ATRIX LABORATORIES INC
Form 10-K/A
November 07, 2002

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

# FORM 10-K/A

# AMENDMENT NO. 2

[X] **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
**For the Fiscal Year Ended December 31, 2001**

**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** | **84-1043826** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| **2579 Midpoint Drive Fort Collins, Colorado** | **80525** |
| (Address of principal executive office) | (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 [X] No [ ]

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

Form 10-K or any amendment to this Form 10-K. [X]

The aggregate market value of voting stock held by non-affiliates of the Registrant as of March 26, 2002 was $446,922,463.

The number of shares of the Registrant s common stock outstanding as of March 26, 2002 was 20,101,315.

**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 May 5, 2002.

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**EXPLANATORY NOTE**

This Amendment No. 2 on Form 10-K/A amends the Registrant s Annual Report on Form 10-K for the year ended December 31, 2001, as amended by Amendment No. 1 on Form 10-K/A. This Amendment No. 2 reflects the restatement of the Registrant s consolidated financial statements discussed in Note 11 to the consolidated financial statements included in Item 14 and includes the audited financial statements of the Registrant s joint venture, Transmucosal Technologies Ltd., as previously filed in Amendment No. 1 on Form 10-K/A.

**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, pain management, growth hormone releasing peptide-1, oral interferon and dermatology products. We also form strategic alliances with large pharmaceutical and biotechnology companies utilizing our various drug delivery systems. We have significant strategic alliances with Pfizer Inc., Sanofi-Synthelabo Inc., MediGene AG, Fujisawa Healthcare, Inc., Elan International Services, Ltd., Geneva Pharmaceuticals, Inc. and CollaGenex Pharmaceuticals, Inc.

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 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.

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**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, particularly proteins, peptides and vaccines. 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 have preclinical feasibility studies with various companies for proteins, peptides and monoclonal antibodies.

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.

**Recent Developments**

The following discussion highlights significant events for our company during the year ended December 31, 2001.

***Significant 2001 Events with Collaborative Partners***

*Sanofi-Synthelabo, Inc.*

Under the terms of our agreement with Sanofi-Synthelabo, we received a $3.0 million milestone payment in June 2001 upon the FDA acceptance of our March 2001 filing of a New Drug Application, or NDA, for our Eligard 7.5-mg one-month product, formerly known as Leuprogel One-Month Depot. We received FDA approval to market our Eligard 7.5-mg one-month product in January 2002 and expect to commence our marketing launch of Eligard 7.5-mg in the third quarter of 2002.

We submitted an NDA to the FDA in September 2001 for our Eligard 22.5-mg three-month product and in December 2001, we received an additional $3.0 million milestone payment from Sanofi-Synthelabo upon the FDA acceptance of this filing. The combined $6.0 million milestone payments from Sanofi will be recognized as revenue over the remaining term of the agreement using the straight-line method.

*MediGene AG*

In April 2001, we entered into an agreement with MediGene to market our Eligard products in Europe. Under the terms of the MediGene agreement, we received an up-front licensing fee of $2.0 million and we may receive future additional licensing fees and milestone payments for certain clinical, regulatory and sales milestones upon approval for marketing by the European Medicine Evaluation Agency, or other

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competent authority. The $2.0 million licensing fee from MediGene will be recognized as revenue over the term of the agreement using the straight-line method. Additionally, MediGene purchased 233,918 shares of our common stock for approximately $3.8 million as part of the agreement and will provide funding to conduct clinical research and regulatory activities associated with seeking European marketing approvals.

In December 2001, MediGene submitted a Marketing Authorization Application, or MAA, for our Eligard 7.5-mg one month product to the German regulatory authority, Bundesinstitut fur Arzneimittel und Medizinprodukte, or BfArM, as a reference member state under a mutual recognition process.

*Fujisawa Healthcare, Inc.*

In October 2001, we entered into a collaboration, license and supply agreement with Fujisawa Healthcare for the exclusive North American marketing and distribution rights of our Atrisone® acne treatment product. The Fujisawa agreement provides up to $25.0 million for an up-front licensing fee and certain milestone payments. Additionally, we may receive a royalty on sales of the Atrisone product and a manufacturing margin. In October 2001, we received a $2.0 million up-front licensing fee from Fujisawa Healthcare, which will be recognized as revenue over the term of the agreement using the straight-line method.

*Elan International Services, Ltd.*

In March 2001, BEMA -Ondansetron, an anti-emetic product using our BEMA drug delivery system, was selected as the second compound under development in the joint venture. BEMA-Ondansetron, which is for the treatment of nausea and vomiting associated with cancer chemotherapy, is currently in preclinical studies.

After we submitted an Investigational New Drug Application, or IND, to the FDA in November 2001 for BEMA-Fentanyl, this product for the treatment of chronic and breakthrough cancer pain advanced from preclinical stage of development to Phase I clinical studies.

*Geneva Pharmaceuticals, Inc.*

In December 2001 and January 2002, we submitted Abbreviated New Drug Applications, or ANDAs, to the FDA for approvals of two separate generic dermatology products.

*Block Drug Termination Agreement*

Under the terms of an August 2001 amendment to our agreement with Block Drug Corporation, we reacquired the marketing rights for our dental products for $7.0 million, of which $3.3 million was paid upon execution of the amendment. The balance of $3.7 million will generally be payable over a four-year period based upon future net sales of the dental products and/or receipt of licensing fees for our dental products. In conjunction with the amendment to the Block agreement, Block paid us $3.0 million owed for the September 2000 FDA approval and Block s first commercial sale obligation of Atrisorb® FreeFlow with Doxycycline, or Atrisorb-D, a periodontal barrier product with the antibiotic doxycycline for gingival surgery. Finally, under the August 2001 amendment, each party agreed to terminate all legal proceedings against the other party relating to the agreement.

*CollaGenex Pharmaceuticals, Inc.*

We licensed the exclusive U.S. marketing rights for Atridox®, Atrisorb FreeFlow GTR Barrier and Atrisorb-D GTR Barrier to CollaGenex following the reacquisition of the sales and marketing rights from Block. Under the terms of the CollaGenex agreement, we received an up-front licensing fee of $1.0 million. Additionally, we will receive a royalty on net sales of the dental products and a manufacturing margin. As part of the transaction, we purchased 330,556 shares of CollaGenex s common stock for $3.0 million, the proceeds of which will primarily fund a revitalized marketing campaign by CollaGenex for Atridox and the Atrisorb Barrier products. CollaGenex commenced U.S. marketing of Atridox and Atrisorb FreeFlow in November 2001 and Atrisorb-D in January 2002.

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*Other Collaborations*

In August 2001, we entered into a marketing agreement with F.H. Faulding & Co. Limited, ABN, trading as Faulding Pharmaceuticals, to market our Eligard products in Australia and New Zealand. The agreement includes an up-front licensing fee, certain milestone payments, royalty payments on net sales, and a manufacturing margin for the Eligard products upon approval for marketing by the Therapeutic Goods Administration of Australia and/or other competent authorities in Australia and New Zealand. Additionally, Faulding will be responsible for regulatory submissions and any studies that may be necessary to gain approval with the Australian and New Zealand authorities.

In August 2001, we entered into a feasibility study agreement with Human Genome Sciences, Inc., a pioneer in the discovery and development of genomics-based drugs, to develop a sustained-release formulation of a Human Genome Sciences new proprietary protein utilizing our Atrigel® drug delivery system. Under the terms of the agreement, Human Genome Sciences will provide funding for the development of this product.

In December 2001, we signed an exclusive marketing agreement with PharmaScience, Inc., for the marketing and distribution of our dental products in Canada.

***Acquired Licensed Products in 2001***

In January 2001, we purchased an exclusive option from Tulane University Health Science Center to license a patented human growth hormone releasing peptide-1 compound, or GHRP-1. We exercised this option in September 2001 and paid Tulane $2.5 million. Possible applications of GHRP-1 include treatment of patients with AIDS or cancer, promotion of growth in children with short stature, and prevention of muscle wasting and frailty in aged individuals. Our intent is to deliver GHRP-1 for an extended period of time using our patented Atrigel drug delivery system. Additionally, under the terms of the Tulane agreement, we will pay Tulane a royalty on sales of any GHRP-1 product that may be developed and subsequently marketed. We will fund the research and development and perform most of the development effort.

We signed a licensing agreement for an oral interferon product with Amarillo Biosciences in September 2001 for $0.5 million. We are currently developing this product for the treatment of oral warts caused by human papilloma virus in HIV-infected patients and for the treatment of Behcet s disease. Behcet s disease is an autoimmune disorder that is characterized by mouth ulcers and generally two additional hallmark symptoms. The FDA granted the oral interferon product orphan drug status for both indications in January 2000. In November 2001, we submitted an IND to the FDA to proceed into human clinical studies for the treatment of oral warts and we commenced a Phase II clinical study for this product in the first quarter of 2002.

***Significant Capital Funding Events in 2001***

During the year ended December 31, 2001, we sold 3,565,000 shares of our common stock at a price of $23.00 per share under our shelf registration statement in two underwritten public offerings. The underwriters exercised their option to purchase 534,750 additional shares of our common stock in connection with our public offerings. We received net proceeds of $87.7 million from our public offerings and the over-allotment exercises, net of issuance costs of $6.6 million. We anticipate using the net proceeds from the offerings to broaden and strengthen our technologies, supplement our product pipeline, and further product development efforts.

Effective September 17, 2001, our Board of Directors approved a new stock repurchase program to acquire up to $5.0 million of our common stock. The stock repurchase program expires in May 2002. During the year ended December 31, 2001, we repurchased a total of 77,500 shares of our common stock in the open market for $1.6 million, or an average share price of $20.11.

During the year ended December 31, 2001, we completed a series of private transactions involving the exchange of 1,725,735 shares of our common stock for $31.0 million of our 7% Convertible Subordinated Notes.

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**Our Marketed Products and Products under Development**

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

| Pharmaceutical Product Candidates | Delivery System | Indication | Status | Collaborative Partner(s) |
|---|---|---|---|---|
| Eligard 7.5-mg one-month | Atrigel | Prostate cancer | FDA approved Jan. 2002; Germany MAA submitted to BfArM Dec. 2001 | Sanofi-Synthelabo, MediGene, Faulding |
| Eligard 22.5-mg three-month | Atrigel | Prostate cancer | NDA submitted to FDA Sept. 2001 | Sanofi-Synthelabo, MediGene, Faulding |
| Eligard 30-mg four-month | Atrigel | Prostate cancer | Phase III | Sanofi-Synthelabo, MediGene, Faulding |
| Eligard unique dosage formulation | Atrigel | Prostate cancer | Preclinical | Sanofi-Synthelabo |
| Atrisone | SMP | Moderate to severe acne<br>Treatment for burn itch<br>Treatment of atopic dermatitis | Phase III<br>Phase II<br>IND submitted | Fujisawa Healthcare<br>None<br>None |
| Growth hormone releasing peptide-1 | Atrigel | Growth promotion and cacexia, or muscle wasting | Preclinical | Tulane University Health Science Center |
| HGSI proprietary protein | Atrigel | Undisclosed compound | Preclinical | Human Genome Sciences |
| BEMA-Fentanyl | BEMA | Chronic and breakthrough cancer pain | Phase I<br>Orphan drug status | Amarillo Biosciences |
| BEMA-Ondanestron | BEMA | Nausea and vomiting associated with cancer chemotherapy | Preclinical | Elan |
| BEMA-Hydrocodone | BEMA | Mild to moderate pain | Preclinical | None |
| BEMA-Migraine | BEMA | Migraine | Preclinical | None |
| Oral interferon | Lozenge | Behcet s disease<br>Oral warts | Preclinical<br>Phase II<br>Orphan drug status for both | Amarillo Biosciences |

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We currently market two dental drug products, two medical device dental products and two over-the-counter, or OTC, drug products. The following table provides a summary of our marketed dental and OTC products and products under development:

| Dental/OTC Products | Delivery System | Indication | Status | Collaborative Partner(s) |
|---|---|---|---|---|
| Atridox | Atrigel | Antibiotic therapy for chronic periodontitis | Marketed Launched 1998 | CollaGenex, Sidus, PharmaScience, Genmedix |
| Atrisorb-Doxycycline FreeFlow GTR Barrier | Atrigel | Tissue regeneration and infection reduction following periodontal surgery | Marketed Launched Jan. 2002 | CollaGenex, Pharmascience |
| Atrisorb FreeFlow GTR Barrier | Atrigel | Tissue regeneration following periodontal surgery | Marketed Launched 1998 | CollaGenex, Pharmascience |
| Atrisorb GTR Barrier | Atrigel | Tissue regeneration following periodontal surgery | Marketed Launched 1996 | Product being phased out |
| Doxirobe® Gel | Atrigel | Periodontitis in companion animals | Marketed Launched 1997 | Pharmacia & Upjohn Animal Health |
| BCP topical antibiotic and wound wash | BCP | Infection protection and minor cuts and abrasions | Future OTC products | None |
| Viractin® cream and gel | Other | Cold sores and fever blisters | Marketed OTC product | J.B. Williams Company |
| Orajel-Ultra® | MCA | Canker sores | Marketed OTC product | Del Pharmaceuticals |

***Pharmaceutical Product Candidates***

*Eligard Products*

We are developing our proprietary Eligard products for prostate cancer incorporating 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 approximately six months.

Numerous 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 Eligard 7.5-mg one-month and the Eligard 22.5-mg three-month Phase III results revealed low testosterone levels with 100% of patients achieving and maintaining castrate suppression by the conclusion of the studies.

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 are safe and effective in treating prostate cancer and offer advantages to the patient, including a smaller needle and subcutaneous, rather than the more painful intramuscular, injection delivery.

According to the American Cancer Society, prostate cancer is the most common cancer, excluding skin cancers, in American men. It is estimated that during the year 2002, approximately 189,000 new cases of prostate cancer will be diagnosed in the United States and an estimated 30,200 men will die of the disease. Approximately one man in six will be diagnosed with prostate cancer during his lifetime.

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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. FDA approval of our Eligard 7.5-mg one-month marketing materials, including labeling, will need to be obtained before Sanofi-Synthelabo commences marketing this product in the United States. We anticipate that the Eligard 7.5-mg one-month marketing launch will commence in the third quarter of 2002.

In December 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 process. If approval is obtained in the Reference State, MediGene intends to submit a modified MAA to specific concerned member states in the European Union for marketing approval in other key countries.

*Eligard 22.5-mg Three-Month Product*

We submitted an NDA for Eligard 22.5-mg three-month product to the FDA in September 2001. Once the submission is accepted by the FDA 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.

*Eligard 30-mg Four-Month Product*

In March 2001, we completed enrollment for a Phase III clinical trial of our Eligard 30-mg four-month product. The Phase III clinical trial is being conducted at 22 centers with each of the 90 patients receiving an Eligard 30-mg injection every four months over an eight-month period. We expect to submit an NDA for the Eligard 30-mg product in the second quarter of 2002.

*Eligard Unique Dosage Formulation Product*

Our Eligard unique dosage formulation product for prostate cancer is currently in preclinical development. If these experiments demonstrate that leuprolide acetate is delivered safely and effectively over an approximately six-month period, we expect to enter Phase III clinical trials in the third quarter of 2002.

*Atrisone*

We are currently developing Atrisone, our proprietary product for the treatment of acne and the itching associated with healing burn wounds. Atrisone incorporates 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 of two Atrisone Phase III clinical trials was completed in October 2001. The first Phase III clinical trial consisted of 500 patients at 19 centers comparing 5% dapsone applied twice a day to a vehicle control. In the first quarter of 2002, we received positive clinical data from the first Phase III clinical trail for Atrisone and we expect to commence a second Phase III clinical trial in the second quarter of 2002.

According to IMS data, the U.S. market for topical products to treat acne was $600 million in 2000, with the combined oral and topical market at more than $1 billion.

Additional indications of Atrisone include treatment of chronic itch associated with healed and healing burn wounds and atopic dermatitis. Positive pilot data for use in burn itch was reported in October 2001 and is currently in Phase II clinical trials. 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, erythema and extreme itch.

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*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. We have begun preclinical studies for the GHRP-1 product. 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, promotion of growth in children of short stature, and possibly prevention of muscle wasting and frailty in aged individuals. We exercised an option to license GHRP-1 from Tulane University Health Sciences Center in September 2001. GHRP-1 is currently in the preclinical stage of research and development and will utilize our Atrigel delivery technology. We anticipate submitting an IND to the FDA for this product and commencing a Phase I clinical safety study in the second quarter of 2002.

*HGSI Proprietary Protein*

We have entered into a feasibility study agreement with Human Genome Sciences, a pioneer in the discovery and development of genomics-based drugs, to develop a sustained-release formulation of a Human Genome Sciences new proprietary protein utilizing our Atrigel drug delivery system. Under the terms of the agreement, Human Genome Sciences will provide funding for the project.

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

*BEMA-Ondansetron*

Through our joint venture with Elan, we are also developing an anti-emetic product using the BEMA system, for the prevention of nausea and vomiting associated with cancer chemotherapy. Preclinical studies have shown that the BEMA technology rapidly delivers the drug to the systemic circulation with sustained levels to six hours. The levels achieved in these preclinical studies were significantly higher and provided a more extended release profile than the oral dosage form.

*BEMA-Hydrocodone*

We are developing a BEMA-Hydrocodone product using our BEMA system with hydrocodone bitartrate, a narcotic analgesic used for the treatment of mild to moderate pain. In combination with acetaminophen or ibuprofen, products containing hydrocodone were the most prescribed generic oral drug products in 2000. These products are oral tablets requiring at least one hour or more to achieve efficacious blood levels after administration. We believe that a non-injectible drug product containing hydrocodone with a rapid onset of action would have definite advantages over these current oral products. Preclinical results with BEMA discs containing hydrocodone bitartrate have shown rapid absorption of the drug with efficacious blood levels in 15 minutes. We anticipate submitting an IND to the FDA for this product and commencing a Phase I clinical safety study in the second quarter of 2002.

*BEMA-Migraine*

We are exploring the development of a migraine product utilizing the BEMA drug delivery system with

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various migraine treatment compounds to provide rapid relief for migraine headaches, with a rapid onset comparable to that of injections. Imitrex (Sumatriptan) dominates the U.S. market for migraine products with sales of $1.0 billion, according to IMS Health. A significant problem with Imitrex and other triptans on the market is their inability to provide pain relief as quickly as desired. Intramuscular injection provides rapid relief, but many patients do not favor this painful method of administration. Preclinical studies with the BEMA delivery system and a number of migraine treatment compounds have shown the potential for rapid absorption and improved bioavailability compared to oral administration. We anticipate submitting an IND to the FDA for this product and commencing a Phase I clinical safety study in the second quarter of 2002.

*Oral Interferon*

We are currently developing an oral interferon product for the treatment of oral warts caused by human papilloma virus in HIV-infected patients and for the treatment of Behcet s disease. Behcet s disease is an autoimmune disorder that is characterized by mouth ulcers and generally two additional hallmark symptoms. Low-dose orally administered interferon is administered as a lozenge, which dissolves slowly in the mouth. The FDA granted the oral interferon product orphan drug status for both indications in January 2000. We signed a licensing agreement for the oral interferon product with Amarillo Biosciences in September 2001. In November 2001, we submitted an IND to the FDA to proceed into human clinical studies for the treatment of oral warts and we commenced a Phase II clinical study in the first quarter of 2002.

***Dental and Over-the-Counter Products***

*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, 2001, 2000 and 1999 were approximately $2.4 million, $4.7 million, and $4.1 million, respectively.

*Over-The-Counter Products*

Over-the-counter products which are currently being marketed include Viractin Cold Sore & Fever Blister Medicine and Orajel-Ultra Mouth Sore Medicine, which utilizes our proprietary MCA drug delivery system. Viractin is marketed by J.B. Williams Company and Orajel-Ultra is marketed by Del Pharmaceuticals. We receive royalties on the sales of these two products.

The BCP delivery system, composed of polymers, solvents and active agents carefully selected for their low toxicity to skin cells, can be formulated as either film-forming gels or liquids for topical applications. 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. 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 the wounds that are too dry. Liquid BCP formulations are designed to provide effective cleansing of topical wounds or

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denuded skin without causing further trauma to the skin, thereby promoting faster healing with minimal scarring. The first two products in development utilizing the BCP technology are a topical antibiotic preparation (with and without local anesthetic) for superficial wound healing and a wound-washing solution for cleansing dirty wounds.

**Our Drug Delivery Technologies**

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

| Technology | Description | Application |
|---|---|---|
| Atrigel System | Biodegradable sustained release implant for local or systemic delivery. | Delivery of drugs from weeks to months. |
| Bioerodible Mucoadhesive Film System (BEMA) | Bioerodible film for fast-acting local or systemic delivery | Delivery of drugs from minutes to hours through mucosal membranes. |
| Solvent Microparticle System (SMP) | Topical gel providing two-stage dermal delivery | 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 to form 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 cannot provide assurance that future products using the Atrigel system will be successfully developed and approved by the FDA or cleared for commercial use.

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.

*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 so as to reduce 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 rapidly across oral or vaginal mucosal tissues. The semi-soft BEMA disc adheres readily to the mucosa, where it softens further on contact with moisture, rapidly becoming unnoticeable as it delivers the drug and erodes away in approximately 10 to 20 minutes. 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, all of which require rapid onset of action and avoidance of first-pass metabolism.

***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

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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 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, 2001, we continued to devote significant resources to the research and development of our Eligard and Atrisone 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. For example, we have multiple undisclosed compounds in preclinical development with Pfizer. Most of these projects are preliminary in nature and we cannot predict whether any of them will be commercialized.

We submitted an NDA to the FDA in March 2001 for the Eligard 7.5-mg one-month product and we received FDA approval to market this product in January 2002. In September 2001, we submitted an NDA for the Eligard 22.5-mg three-month product and in March 2001, we completed patient enrollment in the Eligard 30-mg four-month product Phase III clinical trials.

GHRP-1 is currently in the preclinical stage of research and development and will utilize our Atrigel delivery technology. GHRP-1 is the first of a new class of small synthetic peptides that promotes release of the patient s own growth hormone.

Atrisone for the treatment of acne is in Phase III clinical studies. In the first quarter of 2002, we received positive clinical data from the first Phase III clinical trial and we expect to commence a second Phase III clinical trial in the second quarter of 2002. We are currently in Phase II for the use of Atrisone for the treatment of chronic itch associated with healed and healing burn wounds and reported positive pilot data for use in burn itch in October 2001. In May 2001, we submitted an IND to the FDA for the use of Atrisone in the treatment of atopic dermatitis.

Through our joint venture with Elan, we are researching and developing BEMA-Fentanyl using our BEMA drug delivery system. In November 2001, we submitted an IND to the FDA for BEMA-Fentanyl and commenced a Phase I clinical safety study for BEMA-Fentanyl. Also through our joint venture with Elan, we are developing BEMA-Ondansetron, which is currently in preclinical studies.

We are developing a BEMA-Hydrocodone product using our BEMA system with hydrocodone bitartrate. Preclinical results with BEMA discs containing hydrocodone bitartrate have shown rapid absorption of the drug with efficacious blood levels in 15 minutes. We anticipate submitting an IND to the FDA for this product and commencing a Phase I clinical safety study in the second quarter of 2002.

We are exploring the development of a migraine product utilizing the BEMA drug delivery system with various migraine treatment compounds. Preclinical studies with the BEMA delivery system and a number of migraine treatment compounds have shown the potential for rapid absorption and improved

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bioavailability compared to oral administration. We anticipate submitting an IND to the FDA for this product and commencing a Phase I clinical safety study in the second quarter of 2002.

A low-dose oral interferon product for the treatment of oral warts caused by human papilloma virus in HIV-infected patients is in Phase II clinical studies, and as a treatment for Behcet s disease, it is in the preclinical stage of research and development.

We are also developing a targeted set of generic topical dermatology products with Geneva. We have completed several formulations and, in December 2001 and January 2002, we submitted ANDAs to the FDA for approvals of two separate generic dermatology products.

Our research and development expenses, including licensing fees of $3.0 million in 2001 for GHRP-1 and oral interferon, were $28.6 million, $16.7 million and $15.6 million for the years ended December 31, 2001, 2000 and 1999, respectively.

**Collaborative arrangements**

We form strategic alliances with major pharmaceutical and biotechnology companies utilizing our various drug delivery systems. Our significant strategic alliances include Pfizer, Sanofi-Synthelabo, MediGene, Fujisawa Healthcare, Elan, Geneva 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. As of December 31, 2001, all 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 licensing fee of $8.0 million and will receive research and development support if Sanofi-Synthelabo exercises its option with respect to additional indications of the Eligard products. As part of the agreement, Sanofi purchased 824,572 shares of our common stock for $15.0 million. Total proceeds under the Sanofi agreement provides for payments of up to $60.0 million, including the purchase of our common stock, the licensing fees and payments for clinical, regulatory and sales milestones for the Eligard products upon approval for marketing by the FDA. For the year ended December 31, 2001, we received $6.0 million from Sanofi for milestone payments upon FDA acceptance of our Eligard 7.5-mg one-month and Eligard 22.5-mg three-month NDA filings. In January 2002, Sanofi exercised its option to develop an Eligard unique dosage formulation 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-month, three-month and four-month products. MediGene also has the right to develop the Eligard unique dosage formulation 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 licensing 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

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provides for payments of up to $16.0 million including MediGene s purchase of our common stock, the licensing fee and payments for certain clinical, regulatory and sales milestones. In December 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 process.

***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 million for an up-front licensing fee 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 up-front licensing fee from Fujisawa.

***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. Currently, BEMA-Fentanyl is in Phase I clinical studies. In March 2001, BEMA-Ondansetron, an anti-emetic product, was selected as the second compound under development in the joint venture. The BEMA-Ondansetron product is 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.

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.

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, 2001, 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 $4.1 million, $0.3 million and $0 for the years ended December 31, 2001, 2000 and 1999, respectively.

***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 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

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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. In December 2001 and January 2002, we submitted ANDAs to the FDA for approvals of two separate generic dermatology products.

***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 licensing fee. Additionally, we will 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, the proceeds of which CollaGenex will use primarily to fund a revitalized marketing campaign for the dental products. CollaGenex commenced U.S. marketing of Atridox and Atrisorb FreeFlow in November 2001 and Atrisorb-D marketing 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. Currently, the subsidiary has three employees whose objective is to establish business relations with international distributors for the sale of Atridox upon mutual recognition of the product in key countries. Atrix Laboratories Limited, our wholly owned registered subsidiary, is based in London, England, and was organized in June 1999. Atrix Laboratories Limited, currently holds the marketing authorization for international sales of Atridox. To date, we have received individual marketing authorizations in fourteen European countries. Our German subsidiary commenced Atridox European sales in October 2000.

In December 2001, we signed an exclusive marketing agreement with PharmaScience, Inc., for the marketing and distribution of our dental products in Canada.

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 process in December 2001. If approval is obtained in the reference member state, MediGene will submit a modified MAA to specific concerned member states in the European Union for marketing approval in other key countries.

Our revenues from foreign sources, including the joint venture with Elan, were $5.5 million, $1.2 and $0.8 million for the fiscal years ended December 31, 2001, 2000 and 1999, respectively.

**Patents and Trademarks**

We consider patent protection and proprietary position to be significant to our business. As of December 31, 2001, we maintained 46 United States patents and 63 foreign patents, and 28 United States and 59 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 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.

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Our patents expire at various times between 2008 and 2019. The following table sets forth the number of patents expiring in each year:

| Year Expiring | U.S. Patents | Foreign Patents | Total Patents |
|---|---|---|---|
| 2008 | 7 | | 7 |
| 2009 | 2 | 23 | 25 |
| 2010 | | 17 | 17 |
| 2011 | 7 | | 7 |
| 2012 | | 14 | 14 |
| 2013 | 3 | | 3 |
| 2014 | 6 | 1 | 7 |
| 2015 | 8 | 4 | 12 |
| 2016 | 4 | 1 | 5 |
| 2017 | 2 | 2 | 4 |
| 2018 | 6 | | 6 |
| 2019 | 1 | 1 | 2 |
| Total | 46 | 63 | 109 |

In addition to patents, we also maintain several United States and numerous foreign trademark and service mark applications for registrations of our name, logo, drug delivery systems and products. These include eight U.S. and 38 foreign issued trademarks, with seven U.S. and 24 foreign 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 risky 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.

**Customers**

Our customers include such companies as Pfizer, Sanofi, Fujisawa and Geneva. During 2001, Transmucosal Technologies and Block accounted for 26% and 22%, respectively, 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 among, or any 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, returns of our products, or cause a reduction in the inventory levels of distributors and retailers, any of which could have a material adverse impact on our business. If we lose any of these customer accounts, or if our relationships with them deteriorate, our business could also be materially and adversely affected.

**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

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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., Emisphere Technologies, Inc., Cima Labs, Inc., and ALZA Corporation. Competitors of our Eligard prostate cancer treatment products include AstraZeneca s Zoladex 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. Additional government regulation may be established that could prevent or delay regulatory approval or clearance of our products. Delays or rejections in obtaining regulatory approvals or clearances would adversely affect our ability to commercialize any product we develop and our ability to receive product revenues. 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.

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

Our Eligard, Atrisone, BEMA-Fentanyl, BEMA-Ondansetron, BEMA-Hydrocodon, BEMA-Migraine, 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 and clinical 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

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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 several 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.

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

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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 cGMPs, if the facility manufactures drugs, and quality system regulations, or QSRs, if the facility manufactures devices. In complying with cGMPs 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 member states, certifying that identical dossiers are being submitted to all member states for which recognition is sought. Within 90 days of receiving the application and assessment report, each member state must decide whether or not to recognize the approval. The procedure encourages 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 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 member states of the EU.

***Regulatory Consideration 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

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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.

***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.

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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.

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 19, 2002, we employed 148 employees on a full-time basis. Of the 148 full-time employees, 126 are engaged in production, research and clinical testing and the remaining 22 are in administrative capacities. A total of 35 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**

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.

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We do not believe that any aspect of our business is significantly seasonal in nature, and no significant portion of our business is subject to renegotiation of profits or termination of contracts or subcontracts at the election of the United States Government.

We currently obtain supplies of the polymer used in our polymer delivery systems from Birmingham Polymers 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, PolyPeptide Laboratories in California and, to a lesser extent, Mallinckrodt in Missouri. A solvent used in the Eligard products is obtained from International Specialty Products in Texas. 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 2001.

**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 and anticipate future 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 were $25.6 million, $16.7 million and $15.6 million for the years ended December 31, 2001, 2000 and 1999, respectively, exceeding our total revenue of $15.8, $10.0 million, $5.6 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, 2001 was $132.2 million. We expect that our research and development activities will result in additional operating losses for the foreseeable future. If we do not ultimately achieve and maintain profitability, our stock price may decline.

*We must obtain domestic and foreign regulatory 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 six products for which we have submitted an application to the FDA or appropriate foreign governmental authority and are involved in the regulatory approval process. These products include three Eligard products, Atrisone, BEMA-Fentanyl and oral interferon. 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

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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 manufacture of our drugs, and quality system regulations, or QSRs, with respect to the manufacture of our medical devices. 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, our partners or we 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 the 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 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 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,

lack of sufficient financial resources, and

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.

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Furthermore, to market our products outside the United States, our products are 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.

*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.

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.

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, 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. The transition phase of the U.S. marketing rights from Block to CollaGenex and the Canada marketing rights to PharmaScience resulted in a decrease in our dental product net sales revenue for the fourth quarter of 2001.

*We have limited experience in marketing and selling our products.* Our Atridox and Atrisorb-FreeFlow GTR Barrier products, sales of which accounted for approximately 64% of our net sales and royalty revenue in the fiscal year ended December 31, 2001, have been marketed by our partners and have been on the market for only three and a half years. To achieve commercial success for any 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

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alternative arrangements on acceptable terms and our product sales may decline. To the extent we undertake to market or co-market our own products, however, we will require additional expenditures and management resources.

*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 marketing of our dental products in North America, our dental products have been slow in achieving market acceptance within the dental community. We expect dental product market acceptance to increase in the United States under CollaGenex s marketing leadership. Additionally, 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. In the fiscal year ended December 31, 2001, we generated $3.8 million, or 24% of our $15.8 million total revenue, from net sales and royalties.

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 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 $8.2 million for the fiscal year ended December 31, 2001 represented 52% of our $15.8 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 revenue may decrease and our ability to develop and commercialize our technologies would be hindered. Approximately 50% of our 2001 contract research and development revenue, and 26% of our total 2001 revenue, was attributable to our research and development activities for Transmucosal Technologies. If this joint venture was terminated or if our relationship with Elan 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 would 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 export sales to customers outside of North America amounted to $1.1 million, or 7% of our total revenue, for the fiscal year ended December 31, 2001.

We face foreign exchange rate fluctuations, primarily with respect to the British Pound and the Euro, 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.

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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,

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/or 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 or 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:

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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 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 a suitable replacement. 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*

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*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.

*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 million with a $10,000 deductible per occurrence and an aggregate deductible of $100,000. 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 would 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.

*Our stock price is volatile and the value of your 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 $5.0625 per share to a high of $29.18 per share. 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 you to lose all or a portion of your investment.

**Item 2. Properties.**

We lease a total of 30,092 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 a lease extension agreement of our office and research laboratory space, which extended our lease expiration date 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 April 2001, we entered into a two-year lease agreement for 4,800 square feet warehouse space, located in Fort Collins. Additionally, 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.

We also lease 367 square feet of office space located in Frankfurt, Germany, pursuant to a lease that

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expires in June 2004. 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 not a party to any material legal proceedings.

**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 2001 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:

| | High | Low |
|---|---|---|
| 2001: | | |
| Fourth Quarter | $29.1800 | $18.5800 |
| Third Quarter | 28.4000 | 17.3500 |
| Second Quarter | 24.7600 | 9.6250 |
| First Quarter | 25.0000 | 13.3750 |
| 2000: | | |
| Fourth Quarter | $19.8125 | $12.1250 |
| Third Quarter | 16.1875 | 8.8750 |
| Second Quarter | 11.0625 | 6.8750 |
| First Quarter | 16.5625 | 5.0625 |

**Holders**

As of March 26, 2002, there were 2,313 holders of record of our common stock.

**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. As of December 31, 2001, we issued 856 shares of Series A Convertible Exchangeable Preferred Stock to Elan for accrued preferred stock dividends. Additionally, 454 shares of Series A Convertible Exchangeable Preferred Stock is expected to be issued to Elan in the first quarter of 2002 for accrued preferred stock dividends from July 19, 2001 through December 31, 2001.

**Issued Unregistered Securities**

In April 2001, we entered into a collaboration, license and supply agreement with MediGene under which MediGene was granted the exclusive right to market our Eligard products in Europe. In connection with the transaction, MediGene purchased 233,918 shares of our common stock for $3.8 million at a premium to market, pursuant to a Stock Purchase Agreement. The sale of our common stock in connection with this transaction was made in reliance on the exemption from the registration requirement of the Securities Act of 1933 provided by Section 4(2) of the Securities Act.

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Throughout the year ended December 31, 2001, we completed a series of transactions involving the exchange of 1,725,735 shares of our common stock for $31.0 million of our 7% Convertible Subordinated Notes. 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. Each transaction was privately negotiated and we made no public solicitation in the placement of these securities.

**Item 6. Selected Consolidated 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 Consolidated Financial Condition and Results of Consolidated Operations and the consolidated financial statements and related notes included herein.

| | Years Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2001(1) | 2000(2) | 1999 | 1998 | 1997 |
| | (As Restated) | (As Restated) | | | |
| | (In thousands, except per share data) | | | | |
| **Summary of Consolidated Operations:** | | | | | |
| Total revenues | $ 15,811 | $ 10,043 | $ 5,635 | $ 21,073 | $ 9,849 |
| Total expenses | (37,880) | (23,766) | (21,830) | (19,996) | (15,105) |
| Other income (expense) | (3,145) | (12,773) | (350) | 404 | 1,389 |
| Income tax expense | | | | (48) | |
| Income (loss) before extraordinary item and cumulative effect of change in accounting principle | (25,214) | (26,496) | (16,545) | 1,433 | (3,867) |
| Extraordinary gain (loss) on extinguished debt | (319) | 80 | 3,275 | 257 | |
| Cumulative effect of change in accounting principle | | (20,612) | | | |
| Net income (loss) before preferred stock dividends | $ (25,533) | $ (47,028) | $ (13,270) | $ 1,690 | $ (3,867) |
| Accretion of dividends on preferred stock | (1,171) | (383) | | | |
| Net income (loss) applicable to common stock | $ (26,704) | $ (47,411) | $ (13,270) | $ 1,690 | $ (3,867) |
| Basic and diluted earnings per common share: | | | | | |
| Income (loss) before extraordinary item and cumulative effect of change in accounting principle | $ (1.54) | $ (2.23) | $ (1.46) | $ 0.13 | $ (0.35) |
| Extraordinary item | (0.02) | | 0.29 | 0.02 | |
| Cumulative effect of change in accounting principle | | (1.73) | | | |
| Net income (loss) before preferred stock dividends | $ (1.56) | $ (3.96) | $ (1.17) | $ 0.15 | $ (0.35) |
| Accretion of dividends on preferred stock | (0.07) | (0.03) | | | |
| Net income (loss) applicable to common stock | $ (1.63) | $ (3.99) | $ (1.17) | $ 0.15 | $ (0.35) |

| | | | | | |
|---|---|---|---|---|---|
| Basic and diluted weighted average shares outstanding | 16,348 | 11,884 | 11,327 | 11,270 | 11,134 |
| **Consolidated Balance Sheet Data:** | | | | | |
| Working capital | $135,219 | $ 56,549 | $ 38,646 | $ 63,121 | $ 67,229 |
| Total assets | 157,493 | 74,172 | 54,659 | 79,480 | 78,294 |
| Long-term obligations | 33,579 | 60,408 | 36,690 | 48,500 | 50,000 |
| Convertible exchangeable preferred stock | 13,568 | 12,397 | | | |
| Shareholders equity (deficit) | 99,160 | (4,588) | 14,670 | 28,422 | 26,703 |

(1) The consolidated balance sheets as of December 31, 2001 and 2000 have been restated to reflect the convertible exchangeable preferred stock outside of permanent equity. See further discussion in Note 11 to the consolidated financial statements (as restated).

(2) 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 (as restated).

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

*The following Management s Discussion and Analysis of Consolidated Financial Condition and Results of Consolidated 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 statements 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) the timing of new product launches; and (6) expected future additional equity losses for Transmucosal Technologies. The success of our business operations is dependent on factors such as the receipt and timing of regulatory approvals or clearances for potential products, the effectiveness of our marketing strategies to market our current and any future products, our ability to manufacture products on a commercial scale, the appeal of our mix of products, our success at entering into and collaborating with others to conduct effective strategic alliances and joint ventures, general competitive conditions within the biotechnology and drug delivery industry and general economic conditions. 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.*

**Restatement**

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. Subsequent to the issuance of the 2001 financial statements, it was determined that Emerging Issues Task Force Topic D-98, *Classification and Measurement of Redeemable Securities,* applies to this preferred stock issuance. As a result, our consolidated balance sheets as of December 31, 2001 and 2000, and our consolidated statements of changes in shareholders equity (deficit) for the years ended December 31, 2001 and 2000, have been restated to present our Series A Stock outside of permanent shareholders equity until such time as the exchange feature is exercised or expires. A summary of the significant effects of the restatement is as follows:

| | As of December 31, 2001 (in thousands) | |
|---|---|---|
| | **As previously reported** | **As restated** |
| SERIES A CONVERTIBLE EXCHANGEABLE PREFERRED STOCK | $ | $ 13,568 |
| SHAREHOLDERS EQUITY (DEFICIT) | | |
| Preferred stock | $ | $ |
| Common stock | 20 | 20 |
| Additional paid in capital | 246,471 | 232,903 |
| Treasury stock | (1,558) | (1,558) |
| Accumulated other comprehensive loss | (4) | (4) |
| Accumulated deficit | (132,201) | (132,201) |
| Total shareholders equity (deficit) | $ 112,728 | $ 99,160 |

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| | As of December 31, 2000 (in thousands) | |
|---|---|---|
| | As previously reported | As restated |
| SERIES A CONVERTIBLE EXCHANGEABLE PREFERRED STOCK | $ | $ 12,397 |
| SHAREHOLDERS EQUITY (DEFICIT) | | |
| Preferred stock | $ | $ |
| Common stock | 13 | 13 |
| Additional paid in capital | 113,764 | 101,367 |
| Treasury stock | | |
| Accumulated other comprehensive loss | (471) | (471) |
| Accumulated deficit | (105,497) | (105,497) |
| Total shareholders equity (deficit) | $ 7,809 | $ (4,588) |

**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, pain management, growth hormone releasing peptide-1, or GHRP-1, oral interferon and dermatology products. We also form strategic alliances with large pharmaceutical and biotechnology companies utilizing our various drug delivery systems. These strategic alliances include Pfizer, Sanofi-Synthelabo, MediGene, Fujisawa, Elan, Geneva and CollaGenex. See *Item 1. Business Collaborative Arrangements.*

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.

**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 its 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.

***Principles of Consolidation***

The 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, we account for our investment in Transmucosal Technologies under the equity method of accounting.

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***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 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 it 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, 2001 and 2000***

Total revenues 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. We anticipate that sales and royalty revenues will increase in 2002 as CollaGenex ramps up its sales efforts under our U.S. marketing agreement. 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. We also expect sales and royalty revenues to increase in 2002 as a result of the commencement of our anticipated third quarter 2002 marketing launch of our Eligard 7.5-mg one-month product and possibly our Eligard 22.5-mg three-month product, if the FDA approves the NDA for this product.

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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. We expect contract research and development revenue to increase in 2002 as a result of Fujisawa s partial funding of Atrisone costs over the full year in 2002 compared to six months in 2001. Additionally, as Pfizer and Geneva products advance in development, research and development costs are expected to increase for 2002, hence, the funding we receive for these product costs should increase as well.

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. We expect licensing, marketing and milestone revenue to increase in 2002 as a result of the combined $10.0 million for 2001 licensing and milestone payments received from Sanofi, MediGene and Fujisawa being recognized over a full year in 2002 compared to a partial year of recognition in 2001. Additionally, licensing, marketing and milestone revenue is expected to increase in 2002 as a result of a full year of accelerated revenue recognition of the net effects related to the Block agreement in 2002 compared to four months of increased revenue recognition in 2001. Potential 2002 marketing and milestone payments from Sanofi include FDA acceptance of Eligard 30-mg four-month, first commercial sales of Eligard 7.5-mg one-month and potentially first commercial sales of Eligard 22.5-mg three-month upon FDA approval. These potential marketing and milestone payments from Sanofi will be recognized as revenue over the remaining term of the agreement using the straight-line method should we reach these marketing and milestone events and receive the related payments.

Cost of goods sold 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 goods sold correlates to the decline in product sales. We expect that cost of goods sold will increase in the future proportionately to our increases in sales, including the commencement of Eligard 7.5-mg one-month sales and possibly the commencement of Eligard 22.5-mg three-month sales, if the FDA approves the NDA for the Eligard 22.5-mg three-month product.

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 Atrisone, various dermatology products under the Geneva Pharmaceuticals agreement and GHRP-1. Our strategic goal is to devote substantial resources to our medical research and development efforts with the expectation of expediting products from the development stages through to commercialization. We expect that our partner funded research and development expenses will increase for

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the foreseeable future as we continue to develop the products that we currently have under collaborative agreements, as new products are developed and as new agreements are entered. Additionally, we expect our research and development expenses for our internally funded activities will continue to increase for the foreseeable future as we continue to develop our current products, as well as continue to engage in new product discovery and development activities.

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 or 1999. 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 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. We expect that our administrative and marketing expenses will 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, 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 may incur additional stock-based compensation and the amount may be material, however, we cannot predict the future timing of those charges.

We recognized a loss of $3.3 million for our 80.1% equity share in the loss of Transmucosal Technologies, of $3.3 million 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. Further, we expect to record additional equity losses, consistent with those realized during 2001, as we progress in our research and development activities for the BEMA-Fentanyl and BEMA-Ondansetron products.

Investment income for the year ended December 31, 2001 was $3.1 million compared to $2.0 million for the year ended December 31, 2000, representing a 55% 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. Additionally, we recorded an impairment charge of $0.8 million on our $1.0 million Enron corporate notes during 2001. We expect that our investment income will increase in 2002 as we expect our average cash and investment balances to be greater than 2001 balances and we expect the rates earned on our investments to be consistent with the prior year.

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

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ended December 31, 2001. We expect our interest expense in 2002 to decrease from 2001 due to the conversions in 2001 as well as conversions that have occurred in 2002.

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. 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, representing a 200% increase. We expect that this charge will increase in the future as the amount of our preferred stock increases as a result of issuing preferred stock for accretion of dividends.

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.

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

Effective in the 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 the Securities and Exchange Commission s Staff Accounting Bulletin No. 101 Revenue Recognition in Financial Statements. Previously, 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. There was a $20.6 million cumulative effect for this change in accounting principle that was reported as a charge in the year ended December 31, 2000. The cumulative effect was recorded as deferred revenue that will be recognized as revenue over the remaining contractual terms for each of the specific agreements. During the year ended December 31, 2000, the impact of the change in accounting principle increased net loss by $18.7 million, or $1.58 per share. This amount is comprised of $20.6 million, or $1.73 per share, cumulative effect of the change as described above, net of $1.9 million, or $0.16 per share, recognized as revenue during the year.

Total revenues for the year ended December 31, 2000 were $10.0 million compared to $5.6 million for the year ended December 31, 1999, representing a 79% increase.

Net sales and royalty revenue were $6.2 million for the year ended December 31, 2000 compared to $4.5 million for the year ended December 31, 1999, representing a 38% increase. An increase of $1.7 million in our contract manufacturing business with unaffiliated third parties was the significant factor for the increase in net sales revenue. Additionally, $2.8 million of net sales were made to Block in 2001 compared to $3.8 million of net sales to Block in 1999.

During the fourth quarter of 1999, we incurred a charge of $0.7 million for a change in estimate for revenues from sales of Atridox, Atrisorb FreeFlow GTR Barrier and Atrisorb GTR Barrier. This change

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resulted when Block provided updated information indicating the actual net selling price of these products was less than the estimated net selling price previously provided by Block. Our revenue is based on a set percentage of Block s actual net sales. We recorded this adjustment in the fourth quarter ended December 31, 1999 as a change in estimate at the time it became known. Furthermore, we reduced the rate at which we recognized revenue under the Block agreement during 2000 to reflect these lower selling prices.

Contract research and development revenue represents revenue we earned from third parties and from federal grants for performing contract research and development activities using our various patented drug delivery technologies. Contract research and development revenue was $2.0 million for the year ended December 31, 2000 compared to $1.1 million for the year ended December 31, 1999, representing an 82% increase. Of this increase, $1.3 million was related to work on five research projects with third parties. Additionally, contract research and development revenue earned from our joint venture with Elan, Transmucosal Technologies, was $0.3 million for the year ended December 31, 2000. We commenced research and development activities for Transmucosal Technologies in October 2000.

Licensing, marketing rights and milestone revenue for the year ended December 31, 2000 was $1.9 million, primarily for the Block milestone payments received in 1997 and 1998, in accordance with SAB 101. There was no such revenue recognized in 1999 as we changed our method of recognizing licensing, marketing rights and milestone revenues in 2000 as discussed above.

The Block agreement provided for potential milestone payments totaling up to $50.0 million to us over a three-to-five year period, as well as a manufacturing margin and royalties on sales. Prior to 2000, we had recognized $24.1 million in milestone payments from Block. No additional Block milestone payments were received in 2000.

Cost of goods sold was $2.6 million for the year ended December 31, 2000 compared to $2.0 million for the year ended December 31, 1999, representing a 30% increase. This increase in cost of goods sold is primarily related to the 38% increase in product net sales.

Research and development expenses were $16.7 million for the year ended December 31, 2000 compared to $15.6 million for the year ended December 31, 1999 representing a 7% increase. This increase reflects a shift in our research and development focus from dental to medical products in 2000. Research and development costs for the year ended December 31, 2000 decreased $3.2 million for our dental products, increased $3.5 million for our Eligard products and increased $0.8 million for our Atrisone product. Our strategic goal is to devote substantial resources to our medical research and development efforts with the expectation of expediting products from the development stages through to commercialization.

Administrative and marketing expenses were $4.3 million for the year ended December 31, 2000 compared to $4.0 million for the year ended December 31, 1999.

We recognized a loss of $12.2 million for the year ended December 31, 2000 for our 80.1% equity share in the loss of Transmucosal Technologies, our joint venture with Elan. The joint venture s loss for this period included 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.

Investment income for the year ended December 31, 2000 was $2.0 million compared to $2.7 million for the year ended December 31, 1999, representing a 26% decrease. The decrease was primarily the result of a reduction in average cash and investment balances from 1999 to 2000.

Interest expense for the year ended December 31, 2000 was $2.6 million compared to $3.1 million for the year ended December 31, 1999 representing a 16% decrease. The reduction in interest expense was primarily the result of our repurchase and subsequent retirement of $6.8 million of our 7% Convertible Subordinated Notes since October 1999.

During the year ended December 31, 2000, we repurchased a total of $0.5 million of our 7%

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Convertible Subordinated Notes for $0.4 million, which included approximately $7,000 for accrued interest paid. As a result, we recognized an extraordinary gain of approximately $80,000, net of deferred finance charges of approximately $12,000. As of December 31, 2000, the notes payable balance was $36.2 million.

We issued Series A convertible exchangeable preferred stock to Elan in July 2000 in connection with the formation of our joint venture with Elan. Related to this issuance, we recognized $0.4 million for accretion of dividends on preferred stock during the year ended December 31, 2000.

For the reasons described above, we recorded a consolidated net loss applicable to common stock of $47.4 million, or $3.99 per share, for the year ended December 31, 2000 compared to a consolidated net loss applicable to common stock of $13.3 million, or $1.17 per share, for the year ended December 31, 1999. The $12.2 million equity in loss of our joint venture and the $20.6 million cumulative effect from a change in accounting principle were the primary factors causing the increase in consolidated net loss applicable to common stock between periods.

**Liquidity and Capital Resources**

As of December 31, 2001, we had cash and cash equivalents of $50.1 million, marketable securities (at fair market value) of $87.9 million, net accounts receivable of $3.5 million, inventories of $3.3 million and other current assets of $1.6 million, for total current assets of $146.4 million. We had accounts payable of $3.1 million, short-term deferred revenue of $7.5 million and other current liabilities of $0.6 million, for total current liabilities of $11.2 million, which resulted in working capital of approximately $135.2 million.

In November 1997, we issued $50.0 million in principal amount of our 7% Convertible Subordinated Notes. Interest is payable semi-annually and the Notes mature on December 1, 2004. The Notes are 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 are redeemable, in whole or in part, at our option at any time on or after December 5, 2000. During the year ended December 31, 2001, we completed a series of private transactions involving the exchange of 1,725,735 shares of our 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. During the year ended December 31, 2000, we repurchased a total of $0.5 million of the Notes for $0.4 million, which included approximately $7,000 for accrued interest paid. As a result, we recognized an extraordinary gain of approximately $80,000, net of deferred finance charges. As of December 31, 2001 and December 31, 2000, the 7% Convertible Subordinated Notes payable balance was $5.2 million and $36.2 million, respectively.

In July 2000, we formed Transmucosal Technologies, 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, 2001, we had not drawn any amounts under the note. We are required to fund our 80.1% share of the joint venture s obligations. This funding totaled $2.7 million in 2001. Our future funding obligations are expected to be consistent with the funding in 2001.

During the year ended December 31, 2001, net cash provided by operating activities was $0.7 million. This was a result of the net loss applicable to common stock for the period of $26.7 million, which is offset by certain non-cash expenses, and changes in other operating assets and liabilities, primarily deferred revenue and note receivable for licensing fees, as set forth in the consolidated statements of cash flows. We received an $8.0 million licensing fee from Sanofi-Synthelabo in January 2001 for payment of the December 2000 note receivable licensing fee. Additionally, we recognized non-cash charges for debt conversion expense of $2.2 million and $0.3 million as an extraordinary loss on extinguished debt during the year ended December 31, 2001 as a result of exchanging our common stock for our convertible notes. A non-cash charge of $2.0 million was recognized in the third quarter of 2001 for a non-qualified stock option grant to our chief executive officer. The increase of $8.6 million for deferred revenue included $1.0 million from Block for an Atridox sales milestone, $6.0 million from Sanofi-Synthelabo for FDA acceptance of our

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Eligard one-month and three-month NDA filings, $2.0 million from MediGene for exclusive marketing rights in Europe of our Eligard products and $1.0 million by Sanofi as an advanced research and development payment for our Eligard unique dosage formulation product.

Net cash used by investing activities was $64.7 million during the year ended December 31, 2001, primarily as a result of $82.7 million used for the purchase of 13 U.S. Government bonds, 41 U.S. corporate notes, 330,556 shares of CollaGenex common stock, 348,852 shares of a U.S. Government bond mutual fund and 289,226 shares of a diversified bond mutual fund. This was offset by proceeds of $23.2 million for eight called or matured U.S. Government bond and note investments and one matured corporate note investment.

Net cash provided by financing activities was $109.7 million during the year ended December 31, 2001. This increase was primarily the result of our two underwritten public stock offerings that resulted in a net increase in financing funds of $87.7 million. Additionally, we received $15.0 million from Sanofi- Synthelabo in January 2001 for the issuance of common stock in conjunction with the December 2000 collaboration, license and supply agreement. We received $3.8 million from MediGene for the issuance of our common stock in conjunction with the stock purchase agreement in April 2001. In September 2001, our Board of Directors approved a new stock repurchase program to acquire up to $5.0 million of our common stock. For the year ended December 31, 2001, we repurchased a total of 77,500 shares of our common stock in the open market. The average price per share was $20.11 for total stock repurchases valued at $1.6 million. We received $4.1 million for the issuance of common stock related to employee stock options.

During the year ended December 31, 2001, we sold 3,565,000 shares of our common stock at a price of $23.00 per share under our shelf registration statement in two underwritten public offerings. The underwriters exercised their option to purchase 534,750 additional shares of our common stock in connection with our public offerings. We received net proceeds of $87.7 million from our public offerings and the over-allotment exercises, net of issuance costs of $6.6 million.

At December 31, 2001 we had available for Federal income tax purposes, net operating loss carryforwards of $83.3 million and $2.9 million in research and development tax credits, which expire through 2021. 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. At December 31, 2001, we recorded a full valuation allowance against our net deferred taxes of $50.9 million due to uncertainties related to their future realization.

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. Additionally, we have historically incurred operating losses and expect to continue to incur operating losses for the foreseeable future. At December 31, 2001, we had $50.1 million of cash and cash equivalent investments and $87.9 million of available-for-sale marketable securities (at fair value) to fund future operations and capital requirements. Our available-for-sale marketable securities are primarily in investment grade corporate notes and U.S. government bonds and bond funds. Our portfolio of corporate notes is diversified and, under our policy, we only invest in investment grade corporate notes. We recorded an impairment charge of $0.8 million on our $1.0 million Enron corporate notes during 2001. However, we believe that the quality of the notes we hold and the diversity of our portfolio significantly mitigates our market risk. We believe that we have adequate liquidity and capital resources to fund our operations and capital requirements for the foreseeable future. However, we believe we will have to raise additional funds to complete the development of our technologies as discussed below.

**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,

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the development of our commercial manufacturing facilities,

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 countries, possible repurchases of our notes or common stock and to hire additional management, scientific, manufacturing and administrative personnel. We will also continue to expend a significant amount of funds in 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 with our marketable security investments will be sufficient to fund our operations for the foreseeable future. However, we cannot assure you that underlying assumed levels of revenue and expense will prove accurate.

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, including research and development costs inception-to-date and estimated completion dates and costs (in thousands):

| Technology | Expenses 1999 | Expenses 2000 | Expenses 2001 | Expenses Inception-to-Date | Funded Expenses Inception-to-Date | Anticipated Completion (to market) | Anticipated Costs to Completion (to market) |
|---|---|---|---|---|---|---|---|
| Atrigel | $10,716 | $11,110 | $14,338 | $ 96,926 | $ 7,257 | 2002-2006 | $ 45,000 |
| SMP | 2,328 | 3,090 | 4,604 | 10,021 | 978 | 2004-2005 | 20,000 |
| BEMA | 553 | 260 | 2,430 | 3,243 | 4,387 | 2006-2008 | 10,000 |
| Other | 1,958 | 2,275 | 4,263 | 20,534 | 3,966 | 2003-2008 | 25,000 |
| Total | $15,555 | $16,735 | $25,635 | $130,724 | $16,588 | 2002-2008 | $100,000 |
| Funded | $ 2,429 | $ 1,921 | $10,626 | | | | |
| Not Funded | 13,126 | 14,814 | 15,009 | | | | |
| Total | $15,555 | $16,735 | $25,635 | | | | |

The predominate product lines included under the Atrigel technology are the Eligard and dental products which comprise 26% and 68%, respectively, of the expenses incurred to date. Recently, however, the Eligard products comprised more of the research and development effort with 36%, 66% and 72% of the 1999, 2000, and 2001 Atrigel expenses, respectively. As dental products have moved into market, expenses to support them have stabilized and comprised 55%, 24% and 11% of the 1999, 2000, and 2001 Atrigel expenses, respectively. Of the expenses funded by third parties, 36% of funds received were to support the dental products, 10% of funds have come recently to support the Eligard products domestically as well as internationally, and 53% of funds have come from direct support of research contracts with various companies.

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

Under the BEMA technology, approximately 71% of expenses incurred to date relate to the development of two products through our joint venture with Elan and approximately 99% 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 16% of expenses incurred to date and 28% of funding.

The following table summarizes our future contractual commitments, which consist of operating leases. At December 31, 2001, our future payments under our non-cancelable operating leases are as follows (amounts in thousands):

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| Year Ending December 31, | Minimum Rental Commitments |
|---|---|
| 2002 | $ 461 |
| 2003 | 408 |
| 2004 | 339 |
| 2005 | 311 |
| 2006 | 128 |
| Total | $1,647 |

In 2001, we approved up to a $5.0 million stock repurchase program. During 2001, we repurchased 77,500 shares for a total of $1.6 million. This program expires on December 31, 2002. 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 program.

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**

On June 29, 2001, the Financial Accounting Standards Board (FASB) issued SFAS No. 141, Business Combinations. SFAS No. 141 requires that the purchase method of accounting be used for all business combinations initiated after June 30, 2001. We adopted SFAS No. 141 on July 1, 2001. The adoption of this statement did not have a material impact on our financial position or results of operations.

On June 29, 2001, SFAS No. 142, Goodwill and Other Intangible Assets was issued by the FASB. SFAS No. 142 changes the accounting for goodwill from an amortization method to an impairment-only approach. Goodwill and certain intangible assets will remain on the balance sheet and not be amortized. On an annual basis, and when there is reason to suspect that their values have been diminished or impaired, these assets must be tested for impairment, and write-downs may be necessary. We are required to implement SFAS No. 142 on January 1, 2002 and it has been determined that this statement will not have a material impact on our financial position or results of operations.

In August 2001, the FASB issued SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. SFAS No. 144 provided new guidance on the recognition of impairment losses on long-lived assets to be held and used or to be disposed of and also broadens the definition of what constitutes a discontinued operation and how the results of a discontinued operation are to be measured and presented. SFAS No. 144 is effective for our fiscal year beginning 2002, but is not expected to have a material impact on our financial statements.

**Factors Affecting Our Business and Prospects**

There are numerous factors that affect our business and results of operations. These factors include risks associated with regulatory submissions and product approvals, product demand, pricing, market acceptance of our current and proposed products, changing economic conditions, risks in product and technology

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development, the effect of our accounting policies and other risk factors discussed in more detail under Item 1. Business-Factors Affecting Our Business and Prospects in this Report.

**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. We do not own derivative financial instruments in our portfolio. Due to the nature of our investment portfolio, the investment portfolio contains instruments that are primarily subject to interest rate risk. Our equity investment in CollaGenex is subject to equity price risks. Additionally, our 7% Convertible Subordinated Notes are also subject to interest rate and equity price risks.

We invested $2.0 million in a diversified mutual fund during the year 2001. This mutual fund invests in corporate bonds and Treasuries with remaining maturities, estimated remaining average lives, or durations of five years or less. Additionally, this mutual fund 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 portfolio 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 United States Government and Agency bonds and notes and corporate bonds and notes with maturity dates ranging from one to sixteen years. To mitigate the impact of fluctuations in cash flow, we maintain substantially all of our debt instruments as fixed rate. 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 equity interests in U.S. Government and Agency bond mutual funds. The value of these equity interests is also subject to interest rate risk.

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, investment grade corporate notes, high rated commercial paper and other high rated investments only. As a result, we do not anticipate any material losses in these investments.

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 sensitivity analysis, we assess the loss risk in fair values from the impact of hypothetical changes in interest rates on market sensitive instruments. The fair values are computed based on the present 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, 2001. The fair values that result from these computations are compared with the fair values of these financial instruments at December 31, 2001. 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, 2001 are as follows:

Interest Rate Sensitivity: A 10% decrease in the levels of interest rates, with all other variables held

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constant, would result in an increase in the fair value of our financial instruments by $0.5 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 $0.5 million per year. We maintain a portion of our financial instruments, including debt instruments of $13.4 million at December 31, 2001, at variable interest rates. If interest rates were to increase or decrease 10%, the impact of such instruments on cash flows or earnings would not be material.

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.

The market price of our 7% Convertible Subordinated Notes generally changes in parallel with the market price of our common stock. When our stock price increases or decreases, the price of these notes generally increases or decreases proportionally. Fair market price of our notes can be determined from quoted market prices, where available. The fair value of our long-term debt was estimated to be $6.0 million at December 31, 2001 and is higher than the carrying value by $0.8 million. Market risk was estimated as the potential decrease in fair value resulting from a hypothetical 1% increase in our weighted average long-term borrowing rate and a 1% decrease in quoted market prices, or $0.1 million.

**Exchange Rate Risk**

We face foreign exchange rate fluctuations, primarily with respect to the British Pound and the Euro, as the financial results of our foreign subsidiaries are translated into U.S. 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, 2001 was not material. Based on our overall foreign currency rate exposure at December 31, 2001, we do not believe that a hypothetical 10% change in foreign currency rates would materially affect our financial position.

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

Our consolidated financial statements required by Regulation S-X are attached to this Report. Reference is made to Item 14(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 contained in our definitive proxy statement for our annual shareholders meeting, scheduled to be held on May 5, 2002, regarding our directors and officers and compliance with Section 16(a) of the Exchange Act is incorporated herein by reference in response to this item.

**Item 11. Executive Compensation.**

The information contained in our definitive proxy statement for our annual shareholders meeting, scheduled to be held on May 5, 2002, regarding executive compensation is incorporated herein by reference in response to this item.

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

The information contained in our definitive proxy statement for our annual shareholders meeting, scheduled to be held on May 5, 2002, regarding security ownership of certain beneficial owners and management is incorporated herein by reference in response to this item.

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

The information contained in our definitive proxy statement for our annual shareholders meeting, scheduled to be held on May 5, 2002, regarding certain relationships and related transactions is incorporated herein by reference in response to this item.

**PART IV**

**Item 14. Exhibits, Consolidated 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, 2001 (As Restated) and 2000 (As Restated)

Consolidated Statements of Operations
Years Ended December 31, 2001, 2000, and 1999

Consolidated Statements of Changes in Shareholders Equity (Deficit)
Years Ended December 31, 2001 (As Restated), 2000 (As Restated), and 1999

Consolidated Statements of Cash Flows
Years Ended December 31, 2001, 2000, and 1999

Notes to the Consolidated Financial Statements (As Restated)

2. Consolidated Financial Statement Schedules

The following financial statements of Transmucosal Technologies Ltd., the Registrant s joint venture with Elan International Services Ltd., a wholly owned subsidiary of Elan Corporation plc, are filed as part of this Report.

Independent Auditors Report

Balance Sheets as at December 31, 2001 and 2000

Statements of Loss for the Periods Ended December 31, 2001 and 2000

Statements of Changes in Shareholders Equity for the Periods Ended December 31, 2001 and 2000

Statements of Cash Flows for the Periods Ended December 31, 2001 and 2000

Notes to Financial Statements

Other 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.

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(b) Reports on Form 8-K: We filed the following Current Reports on Form 8-K during the quarter ended December 31, 2001:

Current Report on Form 8-K dated October 15, 2001, filed with the Securities and Exchange Commission on October 17, 2001, under Item 5. Other Events, and Item 7. Exhibits.

Current Report on Form 8-K dated November 16, 2001, filed with the Securities and Exchange Commission on November 27, 2001, under Item 5. Other Events, and Item 7. Exhibits.

Current Report on Form 8-K dated December 7, 2001, filed with the Securities and Exchange Commission on December 10, 2001, under Item 5. Other Events, and Item 7. Exhibits.

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**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: November 7, 2002

By: /s/ David R. Bethune
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.

| Signature | Title | Date |
|---|---|---|
| /s/ David R. Bethune<br>David R. Bethune | Chairman of the Board and Chief Executive Officer (Principal Executive Officer) | November 7, 2002 |
| /s/ Brian G. Richmond<br>Brian G. Richmond | Chief Financial Officer and Assistant Secretary (Principal Financial and Accounting Officer) | November 7, 2002 |
| /s/ Nicolas G. Bazan<br>Nicolas G. Bazan | Director | November 7, 2002 |
| /s/ H. Stuart Campbell<br>H. Stuart Campbell | Director | November 7, 2002 |
| /s/ Dr. D. Walter Cohen<br>Dr. D. Walter Cohen | Director | November 7, 2002 |
| /s/ Sander A. Flaum<br>Sander A. Flaum | Director | November 7, 2002 |
| /s/ C. Rodney O Connor<br>C. Rodney O Connor | Director | November 7, 2002 |
| /s/ Warren L. Troupe<br>Warren L. Troupe | Director | November 7, 2002 |

| | | |
|---|---|---|
| /s/ George J. Vuturo | Director | November 7, 2002 |
| George J. Vuturo | | |

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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; and

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.

Date: November 7, 2002

/s/ David R. Bethune

David R. Bethune
Chairman and Chief Executive Officer

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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; and

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.

Date: November 7, 2002

/s/ Brian G. Richmond

Brian G. Richmond
Chief Financial Officer

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## INDEX TO THE CONSOLIDATED FINANCIAL STATEMENTS

**ATRIX LABORATORIES, INC. AND SUBSIDIARIES**


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**TRANSMUCOSAL TECHNOLOGIES LTD.**


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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 as of December 31, 2001 and 2000, 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, 2001. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our 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, 2001 and 2000, and the results of its operations and cash flows for each of the three years in the period ended December 31, 2001 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. As discussed in Note 11 to the consolidated financial statements, the 2001 and 2000 financial statements have been restated.

DELOITTE & TOUCHE LLP

Denver, Colorado
March 11, 2002 (November 5, 2002 as to Note 11)

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

| | December 31, 2001 (As Restated, see Note 11) | December 31, 2000 (As Restated, see Note 11) |
|---|---|---|
| **ASSETS** | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | $ 50,058 | $ 4,484 |
| Marketable securities available-for-sale, at fair value | 87,910 | 28,911 |
| Notes receivable stock subscription and licensing fee | | 23,000 |
| Accounts receivable, net of allowance for doubtful accounts of $5 and $210 | 3,522 | 2,611 |
| Interest receivable | 995 | 472 |
| Inventories | 3,314 | 1,941 |
| Prepaid expenses and deposits | 606 | 1,085 |
| Total current assets | 146,405 | 62,504 |
| PROPERTY, PLANT AND EQUIPMENT, NET | 7,557 | 6,818 |
| OTHER ASSETS: | | |
| Intangible assets, net of accumulated amortization of $3,421 and $2,399 | 3,446 | 4,049 |
| Deferred finance costs, net of accumulated amortization of $121 and $628 | 85 | 801 |
| Other assets, net | 3,531 | 4,850 |
| TOTAL ASSETS | $ 157,493 | $ 74,172 |
| **LIABILITIES AND SHAREHOLDERS EQUITY (DEFICIT)** | | |
| CURRENT LIABILITIES: | | |
| Accounts payable trade | $ 3,108 | $ 2,198 |
| Accrued expenses and other | 611 | 760 |
| Deferred revenue | 7,467 | 2,997 |
| Total current liabilities | 11,186 | 5,955 |
| DEFERRED REVENUE | 28,373 | 24,218 |
| CONVERTIBLE SUBORDINATED NOTES PAYABLE | 5,206 | 36,190 |
| COMMITMENTS AND CONTINGENCIES (SEE NOTES 4 AND 9) | | |
| SERIES A CONVERTIBLE EXCHANGEABLE PREFERRED STOCK, $.001 par value, 20,000 shares authorized; 12,871 and 12,015 shares issued and outstanding Liquidation preference $13,281 and $12,397 | 13,568 | 12,397 |
| SHAREHOLDERS EQUITY (DEFICIT): | | |
| Preferred stock, $.001 par value; 5,000,000 shares authorized Series A preferred stock, $.001 par value, 200,000 shares authorized and no shares issued or outstanding | | |
| Common stock, $.001 par value; 45,000,000 shares authorized; 19,859,807 and 13,341,681 shares issued; 19,782,307 and 13,341,681 shares outstanding | 20 | 13 |

| | | |
|---|---|---|
| Additional paid-in capital | 232,903 | 101,367 |
| Treasury stock, 77,500 and -0- shares, at cost | (1,558) | |
| Accumulated other comprehensive loss | (4) | (471) |
| Accumulated deficit | (132,201) | (105,497) |
| Total shareholders equity (deficit) | 99,160 | (4,588) |
| TOTAL LIABILITIES AND SHAREHOLDERS EQUITY(DEFICIT) | $ 157,493 | $ 74,172 |

See notes to the consolidated financial statements.

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

| | Year Ended December 31, 2001 | Year Ended December 31, 2000 | Year Ended December 31, 1999 |
|---|---|---|---|
| REVENUE: | | | |
| Net sales and royalties | $ 3,818 | $ 6,156 | $ 4,542 |
| Contract research and development revenue | 8,178 | 2,009 | 1,093 |
| Licensing, marketing rights and milestone revenue | 3,815 | 1,878 | |
| Total revenue | 15,811 | 10,043 | 5,635 |
| OPERATING EXPENSE: | | | |
| Cost of sales | 1,693 | 2,644 | 1,974 |
| Research and development | 25,635 | 16,735 | 15,555 |
| Research and development licensing fees | 2,985 | | |
| Administrative and marketing | 5,450 | 4,262 | 3,992 |
| Administrative stock option compensation | 2,117 | 125 | 309 |
| Total operating expense | 37,880 | 23,766 | 21,830 |
| LOSS FROM OPERATIONS | (22,069) | (13,723) | (16,195) |
| OTHER INCOME (EXPENSE): | | | |
| Equity in loss of joint venture | (3,285) | (12,239) | |
| Investment income | 3,134 | 1,959 | 2,720 |
| Interest expense | (780) | (2,582) | (3,062) |
| Debt conversion expense | (2,194) | | |
| Other | (20) | 89 | (8) |
| Net other expense | (3,145) | (12,773) | (350) |
| LOSS BEFORE EXTRAORDINARY ITEM AND CUMULATIVE EFFECT OF CHANGE IN ACCOUNTING PRINCIPLE | (25,214) | (26,496) | (16,545) |
| Extraordinary gain (loss) on extinguished debt | (319) | 80 | 3,275 |
| Cumulative effect of change in accounting principle | | (20,612) | |
| NET LOSS BEFORE PREFERRED STOCK DIVIDENDS | $ (25,533) | $ (47,028) | $ (13,270) |
| Accretion of dividends on preferred stock | (1,171) | (383) | |
| NET LOSS APPLICABLE TO COMMON STOCK | $ (26,704) | $ (47,411) | $ (13,270) |
| Basic and diluted loss per common share: | | | |
| Loss before extraordinary item and cumulative effect of change in accounting principle | $ (1.54) | $ (2.23) | $ (1.46) |
| Extraordinary gain (loss) on extinguished debt | (.02) | | .29 |
| Cumulative effect of change in accounting principle | | (1.73) | |
| Net loss before preferred stock dividends | $ (1.56) | $ (3.96) | $ (1.17) |
| Accretion of dividends on preferred stock | (.07) | (.03) | |
| Net loss applicable to common stock | $ (1.63) | $ (3.99) | $ (1.17) |

| | | | |
|---|---|---|---|
| Basic and diluted weighted average common shares outstanding | 16,348,365 | 11,883,712 | 11,327,213 |
| Pro forma amounts assuming the change in revenue recognition method is applied retroactively: | | | |
| Net loss before extraordinary item | $ (25,214) | $ (26,496) | $ (14,671) |
| Net loss applicable to common stock | $ (26,704) | $ (26,799) | $ (11,396) |
| Basic and diluted earnings per common share: | | | |
| Net loss before extraordinary item | $ (1.54) | $ (2.23) | $ (1.30) |
| Net loss applicable to common stock | $ (1.63) | $ (2.26) | $ (1.01) |

See notes to the consolidated financial statements.

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**ATRIX LABORATORIES, INC. AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS EQUITY (DEFICIT)**
**(IN THOUSANDS, EXCEPT SHARE DATA)**

| | Common Stock | | Additional | | Accumulated Other | | Total |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | Paid-In Capital | Treasury Stock | Comprehensive Loss | Accumulated Deficit | Shareholders' Equity |
| **BALANCE, December 31, 1998** | 11,203,672 | $ 11 | $ 74,823 | $(1,651) | $ (96) | $ (44,665) | $ 28,422 |
| Comprehensive loss: | | | | | | | |
| Net loss | | | | | | (13,270) | (13,270) |
| Other comprehensive loss: | | | | | | | |
| Cumulative foreign currency translation adjustments | | | | | (1) | | (1) |
| Unrealized loss on investments | | | | | (1,599) | | (1,599) |
| Net comprehensive loss | | | | | | | (14,870) |
| Exercise of stock options and issuance for employee stock purchase plan | 125,032 | | (759) | 1,149 | | (34) | 356 |
| Issuance of restricted stock | 80,000 | | 237 | 421 | | (91) | 567 |
| Issuance for earn-out distribution | 18,850 | | 195 | | | | 195 |
| **BALANCE, December 31, 1999** | 11,427,554 | $ 11 | $ 74,496 | $ (81) | $(1,696) | $ (58,060) | $ 14,670 |
| Comprehensive loss: | | | | | | | |
| Net loss | | | | | | (47,411) | (47,411) |
| Other comprehensive gain: | | | | | | | |
| Cumulative 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 | 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 |
| **BALANCE, December 31, 2000 (As Restated, see Note 11)** | 13,341,681 | $ 13 | $101,367 | $ | $ (471) | $(105,497) | $ (4,588) |
| Comprehensive loss: | | | | | | | |
| Net loss | | | | | | (26,704) | (26,704) |
| Other comprehensive gain (loss): | | | | | | | |
| | | | | | (29) | | (29) |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cumulative foreign currency translation adjustments | | | | | | | |
| 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 compensation | | | 2,117 | | | | 2,117 |
| Exercise of stock options and issuance of employee stock purchase plan | 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 |
| **BALANCE, December 31, 2001 (As Restated, see Note 11)** | 19,782,307 | $ 20 | $232,903 | $(1,558) | $ (4) | $(132,201) | $ 99,160 |

See notes to the consolidated financial statements.

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

| | Year Ended December 31, 2001 | Year Ended December 31, 2000 | Year Ended December 31, 1999 |
|---|---|---|---|
| CASH FLOWS FROM OPERATING ACTIVITIES: | | | |
| Net loss applicable to common stock | $ (26,704) | $(47,411) | $(13,270) |
| Adjustments to reconcile net loss to net cash provided by (used in) operating activities: | | | |
| Accretion of dividends on preferred stock | 1,171 | 382 | |
| Depreciation and amortization | 2,480 | 2,190 | 1,777 |
| Equity in loss of joint venture | 3,285 | 12,239 | |
| Loss on sale and write-downs of marketable securities | 831 | 172 | 140 |
| Stock plan compensation | 2,117 | 125 | 309 |
| Debt conversion expense | 2,194 | | |
| Interest expense converted to equity | 345 | | |
| Extraordinary (gain) loss on extinguished debt | 319 | (80) | (3,275) |
| Cumulative effect of change in accounting principle | | 20,612 | |
| Other non-cash items | 25 | (5) | 140 |
| Net changes in operating assets and liabilities: | | | |
| Accounts receivable | (925) | (1,397) | 4,714 |
| Note receivable licensing fee | 8,000 | | |
| Interest receivable | (523) | 90 | 102 |
| Inventories | (1,387) | (75) | 701 |
| Prepaid expenses and deposits | 479 | (666) | 435 |
| Other assets | | | 475 |
| Accounts payable | 481 | (424) | 805 |
| Accrued expenses and other | (144) | 75 | (69) |
| Deferred revenue | 8,625 | (1,557) | 6 |
| Net cash provided by (used in) operating activities | 669 | (15,730) | (7,010) |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | | |
| Acquisition of property, plant and equipment | (2,069) | (775) | (1,165) |
| Investment in intangible assets | (419) | (246) | (291) |
| Proceeds from maturity and sale of marketable securities | 23,245 | 7,402 | 20,063 |
| Investment in marketable securities | (82,683) | (422) | (19,571) |
| Investment in joint venture | (2,746) | | |
| Net cash provided by (used in) investing activities | (64,672) | 5,959 | (964) |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | | |
| Proceeds from issuance of equity securities, net of issuance costs | 96,247 | 11,678 | 613 |
| Payments to acquire treasury stock | (1,558) | | |
| Note receivable stock subscription | 15,000 | | |
| Extinguished convertible long-term debt | | (408) | (8,173) |
| Net cash provided by (used in) financing activities | 109,689 | 11,270 | (7,560) |
| NET EFFECT OF EXCHANGE RATE ON CASH | (112) | (37) | (1) |
| | 45,574 | 1,462 | (15,535) |

| | | | |
|---|---|---|---|
| NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS | | | |
| CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR | 4,484 | 3,022 | 18,557 |
| CASH AND CASH EQUIVALENTS, END OF YEAR | $ 50,058 | $ 4,484 | $ 3,022 |
| Supplemental cash flow information: | | | |
| Cash paid for interest | $ 614 | $ 2,568 | $ 3,110 |

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: | **2001**<br>Issued preferred stock valued at $883,000 to Elan for accreted dividends.<br>Issued common stock valued at $33,177,000 in exchange for $30,984,000 of 7% Convertible Subordinated Notes.<br><br>**2000**<br>Issued common stock valued at $15,000,000 in exchange for a note receivable to Sanofi-Synthelabo in connection with the marketing agreement.<br>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.<br><br>**1999**<br>Issued common stock valued at $195,000 in connection with the May 1999 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 (AS RESTATED)**
**Years Ended December 31, 2001, 2000 and 1999**

## 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Atrix Laboratories, Inc. was formed in August 1986 as a Delaware corporation. In November 1998, the Company acquired ViroTex Corporation. In June 1999, the Company organized its wholly owned subsidiary Atrix Laboratories Limited, which is based in London, England. In February 2000, the Company organized its wholly owned subsidiary Atrix Laboratories GmbH, which is based in Frankfurt, Germany, to conduct its European operations. Collectively, Atrix Laboratories and its subsidiaries are referred to as Atrix or the Company. In June 2000, the Company entered into a research joint venture, Transmucosal Technologies, with Elan, 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, pain management, growth hormone releasing peptide-1, oral interferon and dermatology products. The Company also partners with large pharmaceutical and biotechnology companies to apply its proprietary technologies to new chemical entities or to extend the patent life of existing products. The Company has strategic alliances with several pharmaceutical companies to use its drug delivery technologies and expertise in the development of new products.

**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.

**Use of estimates**

The preparation of consolidated 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. Actual results could differ from those estimates.

**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 market value with the unrealized holding gain or loss included in shareholders equity as a component of other comprehensive loss. Fair market value is based on quoted market prices or dealer quotes. Premiums and discounts associated with bonds are amortized using the effective interest rate method. The investment portfolio

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includes fixed rate debt instruments that are primarily U.S. Government and Agency bonds and notes and corporate bonds and notes. The maturity dates for these securities range from one to sixteen years. If a decline in market value is other than temporary, a charge is taken to operations.

**Stock subscriptions**

The note receivable for stock subscriptions is shown as a current asset to the extent collected before the consolidated financial statements are published.

**Inventories**

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

| | 2001 | 2000 |
|---|---|---|
| Raw materials | $2,399 | $1,617 |
| Work in progress | 201 | 145 |
| Finished goods | 714 | 179 |
| Total inventories | $3,314 | $1,941 |

**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):

| | 2001 | 2000 |
|---|---|---|
| Land | $ 1,071 | $ 1,071 |
| Building | 3,868 | 3,610 |
| Leasehold improvements | 618 | 470 |
| Furniture & fixtures | 615 | 440 |
| Machinery | 6,004 | 5,039 |
| Office equipment | 1,243 | 813 |
| Total property, plant and equipment | 13,419 | 11,443 |
| Accumulated depreciation and amortization | (5,862) | (4,625) |
| Property, plant and equipment, net | $ 7,557 | $ 6,818 |

**Intangible assets**

Intangible assets consist of patents, purchased technology, purchased royalty rights, and goodwill. Patents are stated at the legal cost incurred to obtain the patents. Upon approval, patent 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, purchased royalty rights, and goodwill arising from the ViroTex acquisition are being amortized using the straight-line method over the period of expected benefit of four to five years.

**Valuation of long-lived assets**

The Company reviews its long-lived assets, including identified intangibles and goodwill, for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If this review indicates that these assets will not be recoverable, based on the forecasted non-discounted future operating cash flows expected to result from the use of these assets and their eventual disposition, the carrying value of these assets is reduced to fair value. Management does not believe current events or circumstances indicate that long-lived assets, including goodwill, are impaired as

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of December 31, 2001.

**Deferred finance costs**

Costs associated with the issuance of the Company s 7% Convertible Subordinated Notes were deferred and are being amortized on a straight-line basis over the seven-year term of the notes. As convertible notes are repurchased and subsequently extinguished or exchanged for the Company s common stock, the pro-rata portion of unamortized deferred finance costs is written off.

**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 and cash equivalents, marketable equity 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 Government-backed securities, investment grade corporate notes, and various equity securities. During 2001, the Company recorded a write-down of $831,000 for its investment in Enron corporate notes. 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 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. In 2001, the Company s revenues were materially impacted due to disputes with Block Drug Company, see Note 5. 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 net sales, royalties on third-party sales of Atrix s products, contract manufacturing, contract research and development and for nonrefundable licensing fees, marketing rights and milestone payments earned under contractual arrangements.

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. Product sales revenue is recorded net of estimated returns and allowances. Royalty revenue is recorded when product is shipped by licensees based on the invoiced amount 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. Billings under the contracts are made

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either monthly or quarterly, depending on the terms of the contract.

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 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 $20,612,000 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 $18,734,000 or $1.58 per share. This amount is comprised of the $20,612,000, or $1.73 per share, cumulative effect adjustment net of $1,878,000, or $0.16 per share, recognized as revenue during the year ended December 31, 2000. During the year ended December 31, 2001, the Company recognized $2,718,000 of the SAB 101 adjustment as revenue. The remainder of the deferred revenue under the SAB 101 adjustment will be recognized as follows: $4,384,000 for each year from 2002 through 2004, $2,926,000 in 2005, $11,000 for each year from 2006 through 2015 and $2,000 in 2016. 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.

**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 by the Company for the years ended December 31 (amounts in thousands):

| | 2001 | 2000 | 1999 |
|---|---|---|---|
| Research and Development Funded | $10,626 | $ 1,921 | $ 2,429 |
| Research and Development Not Funded | 15,009 | 14,814 | 13,126 |
| Research and Development | $25,635 | $16,735 | $15,555 |

**Net loss per common share**

Basic net loss per common share excludes dilution and is computed by dividing net loss by the weighted-average number of common shares outstanding during the periods presented. Diluted net 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. The effect of assuming conversion of the Series A convertible preferred stock is excluded from the diluted earnings per share computations since the conversion option commences July 18, 2002. Additionally, since the Company did not draw any proceeds under the convertible promissory note agreement with Elan as of December 31, 2001, 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

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in loss periods, as their effect would be antidilutive. For the years ended December 31, 2001, 2000 and 1999, 1,681,000, 2,267,000, and 1,932,000 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 loss**

Items of other comprehensive loss include unrealized gains and losses on marketable securities available-for-sale securities and foreign currency translation adjustments. Disclosure of comprehensive loss for the years ended December 31, 2001, 2000 and 1999 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. The Company accounts for stock-based compensation to non-employees using a fair value based method. Pro forma operating results showing the impact of using the intrinsic value method instead of the fair value method for employee stock options is provided in Note 6.

**Income taxes**

The Company accounts for income taxes in accordance with SFAS No. 109, Accounting for Income Taxes, which requires 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. 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. Although the Company s convertible debt and preferred stock include conversion features that are considered to be embedded derivatives, accounting for those instruments is not affected by SFAS No. 133. The adoption of SFAS No. 133 did not have a material affect on the Company s financial position or results of operations.

**Related party transactions**

A member of the Board of Directors, as of November 2001, 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 $1,112,000, $587,000 and

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$366,000 for the years ended December 31, 2001, 2000 and 1999, respectively.

**New accounting pronouncements**

On June 29, 2001, the Financial Accounting Standards Board (FASB) issued SFAS No. 141, Business Combinations . SFAS No. 141 requires that the purchase method of accounting be used for all business combinations initiated after June 30, 2001. The Company adopted SFAS No. 141 on July 1, 2001. The adoption of this statement did not have a material impact on the Company s financial position or results of operations.

On June 29, 2001, SFAS No. 142, Goodwill and Other Intangible Assets was issued by the FASB. SFAS No. 142 changes the accounting for goodwill from an amortization method to an impairment-only approach. Goodwill and certain intangible assets will remain on the balance sheet and not be amortized. On an annual basis, and when there is reason to suspect that their values have been diminished or impaired, these assets must be tested for impairment, and write-downs may be necessary. The Company is required to implement SFAS No. 142 on January 1, 2002 and it has determined that this statement will not have a material impact on its financial position or results of operations.

In August 2001, the FASB issued SFAS 144, *Accounting for the Impairment or Disposal of Long-Lived Assets.* SFAS 144 provided new guidance on the recognition of impairment losses on long-lived assets to be held and used or to be disposed of and also broadens the definition of what constitutes a discontinued operation and how the results of a discontinued operation are to be measured and presented. SFAS 144 is effective for the Company s fiscal year beginning 2002, but is not expected to have a material impact on the Company s financial statements.

**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, 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 |
|---|---|---|---|
| U.S. Government and Agency Bond Funds: | | | |
| Thornburg Fund | 50,718 Shares | $ 637 | $ 635 |
| Pimco Fund | 1,010,194 Shares | 10,809 | 10,567 |
| Sub-total | | 11,446 | 11,202 |
| Other Marketable Securities AFS: | | | |
| 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 |
| MFS Limited Maturity Fund | 289,226 Shares | 2,000 | 2,001 |
| Sub-total | | 76,452 | 76,708 |
| Total | | $87,898 | $87,910 |

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As of December 31, 2000, marketable securities available-for-sale consist of the following (amounts in thousands, except share data):

| | Number of Shares or Principal Amount | Cost | Fair Value |
|---|---|---|---|
| U.S. Government and Agency Bond Funds: | | | |
| Thornburg Fund | 48,172 Shares | $ 605 | $ 592 |
| Pimco Fund | 661,342 Shares | 7,097 | 6,871 |
| Sub-total | | 7,702 | 7,463 |
| U.S. Government and Agency Bonds | $21,695 | 21,692 | 21,448 |
| Total | | $29,394 | $28,911 |

As of December 31, 2001, gross unrealized gains and losses pertaining to marketable securities available-for-sale were $590,000 and $577,000, respectively. As of December 31, 2000, gross unrealized gains and losses pertaining to marketable securities available-for-sale were $-0- and $484,000, respectively.

Realized investment gains and losses are included in investment income and included no gains in 2001 and $1,000 in 2000, and no gains in 1999. Realized losses were $831,000, $172,000, and $141,000, in 2001, 2000, and 1999, respectively. A charge of $831,000 against investment income was recognized in the fourth quarter of 2001 for a write-down of the Company s $1,000,000 Enron corporate note investment, which was adjusted to fair value as of December 31, 2001. The fair value for this investment was $195,000 as of December 31, 2001.

**3. INTANGIBLE ASSETS**

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

| | 2001 | 2000 |
|---|---|---|
| Patents | $ 2,534 | $ 2,115 |
| Purchased technology | 2,800 | 2,800 |
| Purchased royalty rights | 600 | 600 |
| Goodwill | 933 | 933 |
| Sub-total | 6,867 | 6,448 |
| Less: Accumulated amortization | (3,421) | (2,399) |
| Total | $ 3,446 | $ 4,049 |

**4. CONVERTIBLE SUBORDINATED NOTES PAYABLE**

In November 1997, the Company issued $50,000,000 of convertible subordinated notes. The notes bear interest at the rate of 7% and are due in 2004. The notes are 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 are redeemable, in whole or in part, at the Company s option, on or after December 5, 2000.

During the year ended December 31, 2001, the Company completed a series of private transactions involving the exchange of 1,725,735 shares of its common stock for $30,984,000 of the 7% Convertible

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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 $319,000, for the write-off of $664,000 of pro rata unamortized deferred finance charges net of $345,000 interest expense payable eliminated as a result of these exchanges. Additionally, of the 95,009 shares exchanged, a debt conversion expense of $2,194,000 was recognized for the year ended December 31, 2001. In 2000 and 1999, the Company repurchased $500,000 and $11,810,000 of the notes and recognized an extraordinary gain of approximately $80,000 and $3,275,000, respectively. As of December 31, 2001 and 2000, the notes payable balance was $5,206,000 and $36,190,000, respectively. The estimated fair value of the notes payable, based on quoted market prices or dealer quotes, was $5,961,000 and $37,226,000 at December 31, 2001 and 2000, respectively.

**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 $5,000,000.

***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 one-, three-, and four-month Eligard products for the treatment of prostate cancer.

The Company received a licensing fee of $8,000,000 upon signing 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 one-, three, and four-month Eligard products and Sanofi-Synthelabo will fund all research and development for a unique dosage formulation of Eligard. Additionally, in December 2001, Sanofi-Synthelabo exercised its rights under the agreement with the Company for the Eligard unique dosage formulation. The licensing fee was recorded as deferred revenue and is being recognized over the term of the agreement. As part of the agreement, Sanofi-Synthelabo purchased 824,572 shares of the Company s common stock for $15,000,000.

During 2001, the Company received $6,000,000 of milestone payments related to certain FDA filings. The licensing fee and milestone payments were recorded as deferred revenue and are being recognized in revenue over the remaining term of the agreement. Additionally, in 2001, the Company received $1,000,000 as an advanced payment for research and development of the unique dosage formulation of the Eligard product to be performed in 2002. This payment has been reflected as deferred revenue at December 31, 2001.

***MediGene AG***

In April 2001, the Company entered into an exclusive European marketing agreement with MediGene AG, a German biotechnology company, to market the one-, three-, and four-month Eligard products. Additionally, MediGene has the right to develop the Eligard unique dosage formulation product. The Company received a licensing fee of $2,000,000 upon signing the agreement. 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. The

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licensing fee was recorded as deferred revenue and is being recognized over the term of the agreement. As part of the agreement, MediGene purchased 233,918 shares of the Company s common stock for $3,780,000. In December 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 process.

***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 $2,000,000 licensing fee upon signing of the agreement. 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 75% of the research and development costs of the product in July 2001. The licensing fee was recorded as deferred revenue and is being recognized over the term of the agreement.

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

In July 2000, the Company formed a joint venture, Transmucosal Technologies, 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.

In connection with the formation of Transmucosal Technologies, the Company issued to Elan 12,015 shares of its Series A convertible exchangeable preferred stock (Series A), valued at $12,015,000 in exchange for 6,000 shares of common stock and 3,612 shares of preferred stock of Transmucosal Technologies, 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 $856,000. 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 $288,000 for the beneficial conversion feature related to this issuance, which was recorded as an additional dividend on preferred stock. Accreted and unpaid dividends at December 31, 2001 and 2000 were $410,000 and $382,000, respectively.

Series A is convertible commencing in 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 common stock at Atrix 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 $5,000,000 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 $8,010,000 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, 2001 and 2000, no amounts had been drawn under this note.

Because of this exchange feature, the Series A is presented outside of stockholders equity (deficit). Its carrying value equals the fair market 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 aforementioned 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

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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 Preferred Stock. 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 recognized $15,000,000 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 is for use 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, 2001 and 2000, the Company earned contract research and development revenues of $4,086,000 and $251,000, respectively, and had receivables from the joint venture of $946,000 and $251,000, respectively. Additionally, the Company had payables to the joint venture at December 31, 2001 and 2000 of $758,000 and $224,000, respectively. During 2001 and 2000, the Company recognized $3,285,000 and $12,239,000, respectively, for its share of the losses of Transmucosal Technologies.

***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.

***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 to CollaGenex Pharmaceuticals, Inc. following the reacquisition of the sales and marketing rights from Block Drug Corporation. The Company received a $1,000,000 licensing 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 $3,000,000, which was a $500,000 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 of the licensing fee. The net licensing fee was recorded as deferred revenue and is being recognized over the term of the agreement. 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 licensing 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 licensing fee and milestone payments in the amount of $24,100,000. These fees were recorded as revenue when received; however, as discussed in Note 1, in 2000 the Company changed its method of recognizing licensing fee and milestone payments to record them as revenue over the term of the agreement. No additional payments were received in 2000.

In August 2001, the Company reacquired certain marketing rights to the products from Block Drug. Under the terms of the agreement, Block Drug agreed to pay the Company $3,000,000 for milestones previously attained by the Company and the Company agreed to pay Block Drug up to $7,000,000, based on sales of products, over the term of the agreement, which is through August 2005. Upon termination of this agreement, all agreements between the Company and Block Drug will terminate. The Company recorded the additional milestone payments as deferred revenue and is reducing deferred revenue for payments made to Block Drug. As of December 31, 2001, the Company has paid Block Drug $3,800,000

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under the agreement.

***Other***

The Company has several other individually insignificant collaborative agreements that provide for licensing fees, milestone payment and research and development payments. During the years ended December 31, 2001, 2000 and 1999, the Company received licensing fees and milestone payments of $100,000, $195,000 and $145,000, respectively. These payments are being recognized in revenue over the terms of the contracts on a straight-line basis.

**6. STOCK OPTION PLANS**

As of December 31, 2001, 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. There are 3,396 shares that remain available under the 1987 Plan for future employee stock option grants. The 1987 Plan expires in May 2002 and no stock options will be granted under this plan after expiration.

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, 1998 | 1,275,154 | $ .50-21.75 | $ 9.60 |
| Options granted | 342,390 | 5.38 - 12.88 | 13.98 |
| Options canceled or expired | (68,942) | .50 - 21.75 | 12.30 |
| Options exercised | (120,650) | 8.75 - 15.00 | 11.15 |
| 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 outstanding were available for exercise as follows: | | | |
| Exercisable at December 31, 2001 | 816,999 | | $ 9.76 |
| Exercisable at December 31, 2000 | 972,784 | | 9.90 |
| Exercisable at December 31, 1999 | 884,743 | | 9.57 |

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| Range of Exercise Prices | Number Outstanding at December 31, 2001 | Weighted-Average Remaining Contractual Life | Weighted-Average Exercise Price | Number Exercisable at December 31, 2001 | Weighted-Average Exercise Price Exercisable |
|---|---|---|---|---|---|
| $5.50 - 17.25 | 143,770 | 1 year | $ 8.32 | 143,770 | $ 8.32 |
| 5.88 - 7.75 | 36,100 | 2 years | 6.42 | 36,100 | 6.42 |
| 6.75 - 10.00 | 66,769 | 3 years | 7.09 | 66,769 | 7.09 |
| 6.63 - 11.63 | 59,781 | 4 years | 7.89 | 59,781 | 7.89 |
| 9.50 - 12.75 | 119,387 | 5 years | 9.99 | 119,387 | 9.99 |
| 11.75 - 19.00 | 124,202 | 6 years | 16.64 | 124,202 | 16.64 |
| 9.19 - 11.00 | 140,405 | 7 years | 10.24 | 118,150 | 10.30 |
| 5.38 - 16.25 | 361,243 | 8 years | 8.18 | 148,840 | 7.56 |
| 10.06 - 25.99 | 63,000 | 9 years | 19.62 | | |
| $5.38 - 25.99 | 1,114,657 | 7 years | $10.11 | 816,999 | $ 9.76 |

***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 816,246 shares that remain available under the 2000 Plan for future employee stock option grants.

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 $7,000,000. Awards 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 options granted were fully vested at the date of the grant. As a result, the Company recognized $2,000,000 of administrative compensation expense in the year ended 2001.

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 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 |

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Options outstanding were available for exercise as follows:

| | | |
|---|---|---|
| Exercisable at December 31, 2001 | 412,233 | $10.49 |
| Exercisable at December 31, 2000 | | |
| Exercisable at December 31, 1999 | | |

| Range of Exercise Prices | Number Outstanding at December 31, 2001 | Weighted-Average Remaining Contractual Life | Weighted-Average Exercise Price | Number Exercisable at December 31, 2001 | Weighted-Average Exercise Price Exercisable |
|---|---|---|---|---|---|
| $9.31 - 9.75 | 380,474 | 8 years | $ 9.68 | 120,349 | $ 9.75 |
| 9.50 - 23.75 | 1,049,492 | 9 years | 14.37 | 191,381 | 13.84 |
| 5.00 - 28.19 | 486,403 | 10 years | 21.34 | 100,503 | 5.00 |
| $5.00 - 28.19 | 1,916,369 | 9 years | $15.21 | 412,233 | $10.49 |

***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 (5,000 in the case of the Chairman) 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 1987 Performance Stock Option Plan. For the year ended December 31, 2001, 24,000 stock options were issued at a price of $17.00 and none were exercised under this program.

*Stock Fee Program*

Commencing with the 1999 Annual Stockholders Meeting, each Non-Employee Director will receive an annual retainer fee. Each Non-Employee Director was eligible to elect to apply all or any portion of the retainer fee to the acquisition of shares of restricted common stock or the receipt of stock options. The portion of the fee subject to election of restricted common stock is determined by dividing the elected dollar amount by the fair market value per share on the date the fee is due to be paid. The restricted common stock vests ratably over a period of three years.

Beginning with the August 2000 meeting, the annual retainer was amended to provide each Non-Employee Director with 2,800 stock options in place of the retainer fee. 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, 2001, 2000 and 1999, the Non-Employee Directors elected to have 932, 3,092 and 2,474 shares of Restricted Common Stock issued, respectively. Under this plan, no stock options were elected to be granted. There are 18,502 shares that remain available 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

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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 and 2000 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):

| | 2001 | 2000 | 1999 |
|---|---|---|---|
| Net loss applicable to common stock: | | | |
| as reported | $(26,704) | $(47,411) | $(13,270) |
| pro forma | (34,072) | (51,498) | (14,912) |
| Basic and diluted net loss per common share: | | | |
| as reported | $ (1.63) | $ (3.99) | $ (1.17) |
| pro forma | (2.08) | (4.33) | (1.32) |

The weighted-average Black-Scholes fair value per option granted in 2001, 2000, and 1999 was $8.63, $5.65 and $5.63, 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 2001, 2000 and 1999: no dividend yield, expected volatility of 62.2% for 2001, 59.1% for 2000 and 52.5% for 1999, risk free interest rate of 7.0%, 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, 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 weighted-average fair value per option, granted under the Non-Qualified Plan in 2001 and 2000 was $11.65 and $4.66, respectively. 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 $117,000 for the year ended December 31, 2001 and no compensation expense was recorded for the years ended December 31, 2000, and 1999. The following weighted-average assumptions were used in 2001 and 2000: no dividend yield, expected volatility of 62.2% for 2001, and 59.1% for 2000, risk free interest rate of 7.0%, and expected lives of five years.

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

| | Number of Shares | Exercise Price Per Share | Weighted-Average Exercise Price |
|---|---|---|---|
| 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 |

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Options outstanding were available for exercise as follows:

| | | |
|---|---|---|
| Exercisable at December 31, 2001 | 54,000 | $11.56 |
| Exercisable at December 31, 2000 | 48,000 | 9.08 |
| Exercisable at December 31, 1999 | 27,480 | 8.68 |

| Range of Exercise Prices | Number Outstanding at December 31, 2001 | Weighted-Average Remaining Contractual Life | Weighted-Average Exercise Price | Number Exercisable at December 31, 2001 | Weighted-Average Exercise Price Exercisable |
|---|---|---|---|---|---|
| $5.13 | 7,000 | 3 years | $ 5.13 | 7,000 | $ 5.13 |
| 7.00 | 4,000 | 4 years | 7.00 | 4,000 | 7.00 |
| 9.50 - 16.50 | 15,000 | 5 years | 12.01 | 15,000 | 12.01 |
| 15.38 | 3,000 | 6 years | 15.38 | 3,000 | 15.38 |
| 6.00 - 10.13 | 15,000 | 8 years | 8.75 | 15,000 | 8.75 |
| 20.31 | 10,000 | 9 years | 20.31 | 10,000 | 20.31 |
| $5.13 - 20.31 | 54,000 | 6 years | $ 5.13 - 20.31 | 54,000 | $ 11.56 |

**7. INCOME TAXES**

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

| | 2001 | 2000 |
|---|---|---|
| Deferred tax assets: | | |
| Net operating loss carryforwards | $31,169 | $27,976 |
| Research and development tax credit carryforwards | 2,885 | 2,320 |
| Amortization of intangibles | 1,735 | 1,929 |
| Deferred revenue | 13,368 | 7,688 |
| Depreciation | 123 | 115 |
| Stock compensation | 927 | 132 |
| Loss on write-down of marketable security | 310 | |
| Other items | 341 | 284 |
| Net deferred tax assets | 50,858 | 40,444 |
| Less valuation allowance | 50,858 | 40,444 |
| Total | $ | $ |

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, 2001, the Company had approximately $83,279,000 of income tax net operating loss carryforwards, of which $1,769,000 relates to foreign losses available for carryforward. The Company has research and development credits of $2,885,000 which expire through 2021. At December 31, 2001 and 2000, the Company has $1,788,000 and $445,000 of deferred tax assets included in the total deferred tax asset for net operating loss carryforwards. These deferred tax assets resulted from the benefits from the exercise of employee stock options of $5,259,000 and $3,999,792 during 2001 and 2000, 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

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statutory rate and income tax expense as recorded for the years ended December 31 are as follows (amounts in thousands):

| | 2001 | 2000 | 1999 |
|---|---|---|---|
| Income tax computed at federal statutory rate: | $(8,628) | $(16,120) | $(4,512) |
| State income taxes net of federal | (837) | (1,564) | (438) |
| Equity in loss of joint venture | 1,117 | 4,565 | |
| Research and development | (565) | (353) | (359) |
| Amortization of intangibles | 314 | 302 | 294 |
| Other | (27) | 457 | (1,343) |
| Change in valuation allowance | 8,626 | 12,713 | 6,358 |
| Income tax expense | $ | $ | $ |

**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):

| | 2001 | 2000 | 1999 |
|---|---|---|---|
| Dental | $2,436 | $4,705 | $4,144 |
| Contract manufacturing | 1,092 | 1,235 | 163 |
| Other | 290 | 216 | 235 |
| Net sales and royalties | $3,818 | $6,156 | $4,542 |

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

| | 2001 | 2000 | 1999 |
|---|---|---|---|
| United States | $10,306 | $ 8,872 | $4,846 |
| Foreign countries | 5,505 | 1,171 | 789 |
| Total revenue | $15,811 | $10,043 | $5,635 |

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 or in aggregate did not exceed 10% of total long-lived assets of the Company.

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. For the year ended December 31, 1999, revenues from one customer accounted for 56% of total revenue.

At December 31, 2001, amounts due from three customers each exceeded 10% of accounts receivable and accounted for 71% of total accounts receivable. At December 31, 2000, amounts due from three customers each exceeded 10% of accounts receivable and accounted for

97% of total accounts receivable.

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**9. COMMITMENTS AND OTHER**

As of December 31, 2001, minimum rental commitments for future years under non-cancelable operating leases of one year or more are as follows (amounts in thousands):

| Years Ending December 31, | Minimum Rental Commitments |
|---|---|
| 2002 | $ 461 |
| 2003 | 408 |
| 2004 | 339 |
| 2005 | 311 |
| 2006 | 128 |
| Total | $ 1,647 |

Rent expenses were $422,000, $344,000, and $330,000, for the following years ended December 31, 2001, 2000, and 1999, 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 $540,000. In September 2001, the Company exercised its option to license GHRP-1 for an additional $1,960,000. 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.

In September 2001, the Company signed a licensing agreement for an oral interferon product from Amarillo Biosciences, Inc. for an initial licensing fee of $485,000. Under the agreement, the Company will be responsible for all research and development funding and will pay Amarillo Biosciences a royalty on sales of any oral interferon product developed. Additionally, the Company is obligated to make up to $2,050,000 of additional one-time payments upon the attainment of certain regulatory and marketing milestones. These milestones are subject to reduction in certain events and are only payable if and when attained.

The Company has a 401(k)-Employee Savings Plan, or the Savings Plan, that allows eligible employees to contribute from 1% to 17% of their income to the Savings Plan. The Company matches 50% of the first 6% of the employees contributions. Matching contributions to the Savings Plan were $108,000, $106,000, and $119,000 for the following years ended December 31, 2001, 2000, and 1999, 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 279,741 shares remain available at December 31, 2001.

Effective September 17, 2001, the Company s Board of Directors approved a new stock repurchase program to acquire up to $5,000,000 of the Company s common stock. The stock repurchase program is authorized through December 31, 2002. For the year ended December 31, 2001, the Company had repurchased 77,500 shares of its common stock in the open market. The average price per share was $20.11 for total stock repurchases of $1,558,000.

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**10. SELECTED QUARTERLY FINANCIAL INFORMATION (UNAUDITED)**

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

| | 2001 Fiscal Quarters | | | |
|---|---|---|---|---|
| | First | Second | Third | Fourth |
| 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 item | (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 item | (.52) | (.31) | (.58) | (.18) |
| Basic and diluted earnings per common share for net loss applicable to common stock | (.55) | (.32) | (.59) | (.21) |

The following table summarizes the quarterly financial information for the year ended December 31, 2000 (amounts in thousands):

| | 2000 Fiscal Quarters (Restated) | | | |
|---|---|---|---|---|
| | First | Second | Third | Fourth |
| Total revenue | $ 2,164 | $ 2,354 | $ 2,585 | $ 2,940 |
| Total operating expense | 5,207 | 5,461 | 6,444 | 6,651 |
| Net other expense | 97 | 233 | 12,148 | 297 |
| Loss before extraordinary item and cumulative effect of change in accounting principle | (3,140) | (3,340) | (16,007) | (4,008) |
| Net loss applicable to common stock | (23,751) | (3,340) | (16,098) | (4,220) |
| Basic and diluted earnings per common share before extraordinary and cumulative effect of change in accounting principle | (.27) | (.29) | (1.32) | (.32) |
| Basic and diluted earnings per common share for net loss applicable to common stock | (2.08) | (.29) | (1.33) | (.34) |

The quarterly information for 2000 differs from that reported in the Company s quarterly filings on Form 10-Q due to the adoption of SAB No. 101 in the fourth quarter of 2000. The effect of this change resulted in a reduction of loss before extraordinary items and cumulative effect of change in accounting principle of $403,000, $428,000, and $319,000 for the first, second and third quarters of 2000, respectively. The effect of this change resulted in an increase in net loss applicable to common stock of $20,208,000 for the first quarter of 2000. The effect of this change resulted in a reduction of loss on earnings per common share before extraordinary items and cumulative effect of change in accounting principle of $.04, $.04, and $.03 for the first, second and third quarters of 2000, respectively. The effect of this change resulted in an increase of loss on earnings per common share for net loss applicable to common stock of $1.77 for the first quarter of 2000.

**11. RESTATEMENT**

The Company s Series A Convertible Exchangeable Preferred Stock (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 (see Note 5), which is a redemption feature that is outside the Company s control. Subsequent to the issuance of the 2001 financial statements, it was determined that Emerging Issues Task Force Topic D-98, *Classification and Measurement of Redeemable Securities,* applies to this preferred stock issuance. As a result, the Company s consolidated balance sheets as of December 31, 2001 and 2000 and consolidated

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statements of changes in shareholders equity (deficit) for the years ended December 31, 2001 and 2000, have been restated to present the Series A Stock outside of permanent shareholders equity until such time as the exchange feature is exercised or expires. A summary of the significant effects of the restatement is as follows:

| | As of December 31, 2001 (in thousands) | |
|---|---|---|
| | As previously reported | As restated |
| SERIES A CONVERTIBLE EXCHANGEABLE PREFERRED STOCK | $ | $ 13,568 |
| SHAREHOLDERS EQUITY (DEFICIT) | | |
| Preferred stock | $ | $ |
| Common stock | 20 | 20 |
| Additional paid in capital | 246,471 | 232,903 |
| Treasury stock | (1,558) | (1,558) |
| Accumulated other comprehensive loss | (4) | (4) |
| Accumulated deficit | (132,201) | (132,201) |
| Total shareholders equity (deficit) | $ 112,728 | $ 99,160 |

| | As of December 31, 2000 (in thousands) | |
|---|---|---|
| | As previously reported | As restated |
| SERIES A CONVERTIBLE EXCHANGEABLE PREFERRED STOCK | $ | $ 12,397 |
| SHAREHOLDERS EQUITY (DEFICIT) | | |
| Preferred stock | $ | $ |
| Common stock | 13 | 13 |
| Additional paid in capital | 113,764 | 101,367 |
| Treasury stock | | |
| Accumulated other comprehensive loss | (471) | (471) |
| Accumulated deficit | (105,497) | (105,497) |
| Total shareholders equity (deficit) | $ 7,809 | $ (4,588) |

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**INDEPENDENT AUDITOR S REPORT**

The Board of Directors and Shareholders of
Transmucosal Technologies Ltd.

We have audited the accompanying balance sheets of Transmucosal Technologies Ltd. as at December 31, 2001 and 2000 and the related statement of loss, changes in shareholders equity and cash flows for the year ended December 31, 2001 and the period from July 14, 2000 (date of incorporation) to December 31, 2000. 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 financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material aspects, the financial position of Transmucosal Technologies Ltd. as at December 31, 2001 and the results of its operations and its cash flows for the periods then ended in conformity with accounting principles generally accepted in the United States of America.

/s/KPMG
Chartered Accountants
Hamilton, Bermuda
March 7, 2002

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**TRANSMUCOSAL TECHNOLOGIES LTD.**

Balance Sheets

December 31, 2001
*(Expressed in United States Dollars)*

| | 2001 | 2000 |
|---|---|---|
| **Assets** | | |
| Cash and cash equivalents | $ 2,144 | $ |
| Total assets | $ 2,144 | $ |
| **Liabilities** | | |
| Accounts payable and accrued expenses | $ 951,562 | $ 269,931 |
| Total liabilities | 951,562 | 269,931 |
| **Shareholders equity** | | |
| Share capital (Note 5) | 12,000 | 12,000 |
| Share premium (Note 6) | 14,988,000 | 14,988,000 |
| Contributed surplus (Note 7) | 3,436,107 | |
| Retained deficit | (19,385,525) | (15,269,931) |
| Total shareholders equity | (949,418) | (269,931) |
| Total liabilities and shareholders equity | $ 2,144 | $ |

*See accompanying notes to financial statements*

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**TRANSMUCOSAL TECHNOLOGIES LTD.**

Statements of Loss

Periods Ended December 31, 2001 and 2000
*(Expressed in United States Dollars)*

| | 2001 | 2000 |
|---|---|---|
| **Income** | | |
| Net investment income | $ 48 | $ |
| Total income | 48 | |
| **Expenses** | | |
| Research and development (Note 3) | 4,091,081 | 251,482 |
| Audit fees | 9,776 | |
| Government fees | 9,345 | |
| License fee (Note 4) | | 15,000,000 |
| General and administrative | 5,440 | 18,449 |
| Total operating expenses | 4,115,642 | 15,269,931 |
| Net loss | $(4,115,594) | $(15,269,931) |

*See accompanying notes to financial statements*

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**TRANSMUCOSAL TECHNOLOGIES LTD.**

Statements of Changes in Shareholders Equity

Periods Ended December 31, 2001 and 2000
*(Expressed in United States Dollars)*

| | 2001 | 2000 |
|---|---|---|
| **Share Capital** | | |
| Balance at beginning of period | $ 12,000 | $ |
| Shares issued during the period (Note 5) | | 12,000 |
| Balance at end of period | 12,000 | 12,000 |
| **Share premium** | | |
| Balance at beginning of period | 14,988,000 | |
| Share premium during the period (Note 6) | | 14,988,000 |
| Balance at end of period | 14,988,000 | 14,988,000 |
| **Contributed surplus** | | |
| Balance at beginning of period | | |
| Contributed surplus during year (Note 7) | 3,436,107 | |
| | 3,436,107 | |
| **Retained deficit** | | |
| Balance at beginning of period | (15,269,931) | |
| Net loss for the period | (4,115,594) | (15,269,931) |
| Balance at end of period | (19,385,525) | (15,269,931) |
| Total shareholders equity | $ (949,418) | $ (269,931) |

*See accompanying notes to financial statements*

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**TRANSMUCOSAL TECHNOLOGIES LTD.**

Statements of Cash Flows

Periods Ended December 31, 2001 and 2000
*(Expressed in United States Dollars)*

| | 2001 | 2000 |
|---|---|---|
| **Cash flows from operating activities** | | |
| Net loss | $(4,115,594) | $(15,269,931) |
| Adjustments to reconcile net income to net cash provided by operating activities | | |
| Accounts payable and accrued expenses | 681,631 | 269,931 |
| Cash used by operating activities | (3,433,963) | (15,000,000) |
| **Cash flows from financing activities** | | |
| Proceeds from issuance of shares | | 15,000,000 |
| Contributed surplus | 3,436,107 | |
| Cash provided by financing activities | 3,436,107 | 15,000,000 |
| Net increase in cash and cash equivalents | 2,144 | |
| Cash and cash equivalents at beginning of period | | |
| Cash and cash equivalents at end of period | $ 2,144 | $ |

*See accompanying notes to financial statements*

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**TRANSMUCOSAL TECHNOLOGIES LTD.**

Notes to Financial Statements

December 31, 2001 and 2000

**1. General**

Transmucosal Technologies Ltd. (the Company ) was incorporated in Bermuda on July 14, 2000 as Atrix Newco, Ltd. The Company is owned by Atrix Laboratories, Inc. ( Atrix ) and Elan International Services Ltd. ( EIS ), a wholly-owned subsidiary of Elan Corporation plc, holding 80.1% and 19.9% (non-voting shares) of the shares respectively. On December 14, 2000 the Company changed its name to Transmucosal Technologies Ltd.

The primary objective of the Company is to carry on the business of the development, testing, registration, manufacturing, commercialization, and licensing of Products (as defined in the Subscription, Joint Development and Operating Agreement ( JDOA ) dated July 18, 2000 between EIS, Atrix and the Company. The focus of the collaborative venture will be to develop the Products using the Elan Intellectual Property, the Atrix Intellectual Property and the Atrix Technology pursuant to the JDOA.

**2. Significant accounting policy**

The accompanying financial statements are prepared in accordance with accounting principles generally accepted in the United States of America which require 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. Actual results could differ from those estimates. The following are the significant accounting policies adopted by the Company:

*(a) Going concern*

These financial statements have been prepared on the basis that the Company is a going concern. The Company s ability to continue operating is dependent on achieving profitable operations and/or receiving additional development funding. It is the opinion of management that the Company will be a going concern based on additional development funding as described in Note 7.

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**TRANSMUCOSAL TECHNOLOGIES LTD.**

Notes to Financial Statements

December 31, 2001 and 2000

*(b) Research and development costs*

Research costs are charged as an expense of the period in which they are incurred. Development costs are deferred to future periods if certain criteria relating to future benefits are satisfied and if the costs do not exceed the expected future benefits.

**3. Related party transactions**

The following table summarizes the Company s related party transactions for the period:

| | |
|---|---|
| Research and development costs paid to shareholders | $4,091,081 |

These transactions are in the normal course of operations and are measured at the exchange amount, which is the amount of consideration established and agreed to by the related parties.

**4. License fee**

During fiscal 2000, the Company paid a license fee to Elan Corporation plc in the amount of $15,000,000 to acquire rights to certain Elan intellectual property. This license fee, which is non-refundable, was expensed in the prior year.

**5. Share capital**

| | | |
|---|---|---|
| Voting common shares, of par value US$1.00 per share | | |
| 6,000 shares authorised; | | |
| 6,000 shares issued and outstanding | $ | 6,000 |
| | | |
| Non-voting convertible preferred shares, of par value US$1.00 per share | | |
| 6,000 shares authorised; | | |
| 6,000 shares issued and outstanding | | 6,000 |
| | $ | 12,000 |

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**TRANSMUCOSAL TECHNOLOGIES LTD.**

Notes to Financial Statements

December 31, 2001 and 2000

At any time after July 18, 2002, each holder of the preferred shares shall have the right to convert all, or a portion, of such preferred shares into common shares on a one-to-one basis, as outlined in the Bye-laws of the Company.

**6. Share premium**

Share premium represents amounts contributed by shareholders in excess of the par value of the shares subscribed for.

**7. Development funding**

It is estimated that the Company may require an initial research and development budget of approximately $10 million, within the first 24 to 36 months from the date of incorporation, to commence development of the Products based upon the Elan Technology, Atrix Technology and/or Company Technology. The Development Funding shall be applied to the Company s research and development costs associated with development of the products. At December 31, 2001, $3,436,107 had been contributed as development funding.

**8. Taxes**

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

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**EXHIBIT INDEX**

| 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.* |
| 4.1 | Form of Common Stock Certificate.(6) |
| 4.2 | Indenture, dated November 15, 1997, by and among the Registrant and State Street Bank and Trust Company of California, N.A., as trustee thereunder.(7) |
| 4.3 | Form of Note (included in Indenture, see Exhibit 4.2) |
| 4.4 | Amended and Restated Rights Agreement (including form of Right Certificate, as Exhibit A, and form of Summary of Rights, as Exhibit B).(8) |
| 4.5 | Warrant to purchase 6,750 shares of Atrix Common Stock issued to Gulfstar Investments, Limited.(2) |
| 4.6 | Registration Rights Agreement, dated as of July 18, 2000, between Registrant and Elan International Services, Ltd., or EIS.(5) |
| 4.7 | Warrant dated as of July 18, 2000, issued by Registrant to EIS.(5) |
| 4.8 | Convertible Promissory Note, dated as of July 18, 2000, issued by Registrant to EIS.(5) |
| 4.9 | Warrant, dated as of April 4, 2001, issued by Atrix Laboratories, Inc. to Ferghana Partners, Inc.(9) |
| 10.1 | Lease Agreement dated May 11, 1991 between the Registrant and GB Ventures.(6) |
| 10.2 | Agreement dated December 16, 1996 between the Registrant and Block Drug Corporation ( Block Agreement ).(10) |
| 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.(11)** |
| 10.2G | Eighth Amendment to Block Agreement dated as of August 24, 2001.(12)** |
| 10.3 | Registration Rights Agreement, dated as of November 15, 1997, by and among Registrant and NationsBanc Montgomery Securities, Inc. and SBC Warburg Dillon Read, Inc.(7) |

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| Exhibit Number | Description |
|---|---|
| 10.4 | Amended and Restated Performance Stock Option Plan, as amended.(2) |
| 10.5 | Non-Qualified Stock Option Plan, as amended.(2) |
| 10.6 | Non-Employee Director Stock Incentive Plan.(13) |
| 10.7 | Employment Agreement between Registrant and Dr. J. Steven Garrett dated April 17, 1995.(2) |
| 10.8 | Employment Agreement between Registrant and Dr. David W. Osborne dated November 24, 1998.(2) |
| 10.9 | Employment Agreement between Registrant and Dr. Richard L. Jackson dated November 1, 1998.(2) |
| 10.10 | Personal Services Agreement between Registrant and David R. Bethune dated August 10, 1999.(13) |
| 10.11 | Stock Purchase Agreement, dated as of August 8, 2000, by and between Registrant and Pfizer Inc.(14) |
| 10.12 | Collaborative Research Agreement, dated as of August 8, 2000, by and between Registrant and Pfizer Inc.(14)** |
| 10.13 | License and Royalty Agreement, dated as of August 8, 2000, by and between Registrant and Pfizer Inc.(14)** |
| 10.14 | Collaboration, Development and Supply Agreement dated as of August 28, 2000 between Registrant and Geneva Pharmaceuticals, Inc.(15)** |
| 10.15 | Securities Purchase Agreement, dated as of July 18, 2000, between Registrant and EIS.(5)** |
| 10.16 | Newco Registration Rights Agreement, dated as of July 18, 2000, among Registrant, Atrix Newco Ltd., or Newco, and EIS.(5) |
| 10.17 | Subscription, Joint Development and Operating Agreement, dated as of July 18, 2000, among EIS, Registrant, Newco and Elan Pharma International Limited, or EPIL.(5)** |
| 10.18 | Company License Agreement, dated as of July 18, 2000, among Registrant, Newco and Elan Corporation plc, or Elan.(5)** |
| 10.19 | EPIL License Agreement, dated as of July 18, 2000 among Elan, EPIL, Newco and Registrant.(5)** |
| 10.20 | Collaboration, License and Supply Agreement, dated as of December 8, 2000, by and between Registrant and Sanofi-Synthelabo Inc.(16)** |
| 10.21 | Stock Purchase Agreement, dated as of December 29, 2000, by and between Registrant and Sanofi-Synthelabo.(16) |
| 10.22 | 2000 Stock Incentive Plan.(17) |
| 10.23 | License Agreement by and between Registrant and CollaGenex Pharmaceuticals, Inc. dated as of August 24, 2001. (12)** |
| 10.24 | Stock Purchase Agreement by and between Registrant and CollaGenex Pharmaceuticals, Inc. dated as of August 24, 2001.(12)** |
| 10.25 | Collaboration, License and Supply Agreement by and between Registrant and Fujisawa Healthcare, Inc., dated October 15, 2001.(12)** |
| 10.26 | Collaboration, License and Supply Agreement, dated as of April 4, 2001, by and between Registrant and MediGene.(18)** |

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| Exhibit Number | Description |
|---|---|
| 10.27 | Stock Purchase Agreement, dated as of April 4, 2001, by and between Registrant and MediGene.(18)** |
| 10.28 | 2001 Executive Long Term Incentive Compensation Program.* |
| 21 | Subsidiaries of the Registrant. (17) |
| 23.1 | Consent of Deloitte & Touche LLP |
| 23.2 | Consent of KPMG |
| 99.1 | Certification of Chief Executive Officer |
| 99.2 | Certification of Chief Financial Officer |

* Previously filed with, and incorporated by reference to, the Registrant s original Annual Report on Form 10-K for the year ended December 31, 2001, as filed with the Securities and Exchange Commission on April 1, 2002 (File No. 000-18321).

** 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 for the fiscal year ended September 30, 1993, as filed with the Securities and Exchange Commission (File No. 000-18321).

(7) 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. 000-18321).

(8) 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).

(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 December 16, 1996, as amended on May 20, 1998, as filed with the Securities and Exchange Commission (File No. 000-18321).

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(11) 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).

(12) Incorporated by reference to Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2001 (File No. 000-18231).

(13) 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).

(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 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).

(16) 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).

(17) 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).

(18) 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).