002, the Company recorded a loss on sale and write-down of marketable securities of \$1.1 million primarily as a result of the sale of half of its \$1.5 million principal amount of WorldCom Senior Notes and the subsequent write-down of \$0.7 million on the remaining half of the WorldCom Senior Notes upon WorldCom's bankruptcy filing. Management believes that the diversity of the Company's portfolio combined with the credit worthiness of the companies in which it invests mitigates the Company's exposure to credit risk.

Revenues from net sales and royalties, contract research and development, and licensing, marketing rights and milestone revenues are primarily derived from major pharmaceutical and biotechnology companies. However, the Company's revenues could be materially impacted by the loss of one or more of its contractual relationships or due to disputes with a collaborative partner. The Company performs ongoing credit evaluations of its customers' financial conditions and requires no collateral to secure accounts receivable. The Company maintains an allowance for doubtful accounts based on an assessment of the collection probability of delinquent accounts.

**Revenue recognition**

The Company recognizes revenue on product sales and contract manufacturing at the time of shipment when title to the product transfers and the customer bears risk of loss. Royalty revenue is recorded when product is shipped by licensees based on the amount invoiced by the licensee and royalty rates as specified in the agreement with the licensee.

All contract research and development is performed on a best effort basis under signed contracts. Revenue under contracts with a fixed price is recognized over the term of the agreement on a straight-line basis, which is consistent with the pattern of work performed. Billings are made in accordance with schedules as specified in each agreement, which generally include an up-front payment as well as periodic payments. Advance payments are recorded as deferred revenue. Revenue under other contracts is recognized based on terms as specified in the contracts, including billings for time incurred at rates as specified in the contracts and as reimbursable expenses are incurred. Such arrangements are regularly evaluated on an individual basis. Billings under these contracts are made monthly.

Nonrefundable licensing fees, marketing rights and milestone payments received under contractual arrangements are deferred and recognized over the remaining contractual term using the straight-line method. Prior to the fourth quarter of 2000, the Company recognized these payments as revenue when received and the Company had fulfilled all contractual obligations relating to the payments. Effective in the fourth quarter of 2000, the Company changed its method of accounting for nonrefundable licensing

**Table of Contents****ATRIX LABORATORIES, INC. AND SUBSIDIARIES****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

fees, marketing and milestone payments to recognize such payments over the remaining contractual term using the straight-line method in accordance with the Securities and Exchange Commission's Staff Accounting Bulletin No. 101 *Revenue Recognition in Financial Statements*, (SAB 101). The Company recorded a \$20.6 million adjustment, as of January 1, 2000, for the cumulative effect of a change in accounting principle upon adoption of SAB 101. The cumulative effect was recorded as deferred revenue that is being recognized as revenue over the remaining contractual terms of the specific agreements. During the year ended December 31, 2000, the impact of this change in accounting principle increased net loss applicable to common stock by \$18.7 million or \$1.58 per share. This amount is comprised of the \$20.6 million, or \$1.73 per share, cumulative effect adjustment net of \$1.9 million, or \$0.16 per share, recognized as licensing, marketing rights and milestone revenue during the year ended December 31, 2000. During the years ended December 31, 2002 and December 31, 2001, the Company recognized licensing, marketing rights and milestone revenue of \$6.5 million and \$3.8 million, respectively, in accordance with SAB 101. The amount recognized in 2001 and amounts to be recognized in 2002 through 2010 were adjusted in 2001 to reflect an amendment to the agreement with Block Drug Company, see Note 5, and to include additional license and milestone payments received in 2001.

The following table summarizes the deferred revenue to be recognized as revenue during the years ended December 31, 2003 through December 31, 2016:

Years Ended December 31,	Amortization of Deferred Revenue
2003	\$ 7,889
2004	9,253
2005	7,475
2006	3,891
2007	3,891
Thereafter	12,554
Total	<u>\$44,953</u>

**Research and development**

Costs incurred in connection with research and development activities are expensed as incurred. These costs consist of direct and indirect costs associated with specific projects, as well as fees paid to various entities that perform certain research on the Company's behalf. Additionally, licensing fees paid by the Company to acquire technology are expensed as incurred if no alternative future use exists. A portion of overhead costs is allocated to research and development costs on a weighted-average percentage basis among all projects under development.

The following table summarizes research and development activities funded, in whole or in part, by our collaborators, as well as research and development activities funded entirely by the Company for the three years ended December 31 (amounts in thousands):

	2002	2001	2000
Research and Development Funded	\$ 18,721	\$ 10,626	\$ 1,921
Research and Development Not Funded	14,018	15,009	14,814
Research and Development	<u>\$32,739</u>	<u>\$25,635</u>	<u>\$16,735</u>
Research and Development Licensing Fees Not Funded	\$	\$ 2,985	\$





**Table of Contents****ATRIX LABORATORIES, INC. AND SUBSIDIARIES****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Net income (loss) per common share**

Basic net income (loss) per common share excludes dilution and is computed by dividing net income (loss) by the weighted-average number of common shares outstanding during the periods presented. Diluted net income (loss) per common share reflects the potential dilution of securities that could participate in the earnings. Stock options, warrants outstanding and their equivalents are included in diluted earnings per share computations through the treasury stock method unless they are antidilutive. Convertible securities are included in diluted earnings per share computations through the if converted method unless they are antidilutive. There was no diluted effect on earnings per share computations for the assumed conversion of the Series A Convertible Exchangeable Preferred Stock under the if converted method. Additionally, since the Company has not drawn any proceeds under the convertible promissory note agreement with Elan, as of December 31, 2002, there was no effect on earnings per share computations pertaining to this convertible promissory note for the periods presented. Common share equivalents are excluded from the computations in loss periods, as their effect would be antidilutive. For the years ended December 31, 2002, 2001 and 2000, 1.5 million, 1.7 million, and 2.3 million equivalent dilutive securities (primarily convertible notes and common stock options), respectively, have been excluded from the weighted-average number of common shares outstanding for the diluted net loss per share computations as they are antidilutive.

**Comprehensive income (loss)**

Items of other comprehensive income (loss) include unrealized gains and losses on available-for-sale marketable securities and foreign currency translation adjustments. Disclosure of comprehensive income (loss) for the years ended December 31, 2002, 2001 and 2000 is included in the accompanying financial statements as part of the consolidated statements of changes in shareholders' equity.

**Stock based compensation**

The Company accounts for stock-based compensation to employees and directors using the intrinsic value method in accordance with Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*. The Company accounts for stock-based compensation to non-employees using a fair value based method in accordance with SFAS No. 123, *Accounting for Stock Based Compensation*. At December 31, 2002, the Company has three stock-based employee compensation plans, which are described more fully in Note 6. The Company accounts for those plans under the recognition and measurement principles of APB Opinion No. 25. No stock-based employee compensation cost is reflected in net income for options granted under those plans with an exercise price equal to the market value for the underlying common stock on the date of grant. The following table illustrates the effect on net income and earnings per share if the Company had applied the fair value recognition provisions of FASB Statement No. 123, to stock-based employee compensation (amounts in thousands, except share data):

	<u>2002</u>	<u>2001</u>	<u>2000</u>
Net loss applicable to common stock:			
as reported	\$(19,114)	\$(26,704)	\$(47,411)
pro forma	(29,254)	(34,072)	(51,498)
Basic and diluted net loss per common share:			
as reported	\$ (0.95)	\$ (1.63)	\$ (3.99)
pro forma	(1.46)	(2.08)	(4.33)

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**ATRIX LABORATORIES, INC. AND SUBSIDIARIES**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Income taxes**

The Company accounts for income taxes using an asset and liability approach to financial accounting and reporting for income taxes. Deferred income tax assets and liabilities are computed annually for differences between the financial statement basis and the income tax basis of assets and liabilities that will result in taxable or deductible amounts in the future. Such deferred income tax liability computations are based on enacted tax laws and rates applicable to the years in which the differences are expected to affect taxable income. A valuation allowance is established when it is necessary to reduce deferred income tax assets to the expected realized amounts.

**Translation of foreign currencies**

The Company's primary functional currency is the U.S. dollar. Foreign subsidiaries with a functional currency other than the U.S. dollar translate balance sheet accounts at period-end exchange rates. Revenue and expense accounts are translated at average exchange rates in effect during the period. Translation adjustments are recorded as a component of comprehensive income (loss). Cumulative foreign currency translation adjustments included in accumulated other comprehensive income (loss) at December 31, 2002 and 2001 were \$85,000 and (\$17,000), respectively. Some of the Company's transactions and transactions of its subsidiaries are made in currencies different from their functional currency. Gains and losses from these transactions are included in other income or expense as they occur. To date, the effect on income and expenses for such amounts has been immaterial.

**Derivative instruments and hedging activities**

In June 1998, Statement of Financial Accounting Standards (SFAS) No. 133, *Accounting for Derivative Instruments and Hedging Activities*, was issued which, as amended, was effective for all fiscal years beginning after June 15, 1999. SFAS No. 133 provides new standards for the identification, recognition and measurement of derivative financial instruments, including embedded derivatives. Historically, the Company has not entered into derivative contracts to hedge existing risks nor have we entered into speculative derivative contracts. The adoption of SFAS No. 133 did not have a material effect on the Company's financial position or results of operations.

**Related party transactions**

A former member of the Board of Directors is a partner at a law firm that is the primary provider of legal services for the Company. Legal fees paid to this law firm were \$0.7 million, \$1.1 million, and \$0.6 million for the years ended December 31, 2002, 2001 and 2000, respectively.

**New accounting pronouncements**

In June 2001, SFAS No. 143, *Accounting for Asset Retirement Obligations* was issued by the Financial Accounting Standards Board (FASB). SFAS No. 143 addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs and applies to all entities. It applies to legal obligations associated with the retirement of long-lived assets that result from the acquisition, construction, development and (or) the normal operation of a long-lived asset, except for certain obligations of lessees. The Company will adopt SFAS No. 143 on January 1, 2003. The adoption of this statement is not expected to have a material impact on the Company's consolidated financial position or results of operations.

In April 2002, SFAS No. 145, *Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections* was issued by the FASB. SFAS No. 145 rescinds FASB Statement No. 4, *Reporting Gains and Losses from Extinguishment of Debt*, and an amendment

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**ATRIX LABORATORIES, INC. AND SUBSIDIARIES**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

of that Statement, FASB Statement No. 64, *Extinguishments of Debt Made to Satisfy Sinking-Fund Requirements*. This Statement also rescinds FASB Statement No. 44, *Accounting for Intangible Assets of Motor Carriers*. This Statement amends FASB Statement No. 13, *Accounting for Leases*, to eliminate an inconsistency between the required accounting for sale-leaseback transactions and the required accounting for certain lease modifications that have economic effects that are similar to sale-leaseback transactions. This Statement also amends other existing authoritative pronouncements to make various technical corrections, clarify meanings, or describe their applicability under changed conditions. The Company will adopt SFAS No. 145 in the first quarter of 2003, at which time the comparative financial statements will be restated to reclassify the extraordinary gain or loss on extinguishment of debt to be included in loss from continuing operations.

In August 2002, SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* was issued by the FASB. SFAS No. 146 addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force Issue No. 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in Restructuring)*. SFAS No. 146 requires that a liability for a cost associated with an exit or disposal activity is to be recognized when the liability is incurred. The provisions of SFAS No. 146 are effective for exit or disposal activities that are initiated after December 31, 2002. The adoption of this statement is not expected to have a material impact on the Company's consolidated financial position or results of operations.

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*. This statement amends SFAS No. 123, *Accounting for Stock-Based Compensation*, to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based compensation. It also amends the disclosure provisions of that statement and requires disclosure of the pro forma effect in interim financial statements. SFAS No. 148 is effective for the Company's fiscal year ended December 31, 2002. The Company does not currently plan to change to the fair value method of accounting for its stock-based compensation; therefore, the Company anticipates that the adoption of this statement will not have a material impact on its consolidated financial position or results of operations.

In November 2002, the FASB issued Interpretation No. 45 (FIN 45), *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*. FIN 45 requires that a liability be recorded in the guarantor's balance sheet upon issuance of a guarantee. FIN 45 also requires additional disclosures about the guarantees an entity has issued, including a rollforward of the entity's product warranty liabilities. The Company will apply the recognition provisions of FIN 45 prospectively to guarantees issued or modified after December 31, 2002. The disclosure requirements are effective for the Company's financial statements for the year ended December 31, 2002. The adoption of FIN 45 is not expected to have a material impact on the Company's consolidated financial position or results of operation.

In January 2003, the FASB issued Interpretation No. 46 (FIN 46), *Consolidation of Variable Interest Entities*. FIN 46 provides guidance on how to identify a variable interest entity (VIE) and determine when the assets, liabilities, and results of operations of a VIE need to be included in a company's consolidated financial statements. FIN 46 also requires additional disclosures by primary beneficiaries and other significant variable interest holders in a VIE. The provisions of FIN 46 are effective immediately for all VIEs created after January 31, 2003. For VIEs created before February 1, 2003, the provisions of FIN 46 must be adopted at the beginning of the first interim or annual reporting period beginning after June 15, 2003. The adoption of FIN 46 is not expected to have a material impact on the Company's consolidated financial position or results of operation.

**Table of Contents****ATRIX LABORATORIES, INC. AND SUBSIDIARIES****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In November 2002, the Emerging Issues Task Force (EITF) issued EITF Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*. EITF Issue No. 00-21 addresses how to determine whether a revenue arrangement involving multiple deliverables contains more than one unit of accounting for the purposes of revenue recognition and how the revenue arrangement consideration should be measured and allocated to the separate units of accounting. EITF Issue No. 00-21 applies to all revenue arrangements that the Company enters into after June 30, 2003. The Company has not yet determined the impact, if any, that EITF Issue No. 00-21 will have on its consolidated financial position and results of operations.

**Reclassifications**

Certain prior year amounts have been reclassified to conform to the current year's consolidated financial statement presentation.

**2. MARKETABLE SECURITIES**

As of December 31, 2002, marketable securities available-for-sale consist of the following (amounts in thousands, except share data):

	<b>Number of Shares or Principal Amount</b>	<b>Cost</b>	<b>Fair Value</b>
<b>Mutual Funds:</b>			
MFS Limited Maturity Fund CL-A	1,846,298 Shares	\$12,646	\$ 12,684
Pimco Total Return Fund	1,085,830 Shares	11,612	11,586
UBS Pace Government Securities Fund	178,198 Shares	2,310	2,325
Thornburg Limited Term US Government A Fund	52,982 Shares	666	701
Sub-total		<u>27,234</u>	<u>27,296</u>
<b>Other Marketable Securities:</b>			
U.S. Government and Agency Bonds	\$25,200	25,518	26,058
Equitable Guaranteed Growth Annuity	\$1,000	1,000	1,000
Certificates of Deposit	\$1,300	1,300	1,300
Corporate Notes	\$23,668	22,710	22,976
CollaGenex Common Stock	330,556 Shares	2,500	3,137
Sub-total		<u>53,028</u>	<u>54,471</u>
Total		<u>\$80,262</u>	<u>\$81,767</u>

**Table of Contents****ATRIX LABORATORIES, INC. AND SUBSIDIARIES****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

As of December 31, 2001, marketable securities available-for-sale consist of the following (amounts in thousands, except share data):

	Number of Shares or Principal Amount	Cost	Fair Value
<b>Mutual Funds:</b>			
Pimco Total Return Fund	1,010,194 Shares	\$10,809	\$ 10,567
MFS Limited Maturity Fund CL-A	289,226 Shares	2,000	2,001
Thornburg Limited Term US Government A Fund	50,718 Shares	637	635
Sub-total		13,446	13,203
<b>Other Marketable Securities:</b>			
U.S. Government and Agency Bonds	\$30,200	30,413	30,640
Corporate Notes	\$41,079	41,539	41,390
CollaGenex Common Stock	330,556 Shares	2,500	2,677
Sub-total		74,452	74,707
Total		\$87,898	\$87,910

As of December 31, 2002, gross unrealized gains and losses pertaining to marketable securities available-for-sale were \$1.7 million and \$0.2 million, respectively. As of December 31, 2001, gross unrealized gains and losses pertaining to marketable securities available-for-sale were \$0.6 million and \$0.6 million, respectively.

There were no material realized investment gains for the three years ended December 31, 2002 and realized investment losses were \$1.1 million, \$0.8 million, and \$0.2 million, in 2002, 2001, and 2000, respectively. In May 2002, the Company sold \$0.8 million principal amount of its WorldCom, Inc. Senior Corporate Notes for proceeds of \$0.4 million which resulted in a loss on sale of marketable securities of \$0.4 million. In June 2002, the Company incurred a \$0.7 million charge for a write-down of the Company's position in WorldCom Senior Corporate Notes, principal value of \$0.8 million, upon WorldCom's bankruptcy filing. The market value of the Company's WorldCom Senior Notes as of December 31, 2002 was \$0.2 million. During the fourth quarter of 2001, the Company recorded a write-down charge of \$0.8 million for its \$1.0 million Enron corporate note investment. The market value for this investment was \$0.1 million as of December 31, 2002.

**3. INTANGIBLE AND OTHER ASSETS**

Intangible and other assets consist of the following as of December 31 (amounts in thousands):

	2002	2001
Patents and trademarks	\$ 3,397	\$ 2,534
Purchased technology	2,800	2,800
Purchased royalty rights		600
Other assets	883	206
Sub-total	7,080	6,140
Less: Accumulated amortization	(3,116)	(3,008)

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Total	<u>\$ 3,964</u>	<u>\$ 3,132</u>
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**ATRIX LABORATORIES, INC. AND SUBSIDIARIES**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

At December 31, 2002, other assets consisted of deposits on equipment to be purchased for the Company's plant expansion. When the equipment is received, these deposits will be reclassified to property plant and equipment.

**4. CONVERTIBLE SUBORDINATED NOTES PAYABLE**

In November 1997, the Company issued \$50.0 million of 7% Convertible Subordinated Notes. The notes bore interest at the rate of 7% and were due in 2004. The notes were convertible, at the option of the holder, into the Company's common stock, \$.001 par value, at any time prior to maturity, unless previously redeemed or repurchased, at a conversion price of \$19.00 per share, subject to adjustments in certain events. The notes were redeemable, in whole or in part, at the Company's option, on or after December 5, 2000.

During the year ended December 31, 2002, the Company exchanged 279,931 shares of its common stock to extinguish the remaining \$5.2 million in outstanding principal amount of the 7% Convertible Subordinated Notes. Of the 279,931 shares of the Company's common stock issued, 274,014 shares were valued at the conversion price of \$19.00 per share and the remaining 5,917 shares were valued at \$21.09 per share, the closing market price of the Company's common stock on the date of exchange. As a result of the conversions, the Company recognized an extraordinary gain of \$30,000, for the write-off of \$80,000 of pro rata deferred finance charges net of \$110,000 interest expense payable eliminated as a result of these exchanges. Debt conversion expense of approximately \$125,000 was recognized for the year ended December 31, 2002 related to the additional 5,917 shares valued at \$21.09 per share.

During the year ended December 31, 2001, the Company exchanged 1,725,735 shares of its common stock for \$31.0 million of the 7% Convertible Subordinated Notes. Of the 1,725,735 shares issued, 1,630,726 shares were valued at the conversion price of \$19.00 per share and the remaining 95,009 shares were valued at the closing market price as of the various exchange dates. As a result, the Company recognized an extraordinary loss of \$0.3 million, for the write-off of \$0.7 million of pro rata deferred finance charges net of \$0.4 million interest expense payable eliminated as a result of these exchanges. Debt conversion expense of approximately \$2.2 million was recognized for the year ended December 31, 2001 related to the 95,009 shares valued at various prices. The estimated fair value of the notes payable, based on quoted market prices or dealer quotes, was \$6.0 million at December 31, 2001.

During the year ended December 31, 2000, the Company repurchased \$0.5 million of the notes and recognized an extraordinary gain of approximately \$0.1 million.

**5. COLLABORATIVE ARRANGEMENTS**

***Pfizer, Inc.***

In August 2000, the Company entered into a non-exclusive research and worldwide licensing agreement with Pfizer, Inc. to provide access to the Company's proprietary drug delivery systems in the development of new products. Pfizer will provide the funding to develop and commercialize selected products under the agreement. The Company will receive research and development payments, product sales and royalty payments from Pfizer's sales of products. As part of the agreement, Pfizer purchased 447,550 shares of the Company's common stock for \$5.0 million.

***Sanofi-Synthelabo, Inc.***

In December 2000, the Company entered into an exclusive North American marketing agreement with Sanofi-Synthelabo, Inc., a major international pharmaceutical company, for the Eligard 7.5-mg one-, 22.5-mg three-, and 30-mg four-month products for the treatment of prostate cancer. Additionally, in



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**ATRIX LABORATORIES, INC. AND SUBSIDIARIES**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

December 2001, Sanofi-Synthelabo exercised its rights under the agreement with the Company for another Eligard product to be developed.

The Company received a licensing fee of \$8.0 million upon signing the agreement. The licensing fee was recorded as deferred revenue and is being recognized over the term of the agreement. Additionally, the Company will receive payments for certain clinical, regulatory and sales milestones, product sales, and royalty payments based on Sanofi-Synthelabo's sales of the Eligard products. Under the terms of the agreement, the Company will fund all research and development for the Eligard one-, three-, and four-month products and Sanofi-Synthelabo will fund all research and development for a six-month formulation of Eligard. As part of the agreement, Sanofi-Synthelabo purchased 824,572 shares of the Company's common stock for \$15.0 million.

During the year ended December 31, 2001, the Company received \$6.0 million of milestone payments related to certain FDA filings. The milestone payments were recorded as deferred revenue and are being recognized as revenue over the remaining term of the agreement using the straight-line method. Additionally, in 2001, the Company received \$1.0 million as an advanced payment for research and development of the Eligard 45-mg six-month product that was performed in 2002. The \$1.0 million advanced payment was reflected as deferred revenue at December 31, 2001 and recognized as contract research and development revenue as allowable expenses were incurred during the year ended December 31, 2002.

The Company received \$15.0 million of milestone payments from Sanofi-Synthelabo during the year ended December 31, 2002. Atrix received \$6.0 million for the May 2002 first commercial U.S. sales of Eligard 7.5-mg one-month product and \$6.0 million for the September 2002 first commercial U.S. sales of Eligard 22.5-mg three-month product. Additionally, the Company received \$3.0 million for the April 2002 filing of a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, for the Eligard 30-mg four-month product. The milestone payments were recorded as deferred revenue and are being recognized as revenue over the remaining term of the agreement using the straight-line method.

***MediGene AG***

In April 2001, the Company entered into an exclusive European marketing agreement with MediGene AG, a German biotechnology company, to market the Eligard 7.5-mg one-, 22-mg three-, and 30-mg four-month products. Additionally, MediGene has the right to develop the Eligard 45-mg six-month product. The Company received a license fee of \$2.0 million upon signing the agreement. The license fee was recorded as deferred revenue and is being recognized over the term of the agreement on a straight-line basis. Additionally, the Company will receive payments for certain clinical, regulatory and sales milestones, product sales and royalty payments based on MediGene's sales of Eligard products. Under the terms of the agreement, the Company will fund all research and development for the products with the exception of costs required to obtain certain European approvals, which shall be borne by MediGene if it chooses to pursue such approvals. As part of the agreement, MediGene purchased 233,918 shares of the Company's common stock for \$3.8 million. In November 2001, MediGene submitted a Marketing Authorization Application, or MAA, for the Company's Eligard 7.5-mg one-month product to the German regulatory authority, Bundesinstitut für Arzneimittel und Medizinprodukte, or BfArM, as a Reference Member State under a Mutual Recognition Procedure.

In April 2002, MediGene submitted a MAA for the Company's Eligard 22.5-mg three-month product to BfArM as the Reference Member State under a Mutual Recognition Procedure. In conjunction with the regulatory filings of the Eligard 7.5-mg one-month and Eligard 22.5-mg three-month products, the Company received a \$1.0 million milestone payment from MediGene. This milestone payment from MediGene was recorded as deferred revenue and is being recognized as revenue over the remaining term of the agreement using the straight-line method.

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**ATRIX LABORATORIES, INC. AND SUBSIDIARIES**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

***Fujisawa Healthcare, Inc.***

In October 2001, the Company entered into an exclusive North American marketing agreement with Fujisawa Healthcare, Inc. for the Atrisone acne product. The Company received a \$2.0 million license fee upon signing of the agreement. The license fee was recorded as deferred revenue and is being recognized as revenue over the term of the agreement using the straight-line method. Additionally, the Company will receive payments for certain clinical, regulatory and sales milestones, product sales, and royalty payments for Fujisawa's sales of the Atrisone acne product. Under the terms of the agreement, Fujisawa commenced reimbursing the Company for a significant portion of the research and development costs of the product in July 2001.

***Geneva Pharmaceuticals, Inc. (a Subsidiary of Novartis)***

In August 2000, the Company entered into a development agreement with Geneva Pharmaceuticals, Inc. to develop generic topical prescription dermatology products. Under the terms of the agreement, Geneva will reimburse the Company for 50% of the research and development costs incurred on the products. Additionally, the Company and Geneva will split profits from sales of products equally.

***Elan International Services, Ltd.***

In July 2000, the Company formed a joint venture, Transmucosal Technologies Ltd., with Elan International Services, Ltd., a wholly owned subsidiary of Elan Corporation, plc. The purpose of the joint venture is to develop and commercialize oncology and pain management products. As of December 31, 2002, the two joint venture projects are currently under review for further development.

In connection with the formation of Transmucosal Technologies Ltd., the Company issued to Elan 12,015 shares of its Series A convertible exchangeable preferred stock (Series A), valued at \$12.0 million in exchange for 6,000 shares of common stock and 3,612 shares of preferred stock of Transmucosal Technologies Ltd., representing an initial ownership in the joint venture of 80.1%. Series A bears a 7% annual dividend, accruing semi-annually, payable in-kind. During the year ended December 31, 2001, the Company issued 856 shares of Series A stock in payment of accreted dividends of \$0.9 million. When the Series A stock was issued in payment of these dividends, the trading price of the Company's common stock was in excess of the conversion rate of the Series A. As a result, the Company recorded a charge of \$0.3 million for the beneficial conversion feature related to this issuance, which was recorded as an additional dividend on preferred stock. During the year ended December 31, 2002, the Company issued 917 shares of Series A stock in payment of accreted dividends of \$0.9 million. No beneficial conversion feature charges were recorded in 2002 because the trading price of the Company's common stock was less than the conversion rate of the Series A at the time the shares were issued. Accreted and unpaid dividends at December 31, 2002 and 2001 were \$0.4 million and \$0.4 million, respectively.

Series A is convertible as of July 2002, at Elan's option, into the Company's common stock at \$18.00 per common share, subject to anti-dilution adjustments. Elan may elect to exchange its Series A stock for a 30.1% ownership interest in the joint venture, increasing Elan's ownership in Transmucosal Technologies to 50% and decreasing the Company's ownership to 50%. This exchange right will terminate if Elan elects to convert the Series A stock into the Company's common stock. The Series A stock must be redeemed by the Company in July 2006, either in cash or in the Company's common stock at Atrix's option, in an amount equal to the liquidation preference. The liquidation preference of Series A is its stated value plus accreted and unpaid dividends. In connection with the formation of the joint venture, Elan purchased 442,478 shares of the Company's common stock for \$5.0 million and the Company issued Elan a warrant to purchase up to 1,000,000 shares of the Company's common stock at \$18.00 per share. The warrant was exercisable at issuance and expires in July 2005. Additionally, the Company and Elan entered into a convertible promissory note agreement whereby the Company may borrow up to

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**ATRIX LABORATORIES, INC. AND SUBSIDIARIES**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

\$8.0 million from Elan to fund its share of research and development activities undertaken by the joint venture. The note is convertible into the Company's common stock at \$14.60 per share. At December 31, 2002 and 2001, no amounts have been drawn under this note.

Because of the exchange feature, the Series A is presented outside of stockholders' equity (deficit). Its carrying value equals the fair value at the date of issuance increased for accreted dividends. Future adjustments to the Series A value recorded outside of the Company's stockholders' equity (deficit) may be necessary. If the fair value of the Company's preferred stock investment in Transmucosal Technologies exceeds the carrying value of the Series A, the Company will increase the value of the Series A recorded outside of permanent equity by such excess amount. The Company will recognize subsequent increases or decreases in the value of the Series A recorded outside of permanent equity; however, decreases will be limited to amounts previously recorded as increases so as not to reduce the carrying amount of the Series A below the original carrying value plus all accreted dividends.

The exchange right is exercisable by Elan at any time prior to the sixth anniversary of the first issuance of the Company's Series A. If Elan exercises its exchange right then a payment is due to the Company from Elan equal to 30.1% of the aggregate of the development funding provided to the joint venture through the exchange date. This amount is computed for all funding provided to the joint venture regardless of whether it was provided by Elan or the Company. This payment is due only if Elan exercises the exchange right. Further, this payment may be made in cash, through forgiveness of a corresponding amount due to Elan under the convertible promissory note or through a combination of cash and debt forgiveness. Currently, there are no amounts outstanding under the note agreement; consequently, the payment would be due in cash. If there are amounts due under the note at the time of the exchange, it is Elan's option to pay either in cash, through note forgiveness or through a combination of cash and debt forgiveness. For purposes of determining the fair value of the exchange right, the amount of this payment is subtracted from the fair value of 30.1% of the joint venture.

Under the terms of the related agreements, in July 2000, Transmucosal Technologies Ltd. recognized \$15.0 million expense to Elan for a license granted by Elan to the joint venture for exclusive rights to use Elan's nanoparticulate drug delivery technology. This license expense was recognized when incurred in accordance with SFAS No. 2, *Accounting for Research and Development Costs*, as the sole use of the license in research and development activities of the joint venture and the license has no future alternative use. Additionally, the joint venture contracts with Atrix and Elan to perform certain research and development activities. During the years ended December 31, 2002, 2001 and 2000, the Company earned contract research and development revenues of \$1.2 million, \$4.1 million and \$0.3 million, respectively, and had receivables from the joint venture at December 31, 2002 and 2001 of \$0.3 million and \$0.9 million, respectively. Additionally, the Company had payables to the joint venture at December 31, 2002 and 2001 of \$0.2 million and \$0.8 million, respectively. During 2002, 2001 and 2000, the Company recognized \$1.0 million, \$3.3 million and \$12.2 million, respectively, for its share of the losses of Transmucosal Technologies Ltd.

***CollaGenex Pharmaceuticals, Inc.***

In August 2001, the Company licensed the exclusive U.S. marketing rights for Atridox, Atrisorb FreeFlow GTR Barrier and Atrisorb-D GTR Barrier products to CollaGenex Pharmaceuticals, Inc. following the reacquisition of the sales and marketing rights from Block Drug Corporation. The Company received a \$1.0 million license fee upon signing of the agreement. Additionally, the Company will receive payments for product sales and royalty payments for CollaGenex's sales of the dental products. In connection with the transaction, the Company purchased 330,556 shares of CollaGenex's common stock for \$3.0 million which was a \$0.5 million premium to market at the date of purchase. The Company recorded the common stock as an available-for-sale security and the premium was reflected as a reduction

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**ATRIX LABORATORIES, INC. AND SUBSIDIARIES**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

of the license. The net license fee was recorded as deferred revenue and is being recognized as revenue over the term of the agreement using the straight-line method. CollaGenex commenced U.S. sales of Atridox and Atrisorb FreeFlow in November 2001 and commenced Atrisorb-D sales in January 2002.

***Block Drug Corporation***

In 1996, the Company licensed exclusive U.S. marketing rights for Atridox, Atrisorb FreeFlow GTR Barrier and Atrisorb-D GTR Barrier to Block Drug Corporation. Under the terms of the agreement, the Company received a license fee, certain regulatory, marketing and sales milestone payments, product sales and royalty payments from Block Drug's sales of the products. Prior to 2000, the Company received license fee and milestone payments in the amount of \$24.1 million. These fees were recorded as revenue when received; however, as discussed in Note 1, in 2000 the Company changed its method of recognizing license fee and milestone payments to record them as deferred revenue and recognize the revenue over the term of the agreement under the straight-line method.

In August 2001, the Company reacquired certain North American marketing rights to the dental products from Block Drug. Under the terms of the agreement, Block Drug agreed to pay the Company \$3.0 million for milestone events previously achieved by the Company and the Company agreed to pay Block Drug up to \$7.0 million, based on sales of products, over the term of the agreement, which is through August 2005. Upon execution of the termination agreement in August 2001, all previous agreements between the Company and Block Drug were terminated. The Company recorded the additional milestone payments as deferred revenue and records payments made to Block Drug as a reduction to deferred revenue. The additional milestone payments and the payments made to Block Drug are being recognized as revenue and as a reduction to revenue, respectively, over the term of the agreement under the straight-line method. As of December 31, 2002, the Company has paid Block Drug \$3.9 million under this agreement.

***Other Collaborations***

The Company has other various individually less significant collaborative agreements that provide for license fees, milestone payments and research and development payments. During the years ended December 31, 2002, 2001 and 2000, the Company received license fees and milestone payments of \$1.0 million, \$0.1 million, and \$0.2 million, respectively from other collaborations. These payments are being recognized as revenue over the terms of the related contracts using the straight-line method.

**6. STOCK OPTION PLANS**

As of December 31, 2002, the Company has the following stock-based plans: (i) the 1987 Performance Stock Option Plan; (ii) the 2000 Stock Incentive Plan; (iii) the Non-Employee Director Stock Incentive Plan; and (iv) the Non-Qualified Stock Option Plan. These plans are discussed below.

***1987 Performance Stock Option Plan (the 1987 Plan)***

The Company has reserved 2,500,000 of its authorized but unissued common stock for stock options to be granted under the 1987 Plan. Under the terms of the 1987 Plan, options generally vest ratably over a period of three years from the date of grant and expire after ten years. The exercise price of all options is the closing bid price of the stock on the date of grant. The 1987 Plan expired in May 2002 and no stock options will be granted under this plan after expiration. However, all currently outstanding options will vest and will be exercisable pursuant to their terms at grant.

**Table of Contents****ATRIX LABORATORIES, INC. AND SUBSIDIARIES****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following tables summarize information on stock option activity for the 1987 Plan:

	Number of Shares	Exercise Price Per Share	Weighted- Average Exercise Price
Options outstanding, December 31, 1999	1,427,952	\$ 5.38 - 20.75	\$ 9.54
Options granted	289,450	7.88 - 16.25	9.53
Options canceled or expired	(71,526)	5.50 - 18.94	9.37
Options exercised	(135,352)	9.00 - 19.00	14.67
Options outstanding, December 31, 2000	1,510,524	5.38 - 20.75	9.61
Options granted	86,390	5.50 - 25.99	16.12
Options canceled or expired	(88,277)	5.50 - 17.25	8.10
Options exercised	(393,980)	5.50 - 20.75	9.98
Options outstanding, December 31, 2001	1,114,657	5.38 - 25.99	10.11
Options granted	7,000	22.25 - 22.99	22.46
Options canceled or expired	(6,386)	5.50 - 17.25	11.31
Options exercised	(240,073)	5.50 - 17.25	9.065
Options outstanding, December 31, 2002	875,198	\$ 5.37 - 25.99	\$ 10.48
Options outstanding were available for exercise as follows:			
Exercisable at December 31, 2002	753,152		\$ 9.95
Exercisable at December 31, 2001	816,999		9.76
Exercisable at December 31, 2000	972,784		9.90

Range of Exercise Prices	Number Outstanding at December 31, 2002	Weighted- Average Remaining Contractual Life	Weighted- Average Exercise Price	Number Exercisable at December 31, 2002	Weighted- Average Exercise Price Exercisable
\$ 5.38 - 5.88	127,465	7 years	\$ 5.56	127,465	\$ 5.56
6.63 - 8.75	123,127	3 years	6.97	118,027	6.94
9.00 - 9.94	327,790	6 years	9.63	261,566	9.65
10.00 - 12.75	147,355	5 years	10.63	129,776	10.70
14.50 - 16.50	85,880	5 years	16.49	85,200	16.49
17.25 - 25.99	63,578	6 years	23.05	31,118	20.84
\$ 5.38 - 25.99	875,195	5 years	\$ 10.48	753,152	\$ 9.95

**2000 Stock Incentive Plan (the 2000 Plan)**

The Company has reserved 2,750,000 of its authorized but unissued common stock for stock options to be granted under the 2000 Plan. Under the terms of the 2000 Plan, options generally vest ratably over a period of three years from the date of grant and expire ten years after grant. The exercise price of all options is the closing bid price of the stock on the date of grant. There are 118,298 shares that remain available under the 2000 Plan for future employee stock option grants.

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In August 2001, the Company adopted the 2001 Executive Long Term Incentive Compensation Program (the 2001 Program ) pursuant to, and subject to the provisions of, the 2000 Plan. Only the Company's chief executive officer and chairman of the board is eligible to receive awards under the 2001 Program. Grants may be made under the 2001 Program at any time prior to August 5, 2004. The exercise price of the options is determined by the Board of Directors or a designated committee. The aggregate value of awards that may be granted under the 2001 Program, at the time of grant, is \$7.0 million. Awards

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**Table of Contents****ATRIX LABORATORIES, INC. AND SUBSIDIARIES****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

under the 2001 Program vest and become exercisable as determined by the Board of Directors or a designated committee. The Board of Directors or a designated committee may determine that awards shall be fully vested at the time of grant or base vesting or the lapse of a repurchase right on the attainment of designated performance goals and criteria, the passage of time, the occurrence of one or more events, or other factors. On August 6, 2001, the Company granted 100,503 options to the chief executive officer at an exercise price of \$5.00 per share which was below fair value of \$24.90 per share based on stated market quotes at the date of the grant. All of these options granted to the chief executive officer were fully vested at the date of the grant. As a result, the Company recognized \$2.0 million of administrative compensation expense in the year ended December 31, 2001. In 2002, the Company granted the Chief Executive Officer 100,000 options at market and above. In 2002, in connection with the retirement of an officer of the Company, the Company accelerated the vesting of 100,500 options held by that officer. As a result, the Company recognized a one-time charge of \$1.3 million.

The following tables summarize information about stock option activity for the 2000 Plan:

	Number of Shares	Exercise Price Per Share	Weighted- Average Exercise Price
Options outstanding, December 31, 1999			
Options granted	1,064,325	\$ 9.00 - 18.88	\$ 12.09
Options canceled or expired	(3,840)	9.00 - 15.19	10.60
Options outstanding, December 31, 2000	1,060,485	9.00 - 18.88	12.09
Options granted	1,047,238	5.00 - 28.19	18.48
Options canceled or expired	(173,969)	9.00 - 25.99	17.59
Options exercised	(17,385)	9.00 - 17.63	10.43
Options outstanding, December 31, 2001	1,916,369	5.00 - 28.19	15.21
Options granted	820,400	12.88 - 30.00	22.29
Options canceled or expired	(122,452)	9.00 - 28.19	20.13
Options exercised	(149,448)	9.00 - 18.63	10.97
Options outstanding, December 31, 2002	2,464,869	\$ 5.00 - 30.00	\$ 17.58

Options outstanding were available for exercise as follows:

Exercisable at December 31, 2002	887,558	\$ 13.75
Exercisable at December 31, 2001	412,233	\$ 10.49
Exercisable at December 31, 2000		

Range of Exercise Prices	Number Outstanding at December 31, 2002	Weighted- Average Remaining Contractual Life	Weighted- Average Exercise Price	Number Exercisable at December 31, 2002	Weighted- Average Exercise Price Exercisable
\$ 5.00	100,503	9 years	\$ 5.00	100,503	\$ 5.00
9.00 - 9.75	414,566	7 years	9.61	271,233	9.61
10.06 - 14.81	333,778	8 years	11.48	154,136	11.93
15.00 - 19.25	487,531	8 years	16.94	216,353	16.78
20.25 - 24.98	750,950	9 years	22.47	43,725	22.99

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<u>25.00 - 30.00</u>	<u>377,541</u>	<u>9 years</u>	<u>26.18</u>	<u>101,608</u>	<u>25.81</u>
<u>\$ 5.00 - 30.00</u>	<u>2,464,869</u>	<u>8 years</u>	<u>\$ 17.58</u>	<u>887,558</u>	<u>\$ 13.75</u>

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**Table of Contents****ATRIX LABORATORIES, INC. AND SUBSIDIARIES****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)*****Non-Employee Director Stock Incentive Plan (the DSI Plan)***

During the year ended December 31, 1999, the Company adopted the DSI Plan. The purposes of the DSI Plan are to attract and retain the best available Non-Employee Directors, to provide them additional incentives, and to promote the success of the Company's business. This DSI Plan is comprised of two components: an Automatic Option Grant Program and a Stock Fee Program.

***Automatic Option Grant Program***

Immediately following each annual meeting of the Company's stockholders, commencing with the 1999 Annual Stockholders Meeting, each Non-Employee Director is granted a Non-Qualified Stock Option to purchase 4,000 shares of the Company's common stock. These options vest ratably over a period of three years and expire ten years after grant. The exercise price of each option is equal to the market price of the Company's common stock on the date of the grant. All options awarded under this portion of the plan are made under the 2000 Stock Incentive Plan. For the year ended December 31, 2002, 28,000 stock options were issued at a price of \$23.19 and none were exercised under this program.

***Stock Fee Program***

Each non-employee director receives an annual retainer fee of \$1,500 and an annual grant of 2,800 options. The retainer fee is paid in cash, restricted shares of common stock or a combination thereof at the director's selection. The number of shares issued is determined based on the fair value of the Company's common stock on the date paid. The options vest ratably over a period of three years. The exercise price of each stock option, which has a maximum ten-year life, is equal to the market price of the Company's common stock on the date of the grant. The maximum aggregate number of restricted shares that may be issued under the Stock Fee Program portion of the plan is 25,000 shares. During the years ended December 31, 2002, 2001 and 2000, the Non-Employee Directors elected to have 1,871, 932, and 3,092 shares of Restricted Common Stock issued, respectively. As of December 31, 2002, there are 16,689 shares that remain available to be issued under this program.

***Pro Forma Effect of Stock Option Issuances***

The Company accounts for the 1987 Plan, the 2000 Plan and the DSI Plan options using the intrinsic value method. Accordingly, no compensation expense has been recognized for stock option grants. Had compensation cost been determined based on the fair value of the options at the grant dates of awards under the 1987 Plan, 2000 Plan and DSI Plan consistent with SFAS No. 123, the Company's net loss applicable to common stock and basic and diluted loss per common share would have been changed to the pro forma amounts indicated below (amounts in thousands, except share data):

	<u>2002</u>	<u>2001</u>	<u>2000</u>
Net loss applicable to common stock:			
as reported	\$(19,114)	\$(26,704)	\$(47,411)
pro forma	(29,254)	(34,072)	(51,498)
Basic and diluted net loss per common share:			
as reported	\$ (0.95)	\$ (1.63)	\$ (3.99)
pro forma	(1.46)	(2.08)	(4.33)

The weighted-average Black-Scholes fair value per option granted in 2002, 2001, and 2000 was \$6.16, \$8.63, and \$5.65, respectively. The fair value of options was estimated on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions used for grants in 2002, 2001 and 2000: no dividend yield, expected volatility of 60.3% for 2002, 62.2% for 2001, and 59.1%

**Table of Contents****ATRIX LABORATORIES, INC. AND SUBSIDIARIES****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

for 2000, risk free interest rates of 5.0% in 2002 and 7.0% in 2001 and 2000, and expected life of five years.

***Non-Qualified Stock Option Plan (the Non-Qualified Plan)***

The Company has reserved 150,000 shares of its authorized but unissued common stock for stock options to be granted to outside consultants under the Non-Qualified Plan. The Compensation Committee sets the option price and exercise terms granted under the Non-Qualified Plan. The exercise price of all options granted under the Non-Qualified Plan currently outstanding has been the closing market price at the date of grant. There are 42,020 shares as of December 31, 2002, which remain available under the Non-Qualified Plan for future stock option grants.

The Company accounts for grants under the Non-Qualified Plan at fair value. The fair value of options granted under the Non-Qualified Plan was estimated on the grant date using the Black-Scholes option-pricing model and included as compensation expense. The stock compensation recorded under the Non-Qualified Plan was not material for the years ended December 31, 2002, 2001 and 2000. The following weighted-average assumptions were used in 2002, 2001, and 2000: no dividend yield, expected volatility of 60.3% for 2002, 62.2% for 2001, and 59.1% for 2000, risk free interest rates of 5.0% in 2002 and 7.0% in 2001 and 2000, and expected lives of five years.

The following tables summarize information on stock option activity for the Non-Qualified Plan:

	<u>Number of Shares</u>	<u>Exercise Price Per Share</u>	<u>Weighted- Average Exercise Price</u>
Options outstanding, December 31, 1999	33,480	\$5.13 - 16.50	\$ 8.67
Options granted	20,000	6.00 - 10.13	8.06
Options exercised	(4,480)	6.63	6.63
Options outstanding, December 31, 2000	49,000	5.13 - 16.50	9.21
Options granted	10,000	20.31	20.31
Options exercised	(5,000)	6.00	6.00
Options outstanding, December 31, 2001	54,000	5.13 - 20.31	11.56
Options exercised	(6,000)	6.00 - 7.00	6.17
Options outstanding, December 31, 2002	48,000	\$5.13 - 20.31	\$12.24

Options outstanding were available for exercise as follows:

Exercisable at December 31, 2002	48,000	\$12.24
Exercisable at December 31, 2001	54,000	\$11.56
Exercisable at December 31, 2000	48,000	\$ 9.08

<u>Range of Exercise Prices</u>	<u>Number Outstanding at December 31, 2002</u>	<u>Weighted-Average Remaining Contractual Life</u>	<u>Weighted-Average Exercise Price</u>	<u>Number Exercisable at December 31, 2002</u>	<u>Weighted-Average Exercise Price Exercisable</u>
\$ 5.13 - 7.00	10,000	3 years	\$ 5.69	10,000	\$ 5.69

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9.50 - 10.125	13,000	7 years	7.08	13,000	7.08
10.88 - 12.28	9,000	4 years	11.34	9,000	11.34
15.38 - 20.31	16,000	6 years	18.67	16,000	18.67
<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
\$ 5.13 - 20.31	48,000	5 years	\$ 12.24	48,000	\$ 12.24
<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>

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Net deferred tax assets at December 31, consist of (amounts in thousands):

	<u>2002</u>	<u>2001</u>
Deferred tax assets:		
Net operating loss carryforwards	\$ 34,671	\$ 31,169
Research and development tax credit carryforwards	3,836	2,885
Amortization of intangibles	1,649	1,735
Deferred revenue	16,581	13,368
Depreciation	462	123
Stock compensation	789	927
Loss on write-down of marketable security	557	310
Other items	410	341
	<u>          </u>	<u>          </u>
Net deferred tax assets	58,955	50,858
	<u>          </u>	<u>          </u>
Less valuation allowance	58,955	50,858
	<u>          </u>	<u>          </u>
Total	\$ <u>          </u>	\$ <u>          </u>

The gross deferred tax assets have been reduced by a valuation allowance based on management's belief that it is currently more likely than not that such benefits will not be realized.

At December 31, 2002, the Company had approximately \$92.4 million of income tax net operating loss carryforwards, of which \$3.4 million relates to foreign losses available for carryforward. The Company has research and development credits of \$3.8 million which expire through 2022. At December 31, 2002 and 2001, the Company has \$1.0 million and \$1.8 million of deferred tax assets included in the total deferred tax asset for net operating loss carryforwards that resulted from the benefits from the exercise of employee stock options of \$3.0 million and \$5.3 million for the year ended December 31, 2002 and 2001, respectively, which when subsequently recognized will be allocated to additional paid in capital. The Internal Revenue Code places certain limitations on the annual amount of net operating loss carryforwards which can be utilized if certain changes in the Company's ownership occurs.

A reconciliation of the differences in income tax expense from income (loss) computed at the federal statutory rate and income tax expense as recorded for the years ended December 31 are as follows (amounts in thousands):

	<u>2002</u>	<u>2001</u>	<u>2000</u>
Income tax computed at federal statutory rate:	\$(6,177)	\$(8,681)	\$(15,990)
State income taxes net of federal	(599)	(843)	(1,552)
Equity in loss of joint venture	330	1,117	4,565
Research and development	(701)	(565)	(353)
Amortization of intangibles	230	314	302
Other	(146)	32	315
Change in valuation allowance	7,063	8,626	12,713

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	<u>          </u>	<u>          </u>	<u>          </u>
Income tax expense	\$	\$	\$
	<u>          </u>	<u>          </u>	<u>          </u>

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**Table of Contents****ATRIX LABORATORIES, INC. AND SUBSIDIARIES****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****8. SEGMENT, GEOGRAPHIC AND CUSTOMER INFORMATION**

The Company is engaged principally in one line of business, the development and commercialization of drug delivery systems. Enterprise-wide disclosures about net sales and royalties by category and total revenues by geographic area are presented below.

Net sales and royalties by category consisted of the following for the years ended December 31 (in thousands):

	<u>2002</u>	<u>2001</u>	<u>2000</u>
Eligard products	\$2,079	\$	\$
Dental products	2,631	2,436	4,705
Contract manufacturing	848	1,092	1,235
Other	191	290	216
	<u>          </u>	<u>          </u>	<u>          </u>
Net sales and royalties	\$5,749	\$3,818	\$6,156
	<u>          </u>	<u>          </u>	<u>          </u>

Revenues by geographic area consisted of the following for the years ended December 31 (in thousands):

	<u>2002</u>	<u>2001</u>	<u>2000</u>
United States	\$23,289	\$10,306	\$ 8,872
Foreign countries	3,095	5,505	1,171
	<u>          </u>	<u>          </u>	<u>          </u>
Total revenue	\$26,384	\$15,811	\$10,043
	<u>          </u>	<u>          </u>	<u>          </u>

The geographic classification of revenues was based upon the domicile of the entity from which the revenues were earned. Long-lived assets in foreign countries individually and in aggregate did not exceed 10% of total long-lived assets of the Company.

For the year ended December 31, 2002, revenues from four customers accounted for 26%, 17%, 14% and 14% of total revenue. For the year ended December 31, 2001, revenues from two customers accounted for 26% and 22% of total revenue. For the year ended December 31, 2000, revenues from three customers accounted for 49%, 12% and 10% of total revenue.

At December 31, 2002, amounts due from two customers each exceeded 10% of accounts receivable and accounted for 52% of total accounts receivable. At December 31, 2001, amounts due from three customers each exceeded 10% of accounts receivable and accounted for 71% of total accounts receivable.

**9. COMMITMENTS AND CONTINGENCIES**

As of December 31, 2002, minimum rental commitments for future years under non-cancelable operating leases of one year or more are as follows (amounts in thousands):

**Years Ended**

**Minimum Rental**

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December 31,	Commitments
2003	\$ 581
2004	484
2005	449
2006	190
2007	7
Total	\$1,711

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**ATRIX LABORATORIES, INC. AND SUBSIDIARIES**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Rent expenses were \$0.6 million, \$0.4 million, and \$0.3 million for the years ended December 31, 2002, 2001, and 2000, respectively.

In January 2001, the Company acquired an exclusive option from Tulane University Health Sciences Center to license a patented human growth hormone releasing peptide-1 compound, or GHRP-1, for \$0.5 million. In September 2001, the Company exercised its option to license GHRP-1 for an additional \$2.0 million. Under the agreement, the Company will be responsible for all research and development funding and will pay Tulane a royalty on sales of any GHRP-1 product developed.

The Company has a 401(k)-Employee Savings Plan, or the Savings Plan, which allows eligible employees to contribute from 1% to 17% of their income to the Savings Plan. Effective January 1, 2002, the Company amended the Savings Plan Company match from 50% of the first 6% of the employees' contributions to 100% company match on the first 6% of employees' 401(k) contributions and 50% company match of the next 6% of the employees' contributions. The Company's matching contributions to the Savings Plan, which vest immediately, were \$0.4 million, \$0.1 million, and \$0.1 million for the years ended December 31, 2002, 2001, and 2000, respectively.

The Company has an Employee Stock Purchase Plan, or ESPP, that provides eligible employees with the opportunity to purchase shares through authorized payroll deductions at 85% of the average market price on the last day of each quarter. The Company reserved 300,000 shares of its authorized but unissued common stock for issuance under the ESPP, of which 272,846 shares remain available at December 31, 2002.

In November 2002, the Company's Board of Directors amended the September 17, 2001 stock repurchase program to provide that the Company may acquire up to a maximum of \$20.0 million of Atrix common stock in the open market or in privately negotiated transactions under this program. The program terminates on the earlier of the date that the Company has repurchased \$20.0 million of its common stock or December 31, 2003. Since the inception of the stock repurchase program on September 17, 2001 through December 31, 2002, the Company has repurchased a total of 657,700 shares of its common stock in the open market for \$10.7 million, or an average price per share of \$16.33. During the year ended December 31, 2002, the Company repurchased 580,200 shares of its common stock in the open market for \$9.2 million, or an average price per share of \$15.82 under the program. As of December 31, 2002, \$9.3 million remains available to repurchase the Company's common stock under the stock repurchase program.

The Company is involved in certain litigation arising in the ordinary course of business. Although management is of the opinion that these matters will not have a material adverse effect on the consolidated financial position or results of operations of the Company, the ultimate outcome of these matters cannot, at this time, be predicted, in light of the uncertainties inherent in litigation.



**Table of Contents****ATRIX LABORATORIES, INC. AND SUBSIDIARIES****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****10. SELECTED QUARTERLY FINANCIAL INFORMATION (UNAUDITED)**

The following table summarizes the quarterly financial information for the year ended December 31, 2002 (amounts in thousands):

	<b>2002 Fiscal Quarters</b>			
	<b>First</b>	<b>Second</b>	<b>Third</b>	<b>Fourth</b>
Total revenue	\$ 5,017	\$ 6,484	\$ 7,624	\$ 7,259
Total operating expense	10,171	10,711	12,353	13,859
Net other income (expense)	621	(192)	810	1,273
Loss before extraordinary items	(4,533)	(4,419)	(3,919)	(5,327)
Net loss applicable to common stock	(4,775)	(4,608)	(4,161)	(5,570)
Basic and diluted earnings per common share before extraordinary items	(0.23)	(0.22)	(0.20)	(0.27)
Basic and diluted earnings per common share for net loss applicable to common stock	(0.24)	(0.23)	(0.21)	(0.28)

The following table summarizes the quarterly financial information for the year ended December 31, 2001 (amounts in thousands):

	<b>2001 Fiscal Quarters</b>			
	<b>First</b>	<b>Second</b>	<b>Third</b>	<b>Fourth</b>
Total revenue	\$ 3,255	\$ 4,265	\$ 3,257	\$ 5,036
Total operating expense	8,470	8,381	12,877	8,152
Net other expense	2,106	517	243	280
Loss before extraordinary items	(7,320)	(4,633)	(9,863)	(3,396)
Net loss applicable to common stock	(7,815)	(4,856)	(10,092)	(3,938)
Basic and diluted earnings per common share before extraordinary items	(0.52)	(0.31)	(0.58)	(0.18)
Basic and diluted earnings per common share for net loss applicable to common stock	(0.55)	(0.32)	(0.59)	(0.21)

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Exhibit Number	Description
2.1	Agreement and Plan of Reorganization dated November 24, 1998 by and among Atrix Laboratories, Inc., Atrix Acquisition Corporation and ViroTex Corporation.(1)
2.2	Certificate of Merger of Atrix Acquisition Corporation into ViroTex Corporation dated November 24, 1998.(1)
3.1	Amended and Restated Certificate of Incorporation.(2)
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation.(3)
3.3	Certificate of Designation of the Series A Preferred Stock filed with the State of Delaware on September 25, 1998.(4)
3.4	Certificate of Designations of Preferences and Rights of Series A Convertible Exchangeable Preferred Stock filed with the State of Delaware on July 18, 2000.(5)
3.5	Ninth Amended and Restated Bylaws.(6)
4.1	Form of Common Stock Certificate.(7)
4.2	Amended and Restated Rights Agreement (including form of Right Certificate, as Exhibit A, and form of Summary of Rights, as Exhibit B).(8)
4.3	Registration Rights Agreement, dated as of July 18, 2000, between Registrant and Elan International Services, Ltd., or EIS.(5)
4.4	Warrant dated as of July 18, 2000, issued by Registrant to EIS.(5)
4.5	Convertible Promissory Note, dated as of July 18, 2000, issued by Registrant to EIS.(5)
4.6	Warrant, dated as of April 4, 2001, issued by Atrix Laboratories, Inc. to Ferghana Partners, Inc.(9)
4.7	Indenture, dated November 15, 1997, by and among the Registrant and State Street Bank and Trust Company of California, N.A., as trustee thereunder, including the Form of Note.(10)
4.8	Warrant to purchase 6,750 shares of Atrix Common Stock issued to Gulfstar Investments, Limited.(2)
10.1	Lease Agreement dated May 11, 1991 between the Registrant and GB Ventures.(7)
10.2	Agreement dated December 16, 1996 between the Registrant and Block Drug Corporation ( Block Agreement ).(11)
10.2A	First Amendment to Block Agreement dated June 10, 1997.(2)**
10.2B	Second Amendment to Block Agreement dated July 31, 1997.(2)**
10.2C	Third Amendment to Block Agreement dated February 4, 1998.(2)**
10.2D	Fourth Amendment to Block Agreement dated January 12, 1999.(2)**
10.2E	Fifth Amendment to Block Agreement dated January 27, 1999.(2)**
10.2F	Sixth Amendment to Block Agreement dated September 24, 1999.(12)**
10.2G	Eighth Amendment to Block Agreement dated as of August 24, 2001.(13)**
10.3	Amended and Restated Performance Stock Option Plan, as amended.(2)
10.4	Non-Qualified Stock Option Plan, as amended.(2)
10.5	Non-Employee Director Stock Incentive Plan.(14)
10.6	Employment Agreement between Registrant and Dr. J. Steven Garrett dated April 17, 1995.(2)
10.7	Employment Agreement between Registrant and Dr. David W. Osborne dated November 24, 1998.(2)
10.8	Personal Services Agreement between Registrant and David R. Bethune dated August 10, 1999.(14)
10.9	Stock Purchase Agreement, dated as of August 8, 2000, by and between Registrant and Pfizer Inc.(14)
10.10	Collaborative Research Agreement, dated as of August 8, 2000, by and between Registrant and Pfizer Inc.(14)**
10.11	License and Royalty Agreement, dated as of August 8, 2000, by and between Registrant and Pfizer Inc.(14)**
10.12	Collaboration, Development and Supply Agreement dated as of August 28, 2000 between Registrant and Geneva Pharmaceuticals, Inc.(16)**
10.13	Securities Purchase Agreement, dated as of July 18, 2000, between Registrant and EIS.(5)**

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Exhibit Number	Description
10.14	Newco Registration Rights Agreement, dated as of July 18, 2000, among Registrant, Atrix Newco Ltd., or Newco, and EIS.(5)
10.15	Subscription, Joint Development and Operating Agreement, dated as of July 18, 2000, among EIS, Registrant, Newco and Elan Pharma International Limited, or EPIL.(5)**
10.16	Company License Agreement, dated as of July 18, 2000, among Registrant, Newco and Elan Corporation plc, or Elan.(5)**
10.17	EPIL License Agreement, dated as of July 18, 2000 among Elan, EPIL, Newco and Registrant.(5)**
10.18	Collaboration, License and Supply Agreement, dated as of December 8, 2000, by and between Registrant and Sanofi-Synthelabo Inc.(17)**
10.19	Stock Purchase Agreement, dated as of December 29, 2000, by and between Registrant and Sanofi-Synthelabo.(17)
10.20	2000 Stock Incentive Plan.(18)
10.21	License Agreement by and between Registrant and CollaGenex Pharmaceuticals, Inc. dated as of August 24, 2001. (13)**
10.22	Stock Purchase Agreement by and between Registrant and CollaGenex Pharmaceuticals, Inc. dated as of August 24, 2001.(13)**
10.23	Collaboration, License and Supply Agreement by and between Registrant and Fujisawa Healthcare, Inc., dated October 15, 2001.(13)**
10.24	Collaboration, License and Supply Agreement, dated as of April 4, 2001, by and between Registrant and MediGene.(19)**
10.25	Stock Purchase Agreement, dated as of April 4, 2001, by and between Registrant and MediGene.(19)**
10.26	2001 Executive Long Term Incentive Compensation Program.(6)
10.27	Registration Rights Agreement, dated as of November 15, 1997, by and among Registrant and NationsBanc Montgomery Securities, Inc. and SBC Warburg Dillon Read, Inc.(10)
10.28	Amended and Restated Performance Stock Option Plan, as amended.(2)
21	Subsidiaries of the Registrant.(18)
23	Consent of Deloitte & Touche LLP
99.1	Certification of Chief Executive Officer
99.2	Certification of Chief Financial Officer

\*\* We have omitted certain portions of this Exhibit and have requested confidential treatment with respect to such portions.

- (1) Incorporated by reference to Registrant's Current Report on Form 8-K dated November 24, 1998, as filed with the Securities and Exchange Commission (File No. 000-18321).
- (2) Incorporated by reference to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1998, as filed with the Securities and Exchange Commission (File No. 000-18321).
- (3) Incorporated by reference to Registrant's Registration Statement on Form S-3, filed with the Securities and Exchange Commission on June 5, 2001 (File No. 333-55634).
- (4) Incorporated by reference to Registrant's Registration Statement on Form 8-A, as filed with the Securities and Exchange Commission on October 1, 1998 (File No. 000-18231).
- (5) Incorporated by reference to Registrant's Current Report on Form 8-K dated July 18, 2000, as filed with the Securities and Exchange Commission on August 4, 2000 (File No. 000-18321).
- (6) Incorporated by reference to Registrant's Annual Report on Form 10-K dated December 31, 2001, as filed with the Securities and Exchange Commission (File No. 000-18321).
- (7) Incorporated by reference to Registrant's Annual Report on Form 10-K for the fiscal year ended September 30, 1993, as filed with the Securities and Exchange Commission (File No. 000-18321).
- (8)

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Incorporated by reference to Registrant's Current Report on Form 8-K dated November 16, 2001, as filed with the Securities and Exchange Commission on November 27, 2001 (File No. 000-18231).

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- (9) Incorporated by reference to Registrant's Registration Statement on Form S-3, filed with the Securities and Exchange Commission on February 6, 2002 (File No. 333-82250).
- (10) Incorporated by reference to Registrant's Current Report on Form 8-K dated November 6, 1997, as filed with the Securities and Exchange Commission on December 9, 1997 (File No. 000-18231).
- (11) Incorporated by reference to Registrant's Current Report on Form 8-K dated December 16, 1996, as amended on May 20, 1998, as filed with the Securities and Exchange Commission (File No. 000-18321).
- (12) Incorporated by reference to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1999, as filed with the Securities and Exchange Commission (File No. 000-18321).
- (13) Incorporated by reference to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2001 (File No. 000-18231).
- (14) Incorporated by reference to Registrant's Current Report on Form 8-K dated August 8, 2000, as filed with the Securities and Exchange Commission on September 7, 2000 (File No. 000-18321).
- (15) Incorporated by reference to Registrant's Annual Report on Form 10-K for the year ended December 31, 1999, as filed with the Securities and Exchange Commission (File No. 000-18321).
- (16) Incorporated by reference to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2000, as filed with the Securities and Exchange Commission (File No. 000-18321).
- (17) Incorporated by reference to Registrant's Current Report on Form 8-K dated December 29, 2000, as filed with the Securities and Exchange Commission on February 23, 2001 (File No. 000-18231).
- (18) Incorporated by reference to Registrant's Annual Report on Form 10-K for the year ended December 31, 2000, as filed with the Securities and Exchange Commission (File No. 000-18231).
- (19) Incorporated by reference to Registrant's Current Report on Form 8-K dated April 4, 2001, filed with the Securities and Exchange Commission on June 20, 2001 (File No. 000-18231).