

ATRIX LABORATORIES INC

Form 10-K

March 03, 2004

Table of Contents

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

FORM 10-K

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

For the Fiscal Year Ended December 31, 2003

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

For the transition period from to

Commission File Number 0-18231

ATRIX LABORATORIES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

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

80525
(Zip Code)

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

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

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

Common Stock, \$0.001 par value

(Title of Class)

Series A Preferred Stock Purchase Rights

(Title of Class)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Edgar Filing: ATRIX LABORATORIES INC - Form 10-K

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

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

The aggregate market value of voting stock held by non-affiliates of the registrant as of June 30, 2003 was approximately \$360.2 million based upon the closing sale price on The Nasdaq National Market for that date. This calculation excludes shares of common stock held by registrant's officers and directors and each person known by the registrant to beneficially own more than 5% of the registrant's outstanding common stock, as such persons may be deemed to be affiliates. This determination of affiliate status should not be deemed conclusive for any other purpose.

The number of shares outstanding of the registrant's common stock as of March 1, 2004, was 21,629,018.

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III of this report, to the extent not set forth in Part III, is incorporated by reference from the registrant's definitive proxy statement for its Annual Meeting of Stockholders scheduled to be held on May 2, 2004.

TABLE OF CONTENTS

	<u>Page</u>
PART I	1
<u>Item 1.</u> <u>Business</u>	1
<u>Item 2.</u> <u>Properties</u>	31
<u>Item 3.</u> <u>Legal Proceedings</u>	31
<u>Item 4.</u> <u>Submission of Matters to a Vote of Security Holders</u>	31
PART II	32
<u>Item 5.</u> <u>Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	32
<u>Item 6.</u> <u>Selected Financial Data</u>	33
<u>Item 7.</u> <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	35
<u>Item 7A.</u> <u>Quantitative and Qualitative Disclosures About Market Risk</u>	51
<u>Item 8.</u> <u>Financial Statements and Supplementary Data</u>	52
<u>Item 9.</u> <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	52
<u>Item 9A.</u> <u>Controls and Procedures</u>	52
PART III	53
<u>Item 10.</u> <u>Directors and Executive Officers of the Registrant</u>	53
<u>Item 11.</u> <u>Executive Compensation</u>	53
<u>Item 12.</u> <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	53
<u>Item 13.</u> <u>Certain Relationships and Related Transactions</u>	53
<u>Item 14.</u> <u>Principal Accountant Fees and Services</u>	53
PART IV	55
<u>Item 15.</u> <u>Exhibits, Financial Statement Schedules, and Reports on Form 8-K</u>	55
<u>Consent of Deloitte & Touche LLP</u>	
<u>Rule 13a-14(a) Certification of the CEO</u>	
<u>Rule 13a-14(a) Certification of the CFO</u>	
<u>Section 1350 Certification of CEO</u>	
<u>Section 1350 Certification of CFO</u>	

Table of Contents

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**

Atrix Laboratories, Inc. and its subsidiaries are collectively referred to herein as Atrix, the Company, we, our or us. Incorporated in Delaware in 1986, we are an emerging specialty pharmaceutical company focused on advanced drug delivery. With unique patented drug delivery technologies, we are currently developing a diverse portfolio of products, including proprietary oncology and dermatology products. We also form strategic alliances with a variety of pharmaceutical and biotechnology companies to develop products utilizing our various drug delivery systems and/or to commercialize our products. Current significant strategic alliances include, Sanofi-Synthelabo Inc., Fujisawa Healthcare, Inc., Sandoz Inc. (formerly Geneva Pharmaceuticals, Inc.), Pfizer Inc., Sosei Co. Ltd., MediGene AG and Yamanouchi, Mayne Pharma, Tecnofarma, Han All Pharmaceutical Co., Ltd. and CollaGenex Pharmaceuticals, Inc.

Our drug delivery systems deliver controlled amounts of drugs in various time frames to address a range of therapeutic and patient needs. Atrigel is our original proprietary sustained release biodegradable polymer drug delivery system. We believe that the Atrigel system may provide benefits over traditional methods of drug administration such as safety and effectiveness, ease of applications, site-specific or systemic delivery, customized release rates and biodegradability. Our four additional drug delivery systems are SMP™, MCA™, BCP™ and BEMA™.

Table of Contents

Our Strategy

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

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

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

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

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

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

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

2003 Highlights and Recent Developments

The following discussion highlights significant events for our company during the year ended December 31, 2003 and thereafter:

Atrisone Acne Product

In January 2004, we announced successful completion of two pivotal Phase III clinical efficacy studies for our Atrisone acne product. Over 3,000 patients were enrolled in these double-blind, randomized, vehicle-controlled studies, which were conducted in over 100 centers around the United States and Canada. We expect to file a New Drug Application, or NDA, with the FDA for the Atrisone acne product by mid-2004.

Eligard 30-mg Four-Month Product

We received approval from the FDA for our Eligard 30-mg four-month product in February 2003. In March 2003, Sanofi-Synthelabo Inc. launched the product into the U.S. market, and we received a \$6.0 million milestone payment in April 2003 for the first commercial sale.

Eligard 45-mg Six-Month Product

In November 2003, we announced the completion of the pivotal Phase III clinical study for the Eligard 45-mg six-month product. In February 2004, we submitted an NDA to the FDA for this product.

Table of Contents

Eligard International

In January 2003, we entered into an exclusive licensing agreement with Sosei Co., Ltd. to develop and commercialize our Eligard products in Japan. Sosei paid us a one-time non-refundable license fee of \$1.0 million. We may receive additional payments for research and development support and payments for specific regulatory and sales milestones. Additionally, we will receive royalty payments based on sales of the Eligard products if the products are approved for marketing by the Japanese Ministry of Health, Labor and Welfare, or MHLW. Sosei will be responsible for any preclinical and clinical studies required for approval and will be responsible for submission of the necessary documents to obtain marketing authorization from the MHLW. In December 2003, Sosei entered into a co-promotion agreement with Nippon Organon K.K. to market our Eligard products. We will manufacture the Eligard products for Sosei and will earn manufacturing margins.

In February 2003, Tecnofarma received approval to market the Eligard 7.5-mg one-month and 22.5-mg three-month products in Argentina. Tecnofarma launched the Eligard 7.5-mg one-month product in May 2003. In January 2004, Tecnofarma received approval to market the Eligard 7.5-mg one-month and 22.5-mg three-month products in Mexico.

In November 2003, Sanofi-Synthelabo Canada received a notice of compliance from the Therapeutic Products Directorate of Health Canada for our Eligard 7.5-mg one-month and 22.5-mg three-month products. Sanofi-Synthelabo Canada will be responsible for marketing the products in Canada. Sanofi-Synthelabo launched the Eligard 7.5-mg one-month and 22.5-mg three-month products in December 2003. In February 2004, Sanofi-Synthelabo Canada received a notice of compliance from the Therapeutic Products Directorate of Health Canada for our Eligard 30-mg four-month product.

In December 2003, MediGene AG, our European licensee, received marketing authorization from the German pharmaceutical regulatory authority, Bundesinstitut für Arzneimittel und Medizinprodukte, or BfArM, for our Eligard 7.5-mg one-month product. MediGene received marketing authorization from BfArM for our Eligard 22.5-mg three-month product in January 2004. Also, in January 2004 we entered into an agreement with MediGene and Yamanouchi, naming Yamanouchi as our pan-European marketing partner.

In November 2003, Mayne Pharma, our Australian licensee, received marketing approval of Eligard 7.5-mg one-month, 22.5-mg three-month and 30-mg four-month products in Australia from the Australian Drug Evaluation Committee. Mayne Pharma launched the Eligard 7.5-mg one-month, 22.5-mg three-month and 30-mg four-month products in February 2004.

In January 2004, we entered into an exclusive licensing agreement with Han All Pharmaceutical Co., Ltd. to develop and commercialize our Eligard products in Korea. Han All paid us a one-time non-refundable license fee of \$0.3 million in January 2004, and we may receive additional payments for research and development support. Additionally, we will receive royalty payments based on sales of the Eligard products if the products are approved for marketing in Korea. Han All will be responsible for any preclinical and clinical studies required for approval and will be responsible for submission of the necessary documents to obtain marketing authorization. We will manufacture the Eligard products for Han All and will earn manufacturing margins.

Other Products

In January 2004, we announced that Pfizer Inc. completed the initial phase of clinical testing of a novel bone growth product formulated in our Atrigel sustained-release drug delivery system and is advancing the product into additional human clinical testing.

In August 2003, we submitted an investigational new drug application, or IND, to the FDA for an Atrigel formulation of octreotide, which is designed to deliver the pharmaceutical over a 30-day period for the long term treatment of severe diarrhea and flushing episodes associated with carcinoid tumors.

Table of Contents

We received approval from the FDA for our Abbreviated New Drug Application, or ANDA, for lidocaine/prilocaine cream in August 2003, and our partner, Sandoz, subsequently commenced marketing of this product. Our product is the AB-rated generic to EMLA--Registered Trademark-- Anesthetic Cream (lidocaine 2.5% and prilocaine 2.5%).

In August 2003, we received a non-approval letter from the FDA indicating that a generic dermatology product was not approved. We are currently appealing this action through the FDA; however, we cannot provide any assurance that our appeal will be successful.

We received approval from the FDA for our ANDA for mometasone furoate ointment USP, 0.1% in November 2003, and our partner, Sandoz, subsequently commenced marketing of this product. Our product is the AB-rated generic to Elocon--Registered Trademark-- brand of mometasone furoate ointment 0.1%.

In December 2003, we received tentative approval from the FDA for mometasone furoate topical solution, USP, 0.1%, an AB-rated generic of Elocon--Registered Trademark-- lotion 0.1%, which is currently protected by a patent until 2007. Sandoz intends to market this product upon expiration of the patent in 2007.

In January 2004, we announced approval from the FDA for our ANDA for betamethasone dipropionate cream, USP, 0.05% (Augmented), and our partner, Sandoz, subsequently commenced marketing of this product. Our product is an AB-rated generic to Diprolene--Registered Trademark-- AF Cream 0.05% brand augmented betamethasone dipropionate, which is marketed by Schering Plough Corporation.

In January 2004, we announced that we submitted three ANDAs to the FDA for approval of generic formulations of undisclosed dermatology products. With these applications, we currently have six ANDA submissions under FDA review.

In September 2003, we reached an agreement to terminate our joint venture with a subsidiary of Elan Corporation. Termination of the joint venture returns the BEMA-fentanyl product to us. Upon termination, we acquired Elan's ownership interest in the joint venture, Transmucosal Technologies Ltd., in exchange for Elan receiving a portion of any consideration we receive from the licensing of BEMA-fentanyl and a royalty based on net sales of BEMA-fentanyl if the product is commercialized.

Our Marketed Products and Products Under Development

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

Pharmaceutical Products and Product Candidates	Delivery System	Indication	Status	Collaborative Partner(s)
Eligard 7.5-mg one-month	Atrigel	Prostate cancer	Marketed	Sanofi-Synthelabo
			U.S. launch, May 2002	Tecnofarma
			Argentina launch, May 2003	Sanofi-Synthelabo
			Canada launch, Dec 2003	Mayne Pharma
			Australia launch, Feb 2004	MediGene/ Yamanouchi
			Approval in Germany, Dec 2003	Tecnofarma
			Approval in Mexico, Jan 2004	
			Pending approval in Korea, Israel, Latin America and South Africa	Han All, Luxembourg Pharma, Tecnofarma and Key Oncologics
Eligard 3.75-mg three-month	Atrigel	Prostate cancer	Bioequivalence clinical trials	Sosei

Table of Contents

Pharmaceutical Products and Product Candidates	Delivery System	Indication	Status	Collaborative Partner(s)
Eligard 22.5-mg three-month	Atrigel	Prostate cancer	Marketed U.S. launch, Sept. 2002 Canada launch, Dec 2003 Australia launch, Feb 2004 Approval in Argentina, Feb 2003 Approval in Germany, Jan 2004 Approval in Mexico, Jan 2004 Pending approval in Korea, Israel, Latin America and South Africa	Sanofi-Synthelabo Sanofi-Synthelabo Mayne Pharma Tecnofarma MediGene/ Yamanouchi Tecnofarma Han All, Luxembourg Pharma, Tecnofarma and Key Oncologics
Eligard 11.25-mg three-month	Atrigel	Prostate cancer	In development	Sosei
Eligard 30-mg four-month	Atrigel	Prostate cancer	Marketed U.S. launch, March 2003 Australia launch, Feb 2004 Canada approval, Feb 2004 Pending approval in Korea, Israel, Latin America and South Africa	Sanofi-Synthelabo Mayne Pharma Sanofi-Synthelabo Han All, Luxembourg Pharma, Tecnofarma and Key Oncologics
Eligard 45-mg six-month formulation	Atrigel	Prostate cancer	NDA submitted Feb 2004	Sanofi-Synthelabo, MediGene/ Yamanouchi, Mayne Pharma, Han All, and Luxembourg Pharma
One- and three-month leuprolide products for endometriosis	Atrigel	Endometriosis	Preclinical	None
Atrisone	SMP™	Acne vulgaris Other indications (rosacea, atopic dermatitis, other)	Phase III Completed Preclinical/ Phase I/ II	Fujisawa Healthcare Fujisawa Healthcare
Bone growth product	Atrigel	Bone regeneration	Completed Phase I	Pfizer
Octreotide	Atrigel	Symptoms of carcinoid syndrome	INDA submitted Phase I	None
Lidocaine 2.5%/ Prilocaine 2.5% Cream an AB-rated generic to	N/A	Topical anesthetic	Marketed U.S. launch, Sept	Sandoz

Table of Contents

Pharmaceutical Products and Product Candidates	Delivery System	Indication	Status	Collaborative Partner(s)
Mometasone Ointment, 0.1% an AB-rated generic to Elocon® Ointment 0.1%	N/A	Topical corticosteroid	Marketed U.S. launch, Dec 2003	Sandoz
Betamethasone Dipropionate Cream USP, 0.05% (augmented) an AB-rated generic to Diprolene® AF Cream 0.05%	N/A	Topical corticosteroid	Marketed U.S. launch, Jan 2004	Sandoz
Mometasone Furoate Topical Solution USP, 0.1% an AB-rated generic of Elocon® lotion 0.1%	N/A	Topical corticosteroid	Tentative approval, currently on patent until 2007	Sandoz
Growth hormone releasing peptide-1.	Atrigel	Renal insufficiency	Phase I	Tulane University Health Science Center
Atrigel- ¹²⁵ IUDR MICRaS	Atrigel	Treatment of solid tumors	Preclinical	None
Atrigel-Risperidone	Atrigel	Schizophrenia	Preclinical	None
BEMA-fentanyl	BEMA	Chronic and breakthrough cancer pain	Phase I	Terminated Elan joint venture agreement Sept 2003

The following table details certain information about our marketed dental and OTC products:

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

Table of Contents

Marketed Pharmaceutical Products and Product Candidates

Eligard Products

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

Clinical trials have demonstrated that the sustained release of a LHRH agonist decreases testosterone levels to suppress tumor growth in patients with hormone-responsive prostate cancer. The Phase III results for the Eligard 7.5-mg one-month, 22.5-mg three-month, 30-mg four-month and 45-mg six-month products revealed low testosterone levels with 99% of completing 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, which use a small needle and are injected subcutaneously, are safe and effective in treating prostate cancer.

Net sales and royalties for our Eligard products for the years ended December 31, 2003 and 2002 were \$14.1 million and \$2.1 million, respectively. There were no sales of Eligard products in 2001.

Eligard 7.5-mg One-Month Product

We received FDA approval for our Eligard 7.5-mg one-month product in January 2002, and Sanofi-Synthelabo commenced U.S. marketing of this product in May 2002.

In November 2001, MediGene submitted a Marketing Authorization Application, or MAA, for our Eligard 7.5-mg one-month product to the German pharmaceutical regulatory authority, BfArM, as a Reference Member State under a Mutual Recognition Procedure. MediGene received marketing authorization from the BfArM for our Eligard 7.5-mg one-month product in December 2003. In January 2004, we announced that we and MediGene named Yamanouchi as its pan-European marketing partner. We anticipate Yamanouchi will submit a modified MAA to specific Concerned Member States in the European Union for marketing approval in other key countries.

Tecnofarma launched Eligard 7.5-mg in Argentina in May 2003 and received approval in Mexico in January 2004.

Mayne Pharma submitted a General Marketing Authorization, or GMA, with the Australian regulatory authority in August 2002 for our Eligard 7.5-mg one-month product. In November 2003, Mayne Pharma received marketing approval of our Eligard 7.5-mg one-month product from the Australian Drug Evaluation Committee and launched the product in February 2004.

Sanofi-Synthelabo Canada filed a New Drug Submissions, or NDS, with the Canadian regulatory authority in December 2001 for our Eligard 7.5-mg one-month product. In November 2003, Sanofi-Synthelabo Canada received notice of compliance from the Therapeutic Products Directorate of Health Canada for our Eligard 7.5-mg one-month product and launched the product in December 2003.

Eligard 22.5-mg Three-Month Product

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

In April 2002, MediGene submitted an MAA for our Eligard 22.5-mg three-month product to the German pharmaceutical regulatory authority, BfArM, as a Reference Member State under a Mutual Recognition Procedure and in January 2004, received marketing authorization. Yamanouchi intends to submit a modified MAA to specific Concerned Member States in the European Union for marketing approval in other key countries.

Table of Contents

Tecnofarma received approval for Eligard 22.5-mg three-month product in Argentina in February 2003 and received approval in Mexico in January 2004.

Mayne Pharma submitted a GMA with the Australian regulatory authority in August 2002 for our Eligard 22.5-mg three-month product and received marketing approval from the Australian Drug Evaluation Committee in November 2003. Mayne Pharma launched the Eligard 22.5-mg three-month product in February 2004.

Sanofi-Synthelabo Canada filed an NDS with the Canadian regulatory authority in December 2001 for our Eligard 22.5-mg three-month product. In November 2003, Sanofi-Synthelabo Canada received notice of compliance from the Therapeutic Products Directorate of Health Canada for our Eligard 22.5-mg three-month product and launched the product in December 2003.

Eligard 30-mg Four-Month Product

In February 2003, we received FDA approval for Eligard 30-mg four-month product, and Sanofi-Synthelabo commenced U.S. marketing of this product in March 2003.

Mayne Pharma submitted a GMA with the Australian regulatory authority in August 2002 for our Eligard 30-mg four-month product and received marketing approval from the Australian Drug Evaluation Committee in November 2003.

Sanofi-Synthelabo Canada filed an NDS with the Canadian regulatory authority in November 2002 for our Eligard 30.0-mg three-month product and received a notice of compliance from the Therapeutic Products Directorate of Health Canada for our Eligard 30-mg four-month product in February 2004.

Eligard 45-mg Six-Month Product

Our Eligard 45-mg six-month product for prostate cancer completed Phase III clinical trials in November 2003, and we submitted an NDA to the FDA in the February 2004.

One- and Three-Month Leuprolide Products for Endometriosis

In November 2002, we entered into an exclusive North American marketing agreement with EmerGen, Inc. for a one-month and a three-month leuprolide product for the treatment of endometriosis. The new leuprolide products for endometriosis involve the development and clinical testing of half-strength dose versions of Eligard 7.5-mg one-month and Eligard 22.5-mg three-month products. In July 2003, we received the rights back from EmerGen for these products. Currently, these products are in the preclinical stage of development.

Atrisone

We are currently developing Atrisone, our proprietary product for the treatment of acne, rosacea, atopic dermatitis and additional indications. 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 may reduce 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.

In January 2004, we announced successful completion of two pivotal Phase III clinical efficacy studies for our Atrisone acne product. Over 3,000 patients were enrolled in these double-blind, randomized, vehicle-controlled studies, which were conducted in over 100 centers around the United States and Canada. We expect to file an NDA with the FDA for the Atrisone acne product in mid-2004.

Table of Contents

Generic Dermatology Products

We received approval from the FDA for our ANDA for lidocaine/prilocaine cream in August 2003. Our product is the AB-rated generic to EMLA Anesthetic Cream (lidocaine 2.5% and prilocaine 2.5%) and is being marketed by our partner, Sandoz.

We received approval from the FDA for our ANDA for mometasone furoate ointment USP, 0.1% in November 2003. Our product is an AB-rated generic of Elocon® brand of mometasone furoate ointment USP, 0.1% and is being marketed by our partner, Sandoz.

In December 2003, we received tentative approval from the FDA for mometasone furoate topical solution USP, 0.1%, an AB-rated generic of Elocon® lotion 0.1% currently on patent until 2007. Sandoz intends to market this product upon patent expiration.

We received approval from the FDA for our ANDA for betamethasone dipropionate cream USP, 0.05% (augmented) in January 2004. Our product is an AB-rated generic to Diprolene® AF Cream 0.05% brand augmented betamethasone dipropionate, which is marketed by Schering Plough Corporation.

In January 2004, we announced that we submitted three ANDAs to the FDA for approval of generic formulations of undisclosed dermatology products. With these applications, we currently have six ANDA submissions under FDA review. Of the generic topical products approved thus far, we were in each case, the second or later approval, thus sales to date have been minimal.

Bone Growth Product

In January 2004, we announced that Pfizer completed the initial phase of clinical testing of a novel bone growth product, formulated in our proprietary Atrigel sustained-release drug delivery system and is advancing the product into additional human clinical testing. Pfizer plans to conduct all clinical trials of the Atrigel formulation. We will continue to support this product through production of clinical supplies and consultation.

Octreotide

In August 2003, we submitted an INDA to the FDA for an Atrigel formulation of octreotide, which is designed to deliver the pharmaceutical over a 30-day period for the long term treatment of severe diarrhea and flushing episodes associated with carcinoid tumors. We are currently in development stages for this product.

BEMA-Fentanyl

Through our joint venture with Elan, we were 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 across oral 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 late 2001, we submitted an INDA to the FDA and subsequently commenced a Phase I clinical safety study for BEMA-fentanyl. In September 2003, we reached an agreement to terminate our joint venture with a subsidiary of Elan Corporation. Termination of the joint venture returns the BEMA-fentanyl product to us. Upon termination, we acquired Elan's ownership interest in the joint venture, Transmucosal Technologies Ltd., in exchange for Elan receiving a portion of any consideration we receive from the licensing of BEMA-fentanyl and a royalty based on net sales of BEMA-fentanyl if the product is commercialized.

Table of Contents***Marketed Dental and Over-The-Counter Products and Product Candidates******Dental Products***

We have a number of approved products that target the dental market. Atridox, which combines the Atrigel system and the antibiotic doxycycline, is a minimally invasive treatment intended to control the bacteria that cause periodontal disease. Atridox was awarded the American Dental Association Seal of Acceptance 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, Pfizer Animal Health currently has the worldwide marketing right of our Doxirobe Gel product, a periodontal disease treatment for companion animals.

Net sales and royalties for our dental products in the years ended December 31, 2003, 2002 and 2001 were \$4.2 million, \$2.6 million and \$2.4 million, respectively.

Over-The-Counter Products

Orajel-Ultra Mouth Sore Medicine is an over-the-counter product that utilizes our proprietary MCA drug delivery system and is currently marketed by Del Laboratories. We will receive royalties on the net sales of this product through October 2016.

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

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

Edgar Filing: ATRIX LABORATORIES INC - Form 10-K

small gauge needle or placed into accessible tissue sites through a cannula, displacement of the carrier with water in the tissue fluids causes the polymer to precipitate, forming a solid film or implant. The drug encapsulated within the implant is then released in a controlled manner as the polymer matrix biodegrades with time. Depending upon the patient's medical needs, the Atrigel system can deliver small molecules, peptides or proteins over a period ranging from days to months.

Table of Contents

The delivery system containing the suspended drug is injected into the patient. Once injected, the solvent diffuses out as water diffuses into the delivery system with the suspended drug. This process leads to solidification of the polymer to form an implant. Rapid release of a portion of the drug during the initial diffusion of the solvent is called the burst phase. Once the implant is formed, the drug is slowly released in a controlled manner for the specified time period.

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

destruction of the compound in the gastrointestinal system,

difficulty in maintaining uniform drug levels over time,

problems with toxicity and side effects,

high costs due to frequent administration, and

poor patient compliance.

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

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

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 thereby reducing the frequency of drug administration.

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

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

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

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

Table of Contents

drug to permeate into the epidermal layer of the skin, while a high level of the microparticle drug is maintained just above the outermost layer of the skin for later delivery. The consistent microparticle size and distribution maximize drug delivery while minimizing crystal growth over the shelf life of the product.

Mucocutaneous Absorption System

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

Bioerodible Mucoadhesive System

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

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, 2003, we continued to devote significant resources to the research and development of our Eligard, Atrisoron and octreotide products. Currently, we have multiple compounds in various stages of preclinical development, a number of which are being developed through partnerships with a variety of external companies. Most of these projects are preliminary in nature and we cannot predict whether any of them will be commercialized.

Our research and development expenses were \$36.4 million, \$32.7 million and \$28.6 million for the years ended December 31, 2003, 2002 and 2001, respectively.

Table of Contents

Collaborative Arrangements

Our business strategy includes forming collaborations to provide technological, financial, marketing and other resources. We have entered into a number of such collaborative arrangements with a variety of pharmaceutical and biotechnology companies utilizing our various drug delivery systems and/or to commercialize our products. Current significant strategic alliances include Sanofi-Synthelabo Inc., Fujisawa Healthcare, Inc., Sandoz Inc., Pfizer Inc., Sosei Co. Ltd., MediGene AG and Yamanouchi, Mayne Pharma, Tecnofarma, Han All Pharmaceutical Co., Ltd. and CollaGenex Pharmaceuticals, Inc.

Sanofi-Synthelabo, Inc.

In December 2000, we entered into an exclusive North American marketing agreement with Sanofi-Synthelabo for our Eligard one-month, three-month, and four-month prostate cancer treatment products. Under the terms of the agreement, we will manufacture the Eligard products and receive an agreed upon transfer price from Sanofi-Synthelabo as well as royalties from sales. In addition, we received an up-front license fee of \$8.0 million. As part of the agreement, Sanofi-Synthelabo purchased 824,572 shares of our common stock for \$15.0 million. The Sanofi-Synthelabo agreement provides for payments of up to \$60.0 million, including the purchase of our common stock, license fees and payments for clinical, regulatory and sales milestones for the Eligard products. In April 2003, we received a \$6.0 million milestone payment for the first commercial sale of our Eligard 30-mg four-month product. In January 2002, Sanofi-Synthelabo exercised its right to develop a six-month formulation of Eligard. Under the terms of the agreement, we receive reimbursement for research and development expenses related to the development of this six-month formulation. Additionally, we will receive payments for certain regulatory and sales milestones, a royalty based on sales of the product and will manufacture the six-month product at our facility. A Phase III clinical study for Eligard 45-mg six-month product was completed in November 2003, and we submitted an NDA to the FDA in February 2004.

Fujisawa Healthcare, Inc.

In October 2001, we entered into a collaboration, license and supply agreement with Fujisawa for the exclusive North American marketing and distribution rights of our Atrisone acne treatment product. The Fujisawa agreement provides for payments of up to \$25.0 million for an up-front license fee, research and development support and certain milestone payments. Additionally, we will receive a royalty on net sales of the Atrisone product and a manufacturing margin. In October 2001, we received a \$2.0 million license fee upon signing of the agreement. In December 2002, Fujisawa exercised its option to explore additional indications for topical Atrisone. Similar to the original agreement, Fujisawa will be responsible for a significant portion of any research and development costs that arise for development of Atrisone for these additional indications.

In January 2004, we announced successful completion of our two pivotal Phase III clinical efficacy studies for our Atrisone acne product. Over 3,000 patients were enrolled in these double-blind, randomized, vehicle-controlled studies, which were conducted in over 100 centers around the United States and Canada. We expect to file an NDA with the FDA for the Atrisone acne product by mid-2004.

We received no milestone or license fee payments from Fujisawa for the year ended December 31, 2003.

Sandoz, Inc. (formerly Geneva Pharmaceuticals, Inc.)

In August 2000, we entered into a development and supply agreement with Sandoz, Inc. (formerly Geneva Pharmaceuticals, Inc.), a subsidiary of Novartis, to conduct research and development activities on a collaborative basis to develop designated generic topical prescription dermatology products. Under the terms of the agreement, we will be responsible for validation, formulation, development and required clinical studies of selected products. This collaboration extends to the United States, although additional territories may be added at a later date. Sandoz will be responsible for market research and

Table of Contents

commercialization of the products. Sandoz will reimburse us for 50% of the research and development expenses we incur, and both parties will share equally in the net profits from the sale of the products.

We received approval from the FDA for our ANDA for lidocaine/prilocaine cream in August 2003, and Sandoz subsequently commenced marketing of this product. Our product is the AB-rated generic to EMLA Anesthetic Cream (lidocaine 2.5% and prilocaine 2.5%).

We received approval from the FDA for our ANDA for mometasone furoate ointment USP, 0.1% in November 2003. The AB-rated generic to Elocon® brand of mometasone furoate ointment USP Ointment 0.1% will be marketed by Sandoz.

In December 2003, we received tentative approval from the FDA for mometasone furoate topical solution USP, 0.1%, an AB-rated generic of Elocon® lotion 0.1% currently on patent until 2007. Sandoz will market this product upon patent expiration.

In January 2004, we announced approval from the FDA for our ANDA for betamethasone dipropionate cream USP, 0.05% (augmented), an AB-rated generic to Diprolene® AF Cream 0.05% brand augmented betamethasone dipropionate, which is marketed by Schering Plough Corporation.

In January 2004, we announced that we submitted three ANDAs to the FDA for approval of generic formulations of undisclosed dermatology products. With these applications, we currently have six ANDA submissions under FDA review.

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.

In January 2004, we announced that Pfizer completed the initial phase of clinical testing of a novel bone growth product, formulated in our Atrigel sustained-release drug delivery system and is advancing the product into additional human clinical testing.

As of December 31, 2003, all other products under the Pfizer agreement were in preclinical stages of development.

MediGene AG/ Yamanouchi

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 45-mg six-month product. Under the terms of the agreement, we will manufacture the Eligard products and we will receive additional payments for certain clinical, regulatory and sales milestones and royalties on sales. Pursuant to the agreement, we received an up-front license fee of \$2.0 million and MediGene purchased 233,918 shares of our common stock for \$3.8 million. Additionally, MediGene will provide funding to conduct clinical, research and regulatory activities associated with seeking European marketing approvals. The MediGene agreement provides for payments of up to \$16.0 million including MediGene's purchase of our common stock, the license fee and payments for certain clinical, regulatory and sales milestones.

In November 2001, MediGene submitted an MAA for our Eligard 7.5-mg one-month product to the German regulatory authority, BfArM, as a Reference Member State under a Mutual Recognition Procedure. In April 2002, MediGene submitted an MAA for our Eligard 22.5-mg three-month product to BfArM, as a Reference Member State under a Mutual Recognition Procedure. MediGene received marketing authorization from BfArM for our Eligard 7.5-mg one-month and Eligard 22.5-mg three-month

Table of Contents

products in December 2003 and January 2004, respectively. The MAAs submitted by MediGene utilized data for the U.S. dosage strengths of Eligard, which is twice the strength of competing leuprolide acetate products used in Europe for the palliative treatment of hormone-sensitive advanced prostate cancer.

In January 2004, we entered into an agreement with MediGene and Yamanouchi, naming Yamanouchi as our pan-European marketing partner. We anticipate Yamanouchi will submit a modified MAA to specific Concerned Member States in the European Union for marketing approval in other key countries. We received no milestone or license fee payments from MediGene or Yamanouchi for the year ended December 31, 2003.

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 Drug Company. Under the terms of the CollaGenex agreement, we received \$1.0 million for an up-front license fee. Additionally, we receive a royalty on product sales and a manufacturing margin. As part of the transaction, we purchased 330,556 shares of CollaGenex's common stock for \$3.0 million. CollaGenex commenced U.S. marketing of Atridox and Atrisorb FreeFlow in November 2001 and Atrisorb-D in January 2002.

International Operations

In February 2000, our wholly owned registered subsidiary, Atrix Laboratories GmbH, based in Bad Homburg, Germany, commenced operations. Atrix Laboratories GmbH was organized to conduct our European dental operations. Atrix Laboratories GmbH manages our business relationships with European distributors for the dental products and in 2002 commenced promoting Atridox directly to dentists in Germany. Atrix Laboratories GmbH currently holds the marketing authorizations for European sales of Atridox. To date, we have received individual marketing authorizations in sixteen European countries. In 2003, we reorganized our European operations and initiated the closing of our wholly owned subsidiary, Atrix Laboratories Limited in the United Kingdom, which we expect to complete in 2004.

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

In November 2003, Mayne Pharma received marketing authorization from the Australian Drug Evaluation Committee for our Eligard one-month, three-month, and four-month products.

Sanofi-Synthelabo submitted NDSs in Canada for our Eligard 7.5-mg one-month and our Eligard 22.5-mg three-month products in December 2001, and an NDS was filed in Canada for our Eligard 30.0-mg four-month product in November 2002. In November 2003, Sanofi-Synthelabo received marketing authorization in Canada for our Eligard 7.5-mg one-month and Eligard 22.5-mg three-month products. In February 2004, Sanofi-Synthelabo received marketing authorization in Canada for our Eligard 30-mg four-month product.

In January 2003, we entered into an exclusive licensing agreement with Sosei Co., Ltd. to develop and commercialize our Eligard 3.75-mg and 11.25-mg products in Japan. Sosei will be responsible for submission of the necessary documents to obtain marketing authorization from the Japanese Ministry of Health, Labor and Welfare. We received \$1.0 million in January 2003 for an up-front license fee less \$0.1 million for taxes withheld. In December 2003, Sosei entered into a co-promotion agreement with Nippon Organon K.K. for the Eligard products in Japan.

In January 2004, we entered into an exclusive licensing agreement with Han All Pharmaceutical Company, Ltd. to develop and commercialize our four Eligard products in Korea. Han All will be

Table of Contents

responsible for submission of the necessary documents to obtain market authorization. We will earn manufacturing margins on sales.

Our revenues from foreign sources, including the joint venture with Elan, were \$4.5 million, \$3.1 million and \$5.5 million for the fiscal years ended December 31, 2003, 2002 and 2001, respectively.

Patents and Trademarks

We consider patent protection and proprietary position to be significant to our business. As of December 31, 2003, we held 58 United States patents and 160 foreign patents, and 17 United States and 102 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, SMP, MCA, BCP and BEMA 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 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 adversely affect our operations. Furthermore, patent protection may not afford adequate protection against competitors with similar systems, composition or methods, and our patents may be infringed or circumvented by others. Moreover, it may be costly to pursue and to prosecute patent infringement actions against others, and such actions could hamper our business. We also rely on our unpatented proprietary knowledge. Others may be able to develop substantially equivalent proprietary knowledge or otherwise obtain access to our knowledge, and our rights under any patents may not afford sufficient protection.

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

<u>Year Expiring</u>	<u>U.S. Patents</u>	<u>Foreign Patents</u>	<u>Total Patents</u>
2008	6		6
2009	2	30	32
2010		17	17
2011	7	1	8
2012		14	14
2013	4		4
2014	9	16	25
2015	7	25	32
2016	8	15	23
2017	1	34	35
2018	5		5
2019	5	8	13
2020	4		4
	<u>58</u>	<u>160</u>	<u>218</u>
Total	58	160	218

In addition to patents, we also maintain United States and foreign trademark and service mark applications for registrations of our company name, logo and names for drug delivery systems and products. These include ten U.S. and 63 foreign issued trademarks, with two U.S. and 25 foreign trademark applications pending.

Table of Contents

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 have multiple business strategies focused on drug delivery. One of our focuses is on the development of new chemical entities, either licensed or sourced from third-party pharmaceutical companies using our drug delivery technologies. An additional focus is on the development of existing drugs using our current delivery technologies. We believe this strategy may be less costly than attempting to discover new drugs and by 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 Sanofi-Synthelabo, Fujisawa, Sandoz, Pfizer and CollaGenex. During 2003, these five customers accounted for 81% of our total revenues. The distribution network for pharmaceutical products is subject to increasing consolidation. As a result, a few large distributors control a significant share of the market. In addition, the number of independent drug stores and small chains has decreased as retail consolidation has occurred. Further consolidation or financial difficulties of distributors or retailers could result in the combination or elimination of warehouses, which may result in reductions in purchases of our products.

Competition

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

Our competitors include academic institutions, government agencies, research institutions, biotechnology and pharmaceutical companies, including our collaborators, and drug delivery companies. Several companies have drug delivery technologies that compete with our technologies, including Alkermes, Inc., ALZA Corporation, Cima Labs, Inc., Durect Corp., Noven Pharmaceuticals, Inc. and SkyePharma, plc. Competitors of our Eligard prostate cancer treatment products include, AstraZeneca's ZoladexTM product, Bayer's ViadurTM product, Pfizer's TrelstarTM product and TAP Pharmaceuticals, Inc.'s LupronTM product. Competitors of our dental products include OraPharma, Inc., whose ArestinTM 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.

Table of Contents

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 there under govern, among other things, the testing, manufacturing, safety, efficacy, labeling, storage, record keeping, approval, clearance, advertising and promotion of our products. Preclinical studies, clinical trials and the regulatory approval process typically take years and require the expenditure of substantial resources. If regulatory approval or clearance of a product is granted, the approval or clearance may include significant limitations on the indicated uses for which the product may be marketed.

FDA Regulation Approval of Therapeutic Products

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

preclinical studies,

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

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

the submission of an NDA to the FDA, and

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

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

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

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

assess dosage tolerance and optimal dosage, and

identify possible adverse effects and safety risks.

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

Table of Contents

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 that 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 pre-market notifications of new medical devices.

FDA Regulation Approval of Medical Devices

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

FDA Regulation Post-Approval Requirements

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

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

European Regulation Approval of Medicinal Products

Our Eligard and Atridox products are regulated in Europe as medicinal products. In 1993, legislation was adopted which established a new and amended system for the registration of medicinal products in the European Union, or EU. The objective of this system is to prevent the existence of separate national approval systems that have been a major obstacle to harmonization. One of the most significant features of

Table of Contents

this system was the establishment of a European Agency for the Evaluation of Medicinal Products. Under this 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 Mutual Recognition Procedure. The Mutual Recognition Procedure creates a system for mutual recognition of national approvals and establishes procedures for coordinated EU action on product suspensions and withdrawals. Under this procedure, the holder of a national marketing authorization for which mutual recognition is sought may submit an application to one or more Concerned Member States, certifying that identical dossiers are being submitted to all Concerned Member States for which recognition is sought. Within 90 days of receiving the application and assessment report, each Concerned Member State must decide whether or not to recognize the approval. The procedure encourages Concerned Member States to work with applicants and other regulatory authorities to resolve disputes concerning mutual recognition. If such disputes cannot be resolved within the 90-day period provided for review, the application will be subject to a binding arbitration procedure at the request of the applicant. Alternatively, the application may be withdrawn.

European Regulation Approval of Medical Devices

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

Regulatory Considerations for Orphan Drug Products

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

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

Regulatory Considerations for OTC Drug Products

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

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

the drug is the subject of an approved NDA, or

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

Prior FDA approval is required only if an NDA is submitted. A company makes the determination as to which route to market is the most appropriate. If a company determines that the drug product is

Table of Contents

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. The FDA must inspect all registered establishments 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 an 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 and analytical testing of the drug product and provide 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 cGMP and that the applicant has complied with the patent requirements of the Food, Drug and Cosmetic Act.

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

Additional Regulatory Issues

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

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

Table of Contents

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 3, 2004, we employed 158 employees on a full-time basis. Of the 158 full-time employees, 133 are engaged in production, research and clinical testing and the remaining 25 are in administrative capacities. A total of 38 employees have earned doctorate or advanced degrees. None of our employees are represented by a union or collective bargaining unit, and management considers relations with employees to be good.

Additional Information

Environmental

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

Supply of Raw Materials

We currently obtain supplies of the polymer used in our polymer delivery systems from four qualified suppliers. Supplies of doxycycline, used in our Atridox, Atrisorb-D and Doxirobe Gel periodontal disease treatment products, are obtained from one supplier who maintains two qualified manufacturing sites. Supplies of leuprolide acetate, used in our Eligard prostate cancer products, are obtained from two qualified suppliers. A solvent used in the Eligard products is obtained from one qualified supplier. We currently obtain supplies of dapson for our Atrisone™ product from two suppliers. 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 2003, and we do not anticipate any significant shortages or delays in the foreseeable future.

Table of Contents

Available Information

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

Factors Affecting Our Business and Prospects

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

We have a history of operating losses. Since our inception, we have invested a significant amount of time and money in research and development of new products. Our research and development expense, including research and development licensing fees, was \$36.4 million, \$32.7 million and \$28.6 million for the years ended December 31, 2003, 2002 and 2001, respectively. Our total operating expense, including research and development costs, was \$54.5 million, \$47.1 million and \$37.9 million, for the years ended December 31, 2003, 2002 and 2001, respectively, which exceeded our total revenue of \$49.5 million, \$26.4 million and \$15.8 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, 2003 was \$154.2 million. If we do not ultimately achieve and maintain profitability, our stock price may decline.

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

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

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

the regulatory agency might not approve our manufacturing processes or facilities,

the regulatory agency 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.

Delays in obtaining approval may result in our needing to make significant expenditures of additional time and money to bring a new product to market. If we do not obtain approval for any particular product, we will have spent a significant amount of time and money in the approval process and will be unable to market the product to generate revenue.

We are also required to comply with the FDA's cGMPs with respect to the manufacturing of our drugs and QSRs with respect to the manufacturing of our medical devices. These cGMPs and QSRs include requirements relating to quality control, quality assurance and maintenance of records and documentation. Manufacturing facilities are subject to biennial inspections by the FDA and must be approved before we can use them in the commercial manufacturing of our products. If our contract manufacturers, or we are unable to comply with the applicable cGMPs, QSRs and other regulatory requirements, the FDA may seek sanctions and/or remedies against us, including suspending our

Table of Contents

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

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

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

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

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

As our product and product candidates are used commercially, if and when approved, unintended side effects, adverse reactions or incidence of misuse may appear. We cannot predict whether the commercial use of products or product candidates in development, if and when they are approved for commercial use, will produce undesirable or unintended side effects that have not been evident in the use of clinical trials

Table of Contents

conducted for such products, and product candidates, to date. Additionally, incidents of product misuse may occur. These events, among others, could result in product recalls or withdrawals or additional regulatory controls.

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

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, prior to 2002, Block had exclusive rights to market and distribute our Atridox, Atrisorb-FreeFlow GTR Barrier and Atrisorb-D GTR Barrier products in North America. We had disputes with Block relating to product pricing and the payments due to us upon achievement of milestones under our commercialization agreement with Block and were involved in arbitration and litigation proceedings with them until final settlement of all disputes in September 2001. We then entered into a new arrangement for the marketing and distribution of these products in the United States with CollaGenex. Our legal dispute with Block and the transition to CollaGenex as our new marketing partner for these products were the primary factors causing our 39% decrease in product net sales and royalty revenue between our 2000 and 2001 fiscal years and part of the reason for our 28% increase in administrative and marketing expenses between such years.

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

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

We have limited experience in marketing and selling our products. Our sales of Eligard 7.5-mg one-month, Eligard 22.5-mg three-month and Eligard 30-mg four-month products, which accounted for 75% of our net sales and royalty revenue in the fiscal year ended December 31, 2003, have been marketed in the United States by Sanofi-Synthelabo since May 2002, September 2002 and March 2003, respectively. Our Atridox, Doxirobe and Atrisorb-FreeFlow GTR Barrier products, sales of which accounted for

Table of Contents

approximately 22% of our net sales and royalty revenue in the fiscal year ended December 31, 2003, have been marketed by our partners and have been on the market for five and a half years. To achieve commercial success for any of our products, we must either develop a marketing and sales force or contract with another party to perform these services for us. In either case, we are competing with companies that have experienced and well-funded marketing and sales operations. We have historically relied upon arrangements with third parties to market and sell our products. If we do not maintain good relationships with these third parties, we may not be able to make alternative arrangements on acceptable terms and our product sales may decline. To the extent we undertake to market or co-market our own products, however, we would require additional expenditures and management resources. In particular, factors that may inhibit our efforts to commercialize our products without collaborative partners include:

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

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

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

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

If our products do not achieve market acceptance, our revenue will be reduced. Our products may not gain market acceptance among physicians, patients, third-party payors and the medical community. Under Block's and CollaGenex's marketing of our dental products in North America, our dental products have been slow in achieving market acceptance within the dental community. We expect an increase in market acceptance for our dental products in foreign countries as we establish marketing authorizations and commence marketing within these countries through our Germany-based subsidiary, Atrix GmbH. Sanofi-Synthelabo commenced marketing in the United States of our Eligard 7.5-mg one-month, Eligard 22.5-mg three-month and Eligard 30-mg four-month products in May 2002, September 2002 and March 2003, respectively. We anticipate market acceptance to increase for our Eligard products as Sanofi-Synthelabo's marketing and product awareness efforts continue. However, if Sanofi-Synthelabo's efforts were not successful in marketing our Eligard products, our Eligard U.S. sales revenue would decline. In the fiscal year ended December 31, 2003, we generated \$18.8 million in net sales and royalties, or 38% of our \$49.5 million total revenue.

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 that may cost less than our products. Physicians, patients, third-party payors and the medical community may not accept or utilize our products. If our products do not achieve significant market acceptance, we may not generate enough revenue to offset our research and development expenses incurred in obtaining the required regulatory approvals and, therefore, we may not realize profitability.

We have limited experience in manufacturing products on a commercial scale, and, if we are unable to produce enough of our products to meet market demands, this could cause a decrease in our revenue.

Table of Contents

We completed the expansion of our manufacturing facility in the second quarter of 2003 and the validation of the plant and equipment was completed during the third quarter of 2003. Certain areas of the plant require further qualification by the FDA, which is anticipated by the end of 2004. There is a risk that we may fail to meet facility qualification requirements, to meet future market demands, to manufacture present and future products in compliance with applicable regulations and to produce our products at an acceptable cost.

We have a dependence on one contract manufacturer involved in the production of our Eligard products. We currently outsource the sterile filling and lyophilization, also known as freeze drying, process of our Eligard products to an approved contract manufacturer and rely on this manufacturer for this highly specialized service. If the vendor was unable to meet our needs for this manufacturing process, or if our relationship with this vendor was to deteriorate or terminate, production of our Eligard products may be temporarily discontinued for several months. We currently have one other contract manufacturer as a back-up source for the sterile filling and lyophilization process should there be a disruption in our Eligard product supply chain. However, the FDA would need to approve the change in the manufacturer of the sterile filling and lyophilization process for our Eligard products, which could take several months. Additionally, we and our partners have at least three months of inventory safety stock of Eligard products to meet near term future demands, should a disruption in the sterile filling and lyophilization process occur. In order to minimize our risk, we have built and are in the process of qualifying our own sterile filling and lyophilization facility, which is not expected to be commercially operating until the end of 2004.

We generate a significant amount 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 \$22.1 million for the fiscal year ended December 31, 2003 represented 45% of our \$49.5 million total revenue.

If any of our research and development agreements were terminated or substantially modified, or if our relationships with any of these collaborators deteriorated, our contract research and development revenue may decrease and our ability to develop and commercialize our technologies may be hindered. Contract research and development revenue recognized under our agreements with Fujisawa, Sandoz, Sanofi-Synthelabo and Pfizer was \$20.6 million, or 93%, of our 2003 total contract research and development revenue of \$22.1 million, or 42%, of our 2003 total revenue of \$49.5 million. If any of these agreements were terminated, or if our relationship with these collaborators deteriorated, our revenue would likely decrease significantly.

We conduct operations in foreign countries, which are subject to risks, and our plans for international expansion may not succeed, which could harm our revenue and profitability. We conduct our European operations through our wholly owned subsidiary, Atrix Laboratories GmbH, in Bad Homburg, Germany. Revenue from product sales to customers outside of the United States amounted to \$2.6 million, or 14%, of our \$18.8 million net sales and royalties revenue and 5% of our total revenue of \$49.5 million, for the fiscal year ended December 31, 2003.

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

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

difficulties in managing foreign operations or obtaining the required regulatory approvals from foreign governmental authorities,

fluctuations in currency exchange rates or imposition of currency exchange controls,

Table of Contents

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 methods. In that event, such delivery systems, compositions and methods may compete with our systems, compositions and methods and may reduce sales of our products. Our patents may not afford adequate protection against competitors with similar systems, composition and methods, and other companies may circumvent our patents.

In addition to patents, we also maintain numerous U.S. and 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 non-patented proprietary knowledge. Despite our efforts to protect our proprietary rights from unauthorized use or disclosure, parties, including former employees or 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 may require us to make considerable cash outlays and can entail the need for us to issue equity securities, incur debt and contingent liabilities, incur amortization expenses related to intangible assets, and can result in the

Table of Contents

impairment of goodwill, which could harm our profitability. Acquisitions involve a number of additional risks, including:

- difficulties in and costs associated with the assimilation of the operations, technologies, personnel and products of the acquired companies,
- assumption of known or unknown liabilities or other unanticipated events or circumstances,
- risks of entering markets in which we have limited or no experience, and
- potential loss of key employees.

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

We may seek to raise additional funds, and additional funding may be dilutive to stockholders or impose operational restrictions. Any additional equity financing may be dilutive to our stockholders and debt financing, if available, may involve restrictive covenants, which may limit our operating flexibility with 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 dilution in net book value per share and any additional equity securities may have rights, preferences and privileges senior to those of the holders of our common stock.

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

We are subject to environmental compliance risks. Our research, development and manufacturing areas involve the controlled use of hazardous chemicals, primarily flammable solvents, corrosives, and toxins. The biologic materials include microbiological cultures, animal tissue and serum samples. Some experimental and clinical materials include human source tissue or fluid samples. We are not licensed to receive or handle radioactive materials. We are also subject to federal, state and local government regulation in the conduct of our business, including regulations on employee safety and 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.

Table of Contents

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

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

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; however, our insurance may not provide adequate coverage against potential product liability claims or losses. In the future, we may not be able to obtain adequate insurance coverage on reasonable terms and insurance premiums and deductibles may increase. Even if we were ultimately successful in product liability litigation, the litigation could consume substantial amounts of our financial and managerial resources and may create adverse publicity, all of which would impair our ability to generate sales. If we were found liable for any product liability claims in excess of our insurance coverage or outside our coverage, the cost and expense of such liability could severely damage our business and profitability.

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

Our stock price is volatile and the value of a stockholder's investment may be subject to sudden decreases. The price of our stock has been and may continue to be volatile. The price of our stock during the last two years has ranged from a low of \$10.06 on February 14, 2003 per share to a high of \$30.90 per share on September 3, 2003. Our stock price may fluctuate due to a variety of factors, including:

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

fluctuations in our operating results,

sales of our common stock in the marketplace,

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

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

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

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

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

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

Table of Contents

Item 2. Properties.

We lease a total of 43,109 square feet of office and research laboratory space located in Fort Collins, Colorado, pursuant to a lease that expires in June 2006. We own a manufacturing facility in Fort Collins that we acquired in July 1996 and we completed an expansion of this facility in the second quarter of 2003. The expansion increased the square footage of the manufacturing facility from 26,437 square feet to 58,000 square feet. 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 of vacant land. We currently have approximately 4 acres of vacant land for possible future development or expansion.

In the expanded facility, we intend to manufacture the full line of our Eligard products, Atrisone topical dermatological product, generic dermatology products, dental products and clinical supplies for products currently in development. Approximately 40% of the building's expansion is devoted to manufacturing with the remainder allotted for warehousing, quality assurance and laboratory work. Validation of the plant and equipment was completed during the third quarter of 2003. Certain areas of the plant require further qualification by the FDA, which is anticipated by the end of 2004.

We also lease 367 square feet of office space located in Bad Homburg, Germany, pursuant to a lease agreement requiring a three month notice to terminate. 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.

On November 3, 2003, TAP Pharmaceutical Products, Inc. and two additional plaintiffs filed suit in U.S. District Court, Northern District of Illinois, Eastern Division, *Tap Pharmaceutical Products, Inc., et al v. Atrix Laboratories, Inc., et al*, alleging that the Eligard delivery system infringes a patent that claims, among other things, a biodegradable high molecular polymer, which patent is licensed to TAP Pharmaceuticals by the two other plaintiffs. The plaintiffs seek an injunction and unspecified damages. We believe the claims are without merit and intend to defend against them vigorously.

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 2003 fiscal year.

Table of Contents**PART II****Item 5. Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities. Market Information**

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

	<u>High</u>	<u>Low</u>
2003:		
Fourth Quarter	\$26.89	\$18.03
Third Quarter	30.90	19.50
Second Quarter	23.12	13.26
First Quarter	15.88	10.06
2002:		
Fourth Quarter	\$19.67	\$14.51
Third Quarter	22.90	11.04
Second Quarter	25.25	20.82
First Quarter	25.65	19.20

 Holders

On March 1, 2004, the closing price of our common stock as reported on The Nasdaq National Market was \$27.05 per share and there were 2,284 holders of record of the 21,629,018 outstanding shares 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. For the year ended December 31, 2003, we issued 983 shares of Series A Convertible Preferred Stock to Elan for accretion of preferred stock dividends. Additionally, 521 shares of Series A Convertible Preferred Stock were issued to Elan in the first quarter of 2004 for accretion of preferred stock dividends for the period of July 19, 2003 through January 18, 2004.

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

The selected consolidated financial data presented below is derived from our audited consolidated financial statements. The selected consolidated financial data set forth in the table below is not necessarily indicative of our results of future operations and should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations and the consolidated financial statements and related notes included herein.

	Years Ended December 31,				
	2003	2002	2001	2000	1999
(In thousands, except per share data)					
Summary of Consolidated Operations:					
Total revenue	\$ 49,547	\$ 26,384	\$ 15,811	\$ 10,043	\$ 5,635
Total operating expense	(54,536)	(47,094)	(37,880)	(23,686)	(21,830)
Other income (expense)(1)	3,273	2,542	(3,464)	(12,773)	2,925
Income tax expense					
Loss before cumulative effect of change in accounting principle	(1,716)	(18,168)	(25,533)	(26,416)	(13,270)
Cumulative effect of change in accounting principle(2)				(20,612)	
Net loss before preferred stock dividends	(1,716)	(18,168)	(25,533)	(47,028)	(13,270)
Accretion of dividends and beneficial conversion charges on preferred stock	(1,179)	(946)	(1,171)	(383)	
Net loss applicable to common stock	\$ (2,895)	\$ (19,114)	\$ (26,704)	\$ (47,411)	\$ (13,270)
Basic and diluted earnings per common share:					
Loss before cumulative effect of change in accounting principle	\$ (0.08)	\$ (0.90)	\$ (1.56)	\$ (2.23)	\$ (1.17)
Cumulative effect of change in accounting principle				(1.73)	
Net loss before preferred stock dividends	(0.08)	(0.90)	(1.56)	(3.96)	(1.17)
Accretion of dividends and beneficial conversion charges on preferred stock	(0.06)	(0.05)	(0.07)	(0.03)	
Net loss applicable to common stock	\$ (0.14)	\$ (0.95)	\$ (1.63)	\$ (3.99)	\$ (1.17)
Basic and diluted weighted average shares outstanding	20,102	20,077	16,348	11,884	11,327
Consolidated Balance Sheet Data:					
Working capital(3)	\$ 110,780	\$ 114,039	\$ 135,219	\$ 56,549	\$ 38,646
Total assets	149,858	150,025	157,493	74,172	54,659
Long-term obligations(4)	32,415	37,064	33,579	60,408	36,690
Series A Convertible Exchangeable Preferred Stock(5)		14,514	13,568	12,397	
Shareholders' equity (deficit)	103,388	82,255	99,160	(4,588)	14,670

Edgar Filing: ATRIX LABORATORIES INC - Form 10-K

Notes:

- (1) The Company adopted SFAS No. 145 in the first quarter of 2003 and as a result, the comparative financial statements were restated to reclassify the extraordinary loss on extinguishment of debt to be included in loss from operations.
- (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.
- (3) Working capital is computed as current assets less current liabilities.

33

Table of Contents

- (4) Included in long-term obligations are the non-current amounts of deferred revenue. These amounts are not subject to future repayment.
- (5) 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, had an exchange feature that allowed the holder to convert it into an additional holding in Transmucosal Technologies, which had a redemption feature that was outside of our control. As a result, our Series A Stock was presented outside of permanent shareholders' equity prior to the year ended December 31, 2003. We terminated our joint venture with a Elan International in September 2003. In connection with the termination, Elan and its affiliates agreed to forego the exchange right included in the Series A Stock. Accordingly, as of September 30, 2003, we reclassified the Series A Stock to permanent equity.

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations, as well as information contained elsewhere in this report, contain statements that constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, and Section 21E of the Securities Exchange Act of 1934. These include statements regarding the intent, belief or current expectations of us, our directors or our officers with respect to, among other things: (1) whether we will receive, and the timing of, regulatory approvals or clearances to market potential products; (2) the results of current and future clinical trials; (3) the time and expenses associated with the regulatory approval process for products; (4) the safety and effectiveness of our products and technologies; (5) our expectation that our marketing partners will be able to successfully market our products; (6) our expectation of receiving royalties on sales of our products and our plans to manufacture certain of our products at our facility in Fort Collins, Colorado; and (7) the timing of new product launches.

Forward-looking statements are not guarantees of future performance and involve risks and uncertainties. Actual results may differ materially from those projected in the forward-looking statements as a result of various factors, including those described under Item 1. Business Factors Affecting Our Business and Prospects.

Overview

We are an emerging specialty pharmaceutical company focused on advanced drug delivery. With five unique patented drug delivery technologies, we are currently developing a diverse portfolio of products, including proprietary oncology and dermatology products. We also form strategic alliances with a variety of pharmaceutical and biotechnology companies to develop products utilizing our various drug delivery systems and/or to commercialize our products. These strategic alliances include collaborations with Sanofi-Synthelabo, Inc., Fujisawa Healthcare, Inc., Sandoz Inc., Pfizer, Inc., Sosei Co. Ltd., MediGene AG and Yamanouchi, Mayne Pharma, Tecnofarma, Han All Pharmaceutical Co., Ltd. and CollaGenex Pharmaceuticals, Inc.

Our drug delivery systems deliver controlled amounts of drugs in various time frames to address a range of therapeutic and patient needs. Atrigel is our original proprietary sustained release biodegradable polymer drug delivery system. We believe that 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. Our four additional drug delivery systems include: SMP, MCA, BCP and BEMA.

Our Eligard 7.5-mg one-month, Eligard 22.5-mg three-month, and Eligard 30 -mg four-month prostate cancer treatment products are currently marketed in the United States. Our Eligard 7.5-mg one-month and Eligard 22.5-mg three-month products are currently marketed in Canada and our Eligard 30-mg four-month product was approved in February 2004 in Canada. Our marketing partner, MediGene, received marketing authorization in Germany for our Eligard 7.5-mg one-month and Eligard 22.5-mg three-month products in December 2003 and January 2004, respectively. Additionally, our marketing partner, Mayne Pharma, received marketing authorization in Australia for our Eligard one-month, three-month and four-month products in December 2003. Our four dental products are currently marketed worldwide.

We earn revenue and generate cash primarily from three sources. The first is from sales and royalties on our marketed products. Our most significant product line at this time is our Eligard line of products. We receive weekly sales reports from Sanofi-Synthelabo, Inc. for sales in the United States which allows us to monitor expected royalty revenue in a timely manner. The second source of revenue and cash is from contract research and development. Contract research and development revenue represents revenue we earn from unaffiliated third parties for performing contract research and development activities using our various patented drug delivery technologies. The third source of revenue and cash is from licensing, marketing rights and milestone revenue. Cash is also generated from non-revenue sources, including equity issuances and interest from investments.

Table of Contents

We believe that achievement of our short-term and long-term goals are dependent upon our ability to expand sales and royalties on the Eligard product line, control costs incurred for internally funded research and development projects, gain approval in the United States and abroad for the drug delivery products in our pipeline and to develop new drug delivery technologies in the future.

Critical Accounting Policies

Our established accounting policies are outlined in Note 1 in our Notes to the Consolidated Financial Statements entitled *Organization and Summary of Significant Accounting Policies*. As part of its oversight responsibilities, our management continually evaluates the propriety of our accounting methods as new events occur. We have chosen to highlight certain policies that we consider critical to the operations of the business and understanding of our consolidated financial statements.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of Atrix Laboratories, Inc. and our wholly owned subsidiaries Atrix Laboratories, GmbH and Atrix Laboratories, Ltd. All significant intercompany transactions and balances have been eliminated. While we initially owned 80.1% of the outstanding common stock of our joint venture subsidiary, Transmucosal Technologies Ltd., Elan and its subsidiaries retained significant minority investor rights that were 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 were considered *participating rights* included 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, prior to termination of our joint venture with Elan in September 2003, we accounted for our investment in Transmucosal Technologies under the equity method of accounting. Because we obtained control of Transmucosal Technologies in September 2003, Transmucosal Technologies has been consolidated with our consolidated financial statements since that date. See Note 5 for further information related to the joint venture termination.

Revenue Recognition

We recognize revenue on product sales and contract manufacturing at the time of shipment, which is when title to the product transfers and the customer bears risk of loss. Royalty revenue is recorded when product is shipped by licensees based on information provided by the licensee and royalty rates and formulas as specified in agreements with licensees. Generally, royalties are based on estimated net sales (gross sales less discounts, allowances and other items) of a product based on information supplied to us by the licensee and may require future revisions.

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. Payments received in advance of revenue recognition 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 these contracts are made monthly. Revenue is typically recognized through the date the contract research is expected to be completed. The estimated completion date may change based on the progress of the research done. If the project takes longer to complete than originally estimated, the remaining unrecognized revenue will be recognized over a longer period of time. Such arrangements are regularly evaluated on an individual basis.

We have licensing agreements that generally provide for non-refundable license fees and/or milestone payments. The licensing agreements typically require a non-refundable license fee and allow our partners

Table of Contents

to sell our proprietary products in a defined territory for a defined period. Non-refundable license fees are initially reported as deferred revenue and recognized as licensing revenue over the remaining contractual term or as covered by patent protection, whichever is earlier, using the straight-line method or until the agreement is terminated. A milestone payment is a payment made by a partner to us upon the achievement of a pre-determined event, as defined in the applicable agreement. Milestone payments are initially reported as deferred revenue and are subsequently recognized using the straight-line method over the remaining contractual term or the remaining period covered by patent protection, whichever is earlier. No milestone revenue is recognized until we have completed the required milestone-related services.

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 research on our behalf. Additionally, license 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 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 us:

	For the Years Ended December 31,				
	2003	% Change	2002	% Change	2001
(In thousands, except percentages)					
Research and Development Funded, in whole or in part by our collaborators	\$ 29,685	58.6%	\$ 18,721	76.2%	\$ 10,626
Funded 100% by Atrix	6,593	(53.0)%	14,018	(6.6)%	15,009
Total	\$ 36,278	10.8%	\$ 32,739	27.7%	\$ 25,635

Our net expense, research and development expenses less contract research and development revenue, was \$14.3 million in 2003, \$18.6 million in 2002 and \$20.4 million in 2001.

Inventory Reserves

We record inventory reserves based on estimated amounts of inventory that may become obsolete. We increased our inventory reserves by \$1.3 million for the year ended December 31, 2003 as a result of our evaluation of obsolete or potential unmarketable inventory. We manufactured launch quantities of a generic dermatology product during the fourth quarter of 2002 and first quarter of 2003 prior to receiving FDA approval. In 2003, we recorded a reserve allowance for this inventory of approximately \$1.0 million in response to a non-approval letter received from the FDA. We believe we followed the guidelines provided by the FDA in the submission, and we are currently appealing the non-approval.

Stock-Based Compensation

As permitted under Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock-Based Compensation*, we account for stock-based compensation using the intrinsic value method in accordance with Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* and related interpretations. Accordingly, no compensation expense has been recognized for fixed stock option grants to employees with an exercise price equal to market value at the date of grant. We account for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123 and related interpretations. In accordance with the disclosure provisions of SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure, an Amendment of SFAS No. 123*, the following table illustrates the effect on net loss applicable to common stock and basic

Table of Contents

and diluted loss per common stock if we had applied the fair value based method of SFAS No. 123 to stock-based compensation:

	For the Years Ended December 31,		
	2003	2002	2001
	(In thousands, except per share data)		
Net loss applicable to common stock, as reported	\$ (2,895)	\$ (19,114)	\$ (26,704)
Add: Stock-based compensation expense included in reported net loss, net of related tax effects	22	1,257	2,117
Deduct: Total stock-based compensation expense determined under fair-value based method, net of related tax effects	(10,241)	(11,397)	(9,485)
Pro forma net loss applicable to common stock	<u>\$ (13,114)</u>	<u>\$ (29,254)</u>	<u>\$ (34,072)</u>
Basic and diluted net loss per share:			
As reported	\$ (0.14)	\$ (0.95)	\$ (1.63)
Pro forma	\$ (0.65)	\$ (1.46)	\$ (2.08)

Results of Operations*Years Ended December 31, 2003 and 2002**Revenue*

	For the Years Ended December 31,				
	2003		2002		% Change
\$	% of Total Revenue	\$	% of Total Revenue		
	(In thousands, except percentages)				
<i>Revenue</i>					
Net sales and royalties					
Eligard products	14,127	28.5%	2,079	7.9%	579.5%
Dental products	4,225	8.5%	2,631	10.0%	60.6%
Generic dermatology products	314	0.6%			
Contract manufacturing	4		848	3.2%	(99.5)%
Other	120	0.3%	191	0.7%	(37.2)%
Total net sales and royalties	<u>18,790</u>	<u>37.9%</u>	<u>5,749</u>	<u>21.8%</u>	<u>226.8%</u>
Contract research and development revenue	22,135	44.7%	14,170	53.7%	56.2%
Licensing, marketing rights and milestone revenue	8,622	17.4%	6,465	24.5%	33.3%
Total revenue	<u>49,547</u>	<u>100.0%</u>	<u>26,384</u>	<u>100.0%</u>	<u>87.8%</u>

Total revenue for the year ended December 31, 2003 was \$49.5 million compared to \$26.4 million for the year ended December 31, 2002, representing an 88% increase.

Edgar Filing: ATRIX LABORATORIES INC - Form 10-K

Net sales and royalties consist principally of sales and royalties from our Eligard products, Atridox product and Doxirobe product. Net sales and royalties were \$18.8 million for the year ended December 31, 2003 compared to \$5.7 million for the year ended December 31, 2002, representing a 227% increase. This increase is primarily related to the \$12.0 million increase in sales and royalties of our Eligard products, a \$1.6 million increase in domestic and European sales of our dental products and a \$0.3 million increase in sales of generic dermatology products. This increase was offset by a \$0.9 million decrease in other product sales, including contract manufacturing. We expect net sales and royalty revenues to increase in 2004 attributable to a full year of product sales of our Eligard 30-mg four-month product launched in March 2003 and as our Eligard product line gains anticipated market acceptance.

Table of Contents

Contract research and development revenue represents revenue we earned from unaffiliated third parties (and from our now-terminated joint venture with Elan) for performing contract research and development activities using our various patented drug delivery technologies. Contract research and development was \$22.1 million for the year ended December 31, 2003 compared to \$14.2 million for the year ended December 31, 2002, representing a 56% increase. This increase is primarily related to a \$7.4 million increase in revenue from Fujisawa Healthcare, Inc. for partial funding of Phase III clinical research costs for our Atrisone acne product, a \$1.5 million increase in revenue from Sanofi-Synthelabo Inc. for funding of the Eligard 45-mg six-month formulation and a \$0.9 million increase in revenue from our international partners for funding various Eligard formulations. These increases were offset by a \$1.1 million decrease in revenue recognized in conjunction with our joint venture and a \$0.6 million decrease in revenue from research activities funded by other parties. We cannot be certain whether contract research and development revenue from our partner-funded research and development expenses will increase or decrease for the foreseeable future as the timing of such expenses being incurred may vary. Accordingly, the amount and timing of revenue recognition may vary depending on the terms of the corresponding agreements.

Licensing, marketing rights and milestone revenue consists principally of revenue earned on our Eligard products, our dental products, and the Atrisone topical dermatological product for the rights extended to our partners to sell our proprietary products in a defined territory for a defined period or for the achievement of a pre-determined milestone as defined in the applicable agreement. Licensing, marketing rights and milestone revenue for the year ended December 31, 2003 was \$8.6 million compared to \$6.5 million for the year ended December 31, 2002, representing a 32% increase. This increase is primarily related to the recognition of \$1.5 million in additional milestone revenue for our Eligard products under the agreement with Sanofi-Synthelabo Inc., the recognition of \$0.5 million as a result of the termination of our licensing agreement with EmerGen, Inc. and the recognition of \$0.2 million of additional revenue for our Eligard products under various international partner agreements. We expect licensing, marketing rights and milestone revenue to increase in 2004 as a result of a full year of revenue recognition from license fee and milestone payments received from our marketing partners in 2003, including a \$6.0 million milestone payment we received from Sanofi-Synthelabo Inc. in April 2003 for the first commercial sale of our Eligard 30-mg four-month product and recognition of revenue for payments that we may receive from our current or future partners in 2004.

Operating Expense

	For the Years Ended December 31,				
	2003		2002		% Change
	\$	% of Total Revenue	\$	% of Total Revenue	
(In thousands, except percentages)					
<i>Operating Expense</i>					
Cost of sales	7,666	15.5%	3,251	12.3%	135.8%
Research and development	36,278	73.2%	32,739	124.1%	10.8%
Research and development license fees	150	0.3%			
Administrative and marketing	10,420	21.0%	9,847	37.3%	5.8%
Administrative stock compensation	22	0.1%	1,257	4.8%	(98.2)%
Total	54,536	110.1%	47,094	178.5%	15.8%

Cost of sales consists principally of costs associated with the manufacture, packaging, storage, shipping, stability, and other product-related fees for the Eligard products, the Atridox product and the Doxirobe product. Cost of sales for the year ended December 31, 2003 was \$7.7 million compared to \$3.3 million for the year ended December 31, 2002, representing a 133% increase. The increase primarily relates to the costs associated with sales of our Eligard 7.5-mg one-month, Eligard 22.5-mg three-month

Table of Contents

and Eligard 30-mg four-month products and domestic and European sales of Atridox. We expect that cost of sales will increase in line with our expected net sales revenue growth for 2004.

Research and development expenses consist principally of funds paid for services and materials during development, manufacturing and formulation enhancements, clinical trials, statistical analysis, report writing and regulatory compliance costs for both partner-funded and internally-funded projects. Research and development expense, excluding research and development-license fees, for the year ended December 31, 2003 was \$36.3 million compared to \$32.7 million for the year ended December 31, 2002, representing an 11% increase. An increase of \$8.0 million was related to Phase III clinical trials for our Atrisone acne product and an increase of \$1.9 million was related to the development of our generic dermatology products. These increases were offset by a decrease in research and development expenses of \$1.6 million for Eligard development, \$1.3 million for other externally funded projects and \$3.4 million for internal project research. We cannot be certain whether our partner-funded research and development expenses will increase or decrease for the foreseeable future as the timing of such expenses being incurred may vary depending on the terms of the corresponding agreements. However, we expect that research and development expenses for internally funded activities will increase in 2004 due to completion of Phase III clinical studies for our funded Atrisone acne product and Phase III clinical studies for our funded Eligard 45-mg six-month product in 2004.

Research and development license fees for the year ended December 31, 2003 was \$0.2 million, which represents a license fee paid by us for an undisclosed dermatology product. This fee was expensed as incurred, as the technology licensed was for research and development purposes with no future alternative use. 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 consist principally of personnel salaries and benefits, direct marketing costs, business development and corporate relations costs, professional, legal and consulting fees, insurance and general office expenses. Administrative and marketing expense, excluding stock compensation, for the year ended December 31, 2003 was \$10.4 million compared to \$9.8 million for the year ended December 31, 2002, representing a 6% increase. The increase is primarily related to increased European sales and marketing efforts for Atridox of \$1.6 million offset by decreases in general administrative support of \$1.0 million, including personnel, public relations and legal costs.

Administrative-stock compensation for the year ended December 31, 2003 was \$22,000 compared to \$1.3 million for the year ended December 31, 2002. A charge of \$1.3 million for the year ended December 31, 2002 was recognized in connection with the retirement of an executive officer. We may, in the future, incur additional costs for stock compensation and performance-based compensation activities; however, we cannot predict if or when that may happen or what the cost may be.

Other Income (Expense)

	For the Years Ended December 31,		
	2003	2002	% Change
	(In thousands)		
<i>Other Income (Expense)</i>			
Equity in loss of joint venture	\$ (83)	\$ (972)	(91.5)%
Investment income	2,877	4,795	(40.0)%
Gain (loss) on sale and write-down of marketable securities	567	(1,071)	152.9%
Debt conversion expense		(125)	
Other, net	(88)	(85)	4%
Total	\$3,273	\$ 2,542	28.8%

We recognized a loss of \$0.1 million for the year ended December 31, 2003 compared to a loss of \$1.0 million for the year ended December 31, 2002 for our 80.1% equity share in the loss of Transmucosal

Table of Contents

Technologies our joint venture with Elan. In September 2003, we terminated our joint venture with Elan and, therefore, will not recognize any future equity loss charges for Transmucosal Technologies.

Investment income for the year ended December 31, 2003 was \$2.9 million compared to \$4.8 million for the year ended December 31, 2002, representing a 40% decrease. The decrease was primarily the result of a decrease in our average cash, cash equivalents and available-for-sale marketable securities balances. Additionally, interest rates on investments for the year ended December 31, 2003 were lower compared to the year ended December 31, 2002. In 2003, the average rate earned on our portfolio was 3.0% compared to 3.4% in 2002. We expect investment income to increase in 2004 as a result of a projected increase in balances of cash and cash equivalents and marketable securities as compared to 2003 balances.

Gain on sale of marketable securities for the year ended December 31, 2003 was \$0.6 million compared to a loss and write-down of marketable securities of \$1.1 million for the year ended December 31, 2002. The gain on sale of marketable securities for the year ended December 31, 2003 was primarily due to the sale of certain government securities, corporate notes, and corporate equities. The loss and write-down of marketable securities during the year ended December 31, 2002 was due to the sale of our \$0.8 million principal amount of WorldCom, Inc. Senior Corporate Notes in May 2002 for proceeds of \$0.4 million, which resulted in a loss on sale of marketable securities of \$0.4 million. In June 2002, we incurred a \$0.7 million charge for a write-down of our remaining position in WorldCom Senior Corporate Notes, principal value of \$0.8 million, upon WorldCom's bankruptcy filing in July 2002. We cannot be certain whether we will incur gains or losses on the sale of marketable securities or recognize charges for write-downs in the future. At December 31, 2003, we had a net unrealized gain of \$0.5 million in our investment portfolio consisting of \$1.2 million in aggregate unrealized gains offset by \$0.7 million in aggregate unrealized losses.

We recognized \$1.0 million for accretion of dividends on our Series A Convertible Preferred Stock and \$0.2 million for a beneficial conversion feature charge in July 2003 on the shares of such preferred stock for the year ended December 31, 2003 compared to \$0.9 million accretion of dividends for the year ended December 31, 2002. We expect that the charge for accretion of dividends on the Series A Preferred Stock will increase in the future as the amount of the preferred stock increases as a result of issuing preferred stock for accretion of dividends. Additionally, we may incur future beneficial conversion feature charges. These charges are contingent on whether our common share market price exceeds the \$18.00 conversion price of the Series A Convertible Preferred Stock on the dates we are obligated to issue such shares for the accretion of dividends.

Net Loss

For the reasons described above, we recorded a consolidated net loss applicable to common stock of \$2.9 million, or \$0.14 per share, for the year ended December 31, 2003 compared to a consolidated net loss applicable to common stock of \$19.1 million, or \$0.95 per share, for the year ended December 31, 2002.

Table of Contents*Years Ended December 31, 2002 and 2001**Revenue*

	For the Years Ended December 31,				
	2002		2001		% Change
	\$	% of Total Revenue	\$	% of Total Revenue	
(In thousands, except percentages)					
<i>Revenue</i>					
Net sales and royalties					
Eligard products	2,079	7.9%			
Dental products	2,631	10.0%	2,436	15.4%	8.0%
Contract manufacturing	848	3.2%	1,092	6.9%	(22.3)%
Other	191	0.7%	290	1.8%	(34.1)%
Total net sales and royalty revenue	5,749	21.8%	3,818	24.1%	50.6%
Contract research and development revenue	14,170	53.7%	8,178	51.7%	73.3%
Licensing, marketing rights and milestone revenue	6,465	24.5%	3,815	24.2%	69.5%
Total revenue	26,384	100.0%	15,811	100.0%	66.9%

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

Net sales and royalties were \$5.7 million for the year ended December 31, 2002 compared to \$3.8 million for the year ended December 31, 2001, representing a 50% increase. The increase of \$1.9 million was primarily related to net sales and royalties from our marketing partner Sanofi-Synthelabo on our Eligard 7.5-mg one-month and Eligard 22.5-mg three-month products launched in May 2002 and September 2002, respectively. Eligard product sales and royalties were \$2.1 million in 2002.

Contract research and development revenue was \$14.2 million for the year ended December 31, 2002 compared to \$8.2 million for the year ended December 31, 2001, representing a 73% increase. This increase is primarily related to the increase of \$3.4 million in revenue from Fujisawa for partial funding of Atrisine research costs, \$2.5 million for funding of an Eligard 45-mg six-month product by Sanofi-Synthelabo, \$2.9 million increase in revenue from Sandoz for efforts under the generic dermatology program, and \$0.1 million increase in revenue from research activities funded by other parties. These increases were offset by a \$2.9 million decrease in revenue recognized in conjunction with our joint venture as a result of the completion of feasibility work performed by us.

Licensing, marketing rights and milestone revenue for the year ended December 31, 2002 was \$6.5 million compared to \$3.8 million for the year ended December 31, 2001, representing a 71% increase. This increase is primarily related to the recognition of \$1.1 million in additional revenue for the net effects of our 2001 amendment to our agreement with Block and the subsequent agreement with CollaGenex, the recognition of \$1.4 million in additional license fee and milestone revenue for our Eligard products under the Sanofi-Synthelabo, MediGene and other Eligard marketing agreements, and the recognition of \$0.1 million additional milestone revenue for our Atrisine product under the Fujisawa agreement.

Table of Contents*Operating Expense*

	For the Years Ended December 31,				
	2002		2001		% Change
	\$	% of Total Revenue	\$	% of Total Revenue	
(In thousands, except percentages)					
<i>Operating Expense</i>					
Cost of sales	3,251	12.3%	1,693	10.7%	92.0%
Research and development	32,739	124.1%	25,635	162.1%	27.7%
Research and development license fees			2,985	18.9%	
Administrative and marketing	9,847	37.3%	5,450	34.5%	80.7%
Administrative stock compensation	1,257	4.8%	2,117	13.4%	(40.6)%
Total	47,094	178.5%	37,880	239.6%	24.3%

Cost of sales was \$3.3 million for the year ended December 31, 2002 compared to \$1.7 million for the year ended December 31, 2001, representing a 94% increase. The increase in cost of sales primarily relates to the increase in product sales as a result of our Eligard 7.5-mg one-month and Eligard 22.5-mg three-month products.

Research and development expenses, excluding research and development-license fees, for the year ended December 31, 2002 were \$32.7 million compared to \$25.6 million for the year ended December 31, 2001, representing a 28% increase. An increase of \$4.4 million was related to progress in the development of our generic dermatology products under the Sandoz agreement. An increase of \$1.9 million was related to progress in the development of our Atrisine acne product under the Fujisawa agreement. GHRP-1 research and development activities increased \$1.5 million for 2002. Increases of \$1.3 million, \$1.1 million and \$0.8 million were related to research activities for our sumatriptan, octreotide, and various partner-funded projects, respectively. Additionally, an increase of \$1.1 million was directed to development activities to identify potential pipeline projects using our Atrigel and BEMA technologies. These increases were offset by a decrease of \$2.6 million as a result of the completion of clinical studies on our Eligard one-, three- and four-month products and to a decrease in research and development of \$1.6 million on joint venture activities. Further, dental product and other research and development activities decreased \$0.8 million.

Research and development license fees for the year ended December 31, 2002 was \$0 compared to \$3.0 million for the year ended December 31, 2001, which represents license fees paid by us of \$2.5 million to Tulane University for GHRP-1 and \$0.5 million to Amarillo BioSciences for rights to an oral low-dose interferon product. These fees were expensed as incurred, as the technology licensed was for research and development purposes with no future alternative uses.

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

Administrative stock compensation for the year ended December 31, 2002 was \$1.3 million compared to \$2.1 million for the year ended December 31, 2001, representing a 38% decrease. A charge of \$1.3 million for the year ended December 31, 2002 was recognized in connection with the retirement of an executive officer. For the year ended December 30, 2001, we granted a \$2.0 million non-qualified stock option grant to our Chief Executive Officer. The options were fully vested on the date of the grant and expire on August 6, 2011.

Table of Contents*Other Income (Expense)*

	?For the Years Ended December 31,		
	2002	2001	% Change
	(In thousands)		
<i>Other Income (Expense)</i>			
Equity in loss of joint venture	\$ (972)	\$ (3,285)	(70.4)%
Investment income	4,795	3,965	20.9%
Loss on sale and write-down of marketable securities	(1,071)	(831)	28.9%
Debt conversion expense	(125)	(2,194)	(94.3)%
Interest expense	(79)	(780)	(89.9)%
Other, net	(6)	(339)	(98.2)%
Total	\$ 2,542	\$ (3,464)	

We recognized a loss of \$1.0 million for our 80.1% equity share in the loss of Transmucosal Technologies, our now-terminated joint venture with Elan, for the year ended December 31, 2002 compared to a loss of \$3.3 million for the year ended December 31, 2001, representing a 70% decrease. The decrease was primarily related to the completion of feasibility work performed through the joint venture.

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

Loss on sale and write-down of marketable securities for the year ended December 31, 2002 was \$1.1 million compared to \$0.8 million for the year ended December 31, 2001. This increase was primarily due to the sale of our \$0.8 million principal amount of WorldCom, Inc. Senior Corporate Notes in May 2002 for proceeds of \$0.4 million, which resulted in a loss on sale of marketable securities of \$0.4 million. In June 2002, we incurred a \$0.7 million charge for a write-down of our remaining position in WorldCom Senior Corporate Notes, principal value of \$0.8 million, upon WorldCom's bankruptcy filing. The market value of our WorldCom Senior Notes as of December 31, 2002 was \$0.2 million. For the year ended December 31, 2001, we recorded an impairment charge of \$0.8 million on our \$1.0 million Enron corporate notes, upon Enron's bankruptcy filing. The market value of our Enron notes as of December 31, 2002 was \$0.1 million. At December 31, 2002, we had a net unrealized gain of \$1.5 million in our investment portfolio consisting of \$1.7 million in aggregate unrealized gains offset by \$0.2 million in aggregate unrealized losses.

Interest expense for the year ended December 31, 2002 was \$0.1 million compared to \$0.8 million for the year ended December 31, 2001. This decrease was due to the exchange of 279,931 shares of our common stock for \$5.2 million in principal amount of our 7% Convertible Subordinated Notes since the period ended December 31, 2001.

During the year ended December 31, 2002, we exchanged 279,931 shares of our common stock to extinguish \$5.2 million in outstanding principal amount of our 7% Convertible Subordinated Notes. Of the 279,931 shares of our common stock issued, 274,014 shares were valued at the conversion price of \$19.00 per share and the remaining 5,917 shares were valued at \$21.09 per share, the closing market price of our common stock on the date of exchange. As a result of the conversions, we recognized a gain of \$30,000, for the write-off of \$80,000 of pro rata deferred finance charges net of \$110,000 interest expense payable eliminated as a result of these exchanges. Debt conversion expense of approximately \$125,000 was recognized for the year ended December 31, 2002 related to the additional 5,917 shares valued at \$21.09 per share. As of December 31, 2002 and December 31, 2001, the outstanding principal amount of the

Table of Contents

7% Convertible Subordinated Notes was \$0 and \$5.2 million, respectively. In comparison, during the year ended December 31, 2001, we exchanged 1,725,735 shares of our common stock for \$31.0 million of our 7% Convertible Subordinated Notes. As a result of these exchanges, we recognized a \$0.3 million loss on extinguishment of debt and non-cash charges for debt conversion expense of \$2.2 million in 2001.

We recognized \$0.9 million for accretion of dividends on the Series A Preferred Stock for the year ended December 31, 2002 compared to \$0.9 million for accretion of dividends for the year ended December 31, 2001. Additionally, a beneficial conversion charge of \$0.3 million for the year ended December 31, 2001 was recognized as a result of our common stock price being in excess of the preferred stock conversion price of \$19.00 at the time the preferred shares were issued in 2001.

Net Loss

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

Liquidity and Capital Resources

	At December 31,		
	2003		2002
	\$	% Change	\$
	(In thousands)		
Cash and cash equivalents	\$ 19,074	(38.4)%	\$ 30,698
Marketable securities available-for-sale	\$ 80,688	(1.3)%	\$ 81,767

Sources and Use of Cash

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 product sales and royalties. We anticipate future funding of our operations to be achieved through continued license fees, milestone payments and net sales and royalties of our products. At December 31, 2003, we had \$19.1 million of cash and cash equivalent investments and \$80.7 million of marketable securities available-for-sale (at fair value) to fund future operations and capital requirements. Our available-for-sale marketable securities include primarily U.S. government bonds, diversified bond mutual funds and investment grade corporate obligations. We believe the quality of the notes we hold and the diversity of our portfolio mitigates our credit and market risks; however, from time to time we have experienced investment losses as some of the issuers of our investment grade corporate notes have declared bankruptcy.

We filed a shelf registration statement with the Securities and Exchange Commission in January 2004 which will permit us to offer and sell up to \$150 million of our common stock, preferred stock or debt securities. While we believe that we have adequate liquidity and capital resources to fund our operations and capital requirements for the foreseeable future, we may have to raise additional funds to complete the development of our technologies as discussed below. In the normal course of business, we may investigate, evaluate, and discuss acquisitions, joint ventures, strategic alliance relationships and other business combination opportunities. In the event of any future acquisition or joint venture opportunities, we may consider using then-available cash or cash equivalents or issuing equity or other securities.

As of December 31, 2003, we had cash and cash equivalents of \$19.1 million, marketable securities (at fair value) of \$80.7 million, net accounts receivable of \$10.2 million, inventories of \$11.5 million and other current assets of \$3.3 million, for total current assets of \$124.8 million. We had accounts payable of \$2.5 million, short-term deferred revenue of \$9.9 million and other current liabilities of \$1.7 million, for total current liabilities of \$14.1 million, which resulted in working capital of \$110.7 million.

Table of Contents

We have a revolving line of credit with a bank that expires in May 2004. Under the terms of the line of credit, we may borrow up to \$1.0 million. Borrowings under the line of credit bear interest at the prime rate and are subject to financial covenants requiring us to maintain certain levels of net worth and liquidity. Additionally, in July 2003, we renewed a second \$1.0 million line of credit with another bank. The second line of credit expires in June 2004. Borrowings under the second line of credit bear interest at the prime rate plus 1/2%. As of December 31, 2003, there was no obligation outstanding under either of these lines of credit.

Investment Policy

We have a cash and investments policy which establishes guidelines for the management of our cash and investments. The objective of the policy is to invest funds in a manner that assures maximum safety and liquidity first, and secondly, maximizes yield within such constraints. Investments will typically be limited to government securities, government-backed securities, investment grade commercial debt instruments, certificates of deposit or other similar instruments.

	Years Ended December 31,				
	2003		2002		2001
	\$	% Change	\$	% Change	\$
	(In thousands)				
Net cash provided by (used in) operating activities	\$ (13,368)	84.7%	\$ (7,236)		\$ 669
Net cash used in investing activities	\$ (8,593)	24.6%	\$ (6,895)	(89.3)%	\$ (64,672)
Net cash provided by (used in) financing activities	\$ 8,867		\$ (5,971)		\$ 109,689

Cash Used in Operating Activities

During the year ended December 31, 2003, net cash used in operating activities was \$13.4 million. This was primarily the result of the net loss for the year ended December 31, 2003 of \$1.7 million, adjusted for certain non-cash income and expenses, and changes in operating assets and liabilities as set forth in the consolidated statements of cash flows. We recognized a cash inflow from the receipt of milestone payments, license fees and certain contract research and development payments of \$7.0 million, offset by amortization of deferred revenue of \$9.7 million. Other significant uses of cash included: \$4.5 million due to an increase in accounts receivable primarily related to Eligard product sales and royalty accruals, \$4.0 million due to increasing inventory levels primarily related to the production of our Eligard products and inventory buildup related to our generic dermatology products and \$6.1 million decrease in accounts payable primarily related to payments for inventory raw materials and components and plant expansion costs since December 31, 2002.

Cash Flows From Investing Activities

We used net cash in investing activities of \$8.6 million during the year ended December 31, 2003. Cash used to fund investing activities included \$7.9 million for capital expenditures primarily related to our plant expansion as discussed further under Future Capital Requirements below. Other uses of cash totaled \$0.9 million for various investing activities. Net marketable securities activity resulted in a cash inflow of \$0.2 million as a result of the maturity and sale of marketable securities of \$38.5 million offset by \$38.3 million to fund the purchases of various marketable securities. During the year ended December 31, 2003, various marketable securities were sold, matured or were called and the majority of proceeds were subsequently reinvested in high rated corporate notes, U.S. government securities, and diversified bond mutual funds.

Table of Contents***Cash Flows From Financing Activities***

Net cash provided by financing activities was \$8.9 million during the year ended December 31, 2003. This was primarily the result of proceeds from issuance of equity securities of \$11.8 million in conjunction with the exercise of incentive stock options. This was offset by the repurchase of \$2.9 million of our common stock in the open market. In November 2002, our Board of Directors amended our stock repurchase program to provide that we may acquire up to a maximum of \$20.0 million of our common stock in the open market or in privately negotiated transactions under this program. Since the inception of the program, we repurchased a total of 866,800 shares of our common stock in the open market for \$13.6 million, or an average price per share of \$15.71. For the year ended December 31, 2003, we repurchased 209,100 shares of our common stock in the open market for \$2.9 million, or an average price per share of \$13.75 under the program. Our stock repurchase program terminated on December 31, 2003. The following table presents our stock repurchases in 2003. All repurchases in 2003 were made under the program discussed above.

Broker-Dealer	Number of Shares Purchased	Average Price Paid per Share
Stifel, Nicolaus & Company	201,600	\$ 13.80
CIBC Oppenheimer	7,500	\$ 12.47
	<hr/>	
Total for 2003	209,100	\$ 13.75
	<hr/>	

At December 31, 2003 we had available for federal income tax purposes, net operating loss carry-forwards of \$108.5 million and \$4.1 million in research and development tax credits, which expire through 2023. Our ability to utilize our net operating loss acquired with the acquisition of ViroTex Corporation, alternative minimum tax, and research and development credit carry-forwards is subject to an annual limitation in future periods. This limitation is pursuant to the change in ownership rules under Section 382 of the Internal Revenue Code of 1986, as amended.

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

Future Capital Requirements

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

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

We expect to continue to incur substantial expenditures for research and development, testing, regulatory compliance, possible repurchases of our common stock and for hiring additional management, scientific, manufacturing and administrative personnel. We will also continue to expend a significant amount of funds for our ongoing clinical studies. Depending on the results of our research and development activities, we may determine to accelerate or expand our efforts in one or more proposed areas and may, therefore, require additional funds earlier than

previously anticipated. We believe our existing cash and cash equivalent assets, in addition to our marketable securities will be sufficient to fund

Table of Contents

our operations for the foreseeable future. However, our underlying assumed levels of revenue and expense may not prove to be accurate.

Research and 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 solely by us, for the years ended December 31, 2003, 2002 and 2001 including research and development costs inception-to-date and estimated completion dates and costs (in thousands):

Technology	Expenses 2001	Expenses 2002	Expenses 2003	Expenses Inception- to-Date	Total Funded Expenses- Inception- to-Date	Anticipated Completion (to market)	Anticipated Costs to Completion (to market)
Atrigel	\$ 13,727	\$ 13,011	\$ 9,847	\$ 120,368	\$ 15,087	2004 - 2009	\$ 35,000
SMP	4,604	6,547	14,580	31,148	17,004	2005	9,000
Other	7,304	13,181	11,851	51,211	16,151	2004 - 2007	64,000
	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>		<u> </u>
Total	\$ 25,635	\$ 32,739	\$ 36,278	\$ 202,727	\$ 48,242		\$ 108,000
	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>		<u> </u>
Funded, in whole or in part by our collaborators	\$ 10,626	\$ 18,721	\$ 29,685				
Funded 100% by Atrix	15,009	14,018	6,593				
	<u> </u>	<u> </u>	<u> </u>				
Total	\$ 25,635	\$ 32,739	\$ 36,278				
	<u> </u>	<u> </u>	<u> </u>				

The predominate product lines included under the Atrigel technology are the Eligard products and the dental products which comprised 32% and 56%, respectively, of the expenses from inception-to-date. Recently, the Eligard products comprised more of the research and development effort with 64%, 59% and 62% of the 2001, 2002 and 2003 Atrigel expenses, respectively. As our dental products have moved into the market, research and development expenses have stabilized and comprised 10%, 7% and 3% of the 2001, 2002 and 2003 Atrigel expenses, respectively. Of the expenses funded by third parties, 11% of funds received were to support the dental products, 59% of funds were to support the Eligard products, and 30% of funds was from direct support of research contracts with various companies.

The Atrisone acne product represents 100% of expenses and funding under the SMP technology. Other research and development expenses from inception-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 represent 39% of expenses inception-to-date and 54% of the funding.

Series A Preferred Stock

On September 10, 2003 we entered into a termination agreement with Elan for the termination of our joint venture, Transmucosal Technologies, Ltd. In connection with the termination, Elan and its affiliates agreed to forego the exchange right included in the Series A Convertible Exchangeable Preferred Stock. As a result, we reclassified the Series A Convertible Exchangeable Preferred Stock to permanent equity in 2003.

Plant Expansion

In April 2002, we announced our plans to expand our manufacturing and laboratory facilities to support current and future projects. The original 26,000 square foot facility was expanded to 58,000 square feet. In the expanded facility, we intend to manufacture the full line of our Eligard products, Atrisone topical dermatological product, generic dermatology products, dental products and clinical supplies for products currently in development. Approximately 40% of the building's expansion is devoted to manufacturing with the remainder allocated for warehousing, quality assurance and laboratory work. Construction began in the second quarter of 2002 and was completed during the second quarter of 2003.

Table of Contents

and validation of the plant and equipment was completed during the third quarter of 2003. Certain areas of the plant require further qualification by the FDA, which is anticipated by the end of 2004. As of December 31, 2003, approximately \$9.6 million has been spent on construction costs and \$3.7 million has been spent on equipment within the expanded facility.

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2003:

Contractual Obligations(1)	Payments Due by Period				Total
	Less than 1 Year	1-3 Years	3-5 Years	More Than 5 Years	
	(In thousands)				
Long-term debt obligations	\$	\$	\$	\$	\$
Capital lease obligations					
Operating lease obligations	502	727	47		1,276
Purchase obligations	16,491	4,825	2,510	50	23,876
Other long-term liabilities reflected on the company's balance sheet under GAAP					

- (1) Currently, we have no long-term debt, capital lease or other long-term liabilities that are subject to future payment. We may enter into such obligations in the future.

Purchase obligations represent commitments for the purchase of research services and studies of \$8.6 million in 2004, marketing programs with certain collaborative partners of \$2.3 million in 2004 and supply agreements and issued purchase orders we have entered into for the supply of raw materials in the years 2004 through 2009 that total \$13.0 million. These research services and studies are for both internally and externally funded research projects. Marketing programs are amounts we have committed to spend in conjunction with our marketing partners in advertising campaigns. The amounts presented for supply agreements represent minimum quantities at fixed prices. Commitments under certain of the agreements are contingent upon regulatory approval of the raw material to be supplied. We believe the minimum quantities in the supply agreements are not in excess of the anticipated demand for the raw material.

Common Stock Repurchases

As of December 31, 2003, our stock repurchase program terminated.

Other Future Capital Requirements

We believe that it is advisable to augment our cash to fund all of our activities, including potential product acquisitions. Therefore, we will consider raising cash whenever market conditions are favorable. Such capital may be raised through additional public or private financing, as well as collaborative relationships, borrowings and other available sources. Additionally, 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.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources that are material.

Table of Contents

Impact of Inflation

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

Recent Accounting Pronouncements

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

In April 2003, the FASB issued SFAS No. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities*. SFAS No. 149 amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts (collectively referred to as derivatives) and for hedging activities. The accounting and reporting requirements is effective for contracts entered into or modified after June 30, 2003 and for hedging relationships designated after June 30, 2003. The adoption of SFAS No. 149 did not have a material impact on our consolidated financial statements.

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* (SFAS 150). SFAS 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It generally requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances), many of which were previously classified as equity. The provisions of SFAS 150 are effective for financial instruments entered into or modified after May 31, 2003 and, with one exception, are effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of SFAS 150 did not have a material effect on our consolidated financial statements.

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

In January 2003, the FASB issued Financial Interpretation No. 46 (FIN 46), *Consolidation of Variable Interest Entities*. FIN 46 provides guidance on how to identify a variable interest entity (VIE) and determine when the assets, liabilities, and results of operations of a VIE need to be included in a company's consolidated financial statements. FIN 46 also requires additional disclosures by primary beneficiaries and other significant variable interest holders in a VIE. The provisions of FIN 46 are effective immediately for all VIEs created or acquired after January 31, 2003. For VIEs created or acquired prior to February 1, 2003, the provisions of FIN 46 must be adopted at the beginning of the first interim or annual

Table of Contents

reporting period beginning after December 15, 2003. We do not have VIES and, as such, the adoption of FIN 46 did not have a material effect on our consolidated financial statements.

In November 2002, the FASB issued Emerging Issues Task Force Issue No. 00-21 (EITF 00-21), *Accounting for Revenue Arrangements with Multiple Deliverables*. EITF 00-21 addresses how to determine whether a revenue arrangement involving multiple deliverables contains more than one unit of accounting for the purposes of revenue recognition and how the revenue arrangement consideration should be measured to the separate units of accounting. EITF 00-21 provides guidance with respect to the effect of certain customer rights due to company nonperformance on the recognition of revenue allocated to delivered units of accounting. EITF 00-21 also addresses the impact on the measurement and/or allocation of arrangement consideration of customer cancellation provisions and consideration that varies as a result of future actions of the customer or us. Finally, EITF 00-21 provides guidance with respect to the recognition of the cost of certain deliverables that are excluded from the revenue accounting arrangement. EITF 00-21 applies to revenue arrangements that we enter into after June 15, 2003.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

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

As of December 31, 2003, our investment in cash, cash equivalents and available-for-sale marketable securities totaled \$99.8 million. These current assets are invested primarily in cash funds, high rated commercial paper, U.S. government and agency investments, U.S. corporate obligations, and bond mutual funds. The bond mutual funds may invest in foreign securities, which may be unfavorably affected by interest-rate and currency-exchange-rate changes as well as by market, economic and political conditions of the countries where investments are made. The funds may invest in mortgage-backed securities, which are subject to unique interest and maturity risks. When interest rates fall, mortgages may be paid early through refinancing, which may shorten the expected maturity of these securities. Alternatively, when interest rates rise, mortgages are not likely to be paid early, which may lengthen the expected maturity of these securities. Therefore, during times of fluctuating interest rates, these factors may cause the value of mortgage-backed securities to increase or decrease more than those of other fixed-income securities.

Interest Rate Risk

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

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

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

Table of Contents

material losses in these investments, however, losses may still occur due to market, political and economic conditions.

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

To perform a sensitivity analysis, we assess the fair values loss risk from the impact of hypothetical interest rate changes on market sensitive instruments. The fair values are computed based on the present 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, 2003. The fair values that result from these computations are compared with the fair values of these financial instruments at December 31, 2003. 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, 2003 are as follows:

Interest Rate Sensitivity: A 0.5% decrease in interest rates, with all other variables held constant would result in an increase in the fair value of our financial instruments by \$0.5 million. A 0.5% increase in 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 long-term debt instruments of \$32.4 million at December 31, 2003, at variable interest rates.

The use of a 0.5% change in interest rate estimate is strictly for estimation and evaluation purposes only. The value of our assets may rise or fall by a greater amount depending on actual general market performances and the value of the individual securities we own.

Exchange Rate Risk

We face foreign exchange rate fluctuations, primarily with respect to the British Pound and the Euro foreign currencies, as the financial results of our foreign subsidiaries are translated into United States dollars for consolidation. As exchange rates vary, these results, when translated may vary from expectations and adversely impact net income (loss) and overall profitability. The effect of foreign exchange rate fluctuation for the year ended December 31, 2003 was not material. Based on our overall foreign currency rate exposure at December 31, 2003, we do not believe that a hypothetical 10% change in foreign currency rates would materially affect our financial position.

Item 8. Financial Statements and Supplementary Data.

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

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

None.

Item 9A. Controls and Procedures.

As of December 31, 2003, we carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Our disclosure controls and procedures are designed with the objective of ensuring that information required to be disclosed in our reports filed under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective in timely alerting them to material information required to be included in our periodic SEC reports. In addition, our

Table of Contents

Chief Executive Officer and our Chief Financial Officer concluded that during the year ended December 31, 2003, there has been no change in our internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. Our internal control over financial reporting is designed with the objective of providing reasonable assurance regarding the reliability of our financial reporting and preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

It should be noted that the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

PART III

Item 10. Directors and Executive Officers of the Registrant.

The information required by this item is incorporated herein by reference to the sections entitled Election of Directors, Audit Committee Report and Section 16(a) Beneficial Ownership Reporting Compliance in our definitive proxy statement for our annual stockholders meeting scheduled to be held on May 2, 2004.

The Board of Directors has adopted a code of business conduct and ethics that applies to all employees and a supplemental code of ethics that applies to our principal executive officer, principal financial officer, and principal accounting officer or controller. A copy of this code of business conduct and ethics and the supplemental code of ethics may be requested, without charge, by writing to the following address:

Atrix Laboratories, Inc.

Attention: Investor Relations
2579 Midpoint Drive
Fort Collins, Colorado 80525

Item 11. Executive Compensation.

The information required by this item is incorporated herein by reference to the section entitled Executive Compensation in our definitive proxy statement for our annual stockholders meeting scheduled to be held on May 2, 2004.

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

The information required by this item is incorporated herein by reference to the sections entitled Security Ownership of Certain Beneficial Owners and Management and Equity Compensation Plan Information in our definitive proxy statement for our annual stockholders meeting scheduled to be held on May 2, 2004.

Item 13. Certain Relationships and Related Transactions.

The information required by this item is incorporated herein by reference to the section entitled Certain Relationships and Related Transactions in our definitive proxy statement for our annual stockholders meeting scheduled to be held on May 2, 2004.

Table of Contents

Item 14. Principal Accountant Fees and Services.

The information required by this item is incorporated by reference to the information set forth under the heading "Audit Fees" in our definitive proxy statement for our Annual Meeting of Stockholders to be held on May 2, 2004.

Table of Contents

PART IV

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

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

1. Consolidated Financial Statements

Independent Auditors' Report

Consolidated Balance Sheets - December 31, 2003 and 2002

Consolidated Statements of Operations

Years Ended December 31, 2003, 2002, and 2001

Consolidated Statements of Changes in Shareholders' Equity

Years Ended December 31, 2003, 2002, and 2001

Consolidated Statements of Cash Flows

Years Ended December 31, 2003, 2002, and 2001

Notes to the Consolidated Financial Statements

2. Consolidated Financial Statement Schedules

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

3. Exhibits

The exhibits are set forth in the Exhibit Index.

(b) Reports on Form 8-K:

We filed or furnished the following Current Reports on Form 8-K during the quarter ended December 31, 2003. The information provided under Item 12. Results of Operations and Financial Condition is not deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934.

Current Report on Form 8-K dated October 30, 2003, furnished to the Securities and Exchange Commission on October 30, 2003, under Item 12. Results of Operations and Financial Condition.

Table of Contents

SIGNATURES

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

ATRIX LABORATORIES, INC.
(Registrant)

Date: March 3, 2004

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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
/s/ David R. Bethune <hr/> David R. Bethune	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)	March 3, 2004
/s/ Gregory A. Gould <hr/> Gregory A. Gould	Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)	March 3, 2004
/s/ Nicolas G. Bazan <hr/> Dr. Nicolas G. Bazan	Director	March 3, 2004
/s/ H. Stuart Campbell <hr/> H. Stuart Campbell	Director	March 3, 2004
/s/ D. Walter Cohen <hr/> Dr. D. Walter Cohen	Director	March 3, 2004
/s/ C. Rodney O Connor <hr/> C. Rodney O Connor	Director	March 3, 2004
/s/ Richard R. Vietor <hr/> Richard R. Vietor	Director	March 3, 2004
/s/ George J. Vuturo <hr/> Dr. George J. Vuturo	Director	March 3, 2004

Table of Contents

INDEX TO THE CONSOLIDATED FINANCIAL STATEMENTS

	Page
INDEPENDENT AUDITORS REPORT	F-2
CONSOLIDATED FINANCIAL STATEMENTS:	
Consolidated Balance Sheets December 31, 2003 and 2002	F-3
Consolidated Statements of Operations Years Ended December 31, 2003, 2002 and 2001	F-4
Consolidated Statements of Changes in Shareholders Equity Years Ended December 31, 2003, 2002 and 2001	F-5
Consolidated Statements of Cash Flows Years Ended December 31, 2003, 2002 and 2001	F-7
Notes to the Consolidated Financial Statements	F-8

Table of Contents

INDEPENDENT AUDITORS REPORT

To the Board of Directors and Shareholders

Atrix Laboratories, Inc. and Subsidiaries
Fort Collins, Colorado

We have audited the accompanying consolidated balance sheets of Atrix Laboratories, Inc. and subsidiaries (the Company) as of December 31, 2003 and 2002, and the related consolidated statements of operations, changes in shareholders' equity and cash flows for each of the three years in the period ended December 31, 2003. 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, 2003 and 2002, and the results of its operations and cash flows for each of the three years in the period ended December 31, 2003 in conformity with accounting principles generally accepted in the United States of America.

DELOITTE & TOUCHE LLP

Denver, Colorado

March 2, 2004

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

	December 31, 2003	December 31, 2002
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 19,074	\$ 30,698
Marketable securities available-for-sale, at fair value	80,688	81,767
Accounts receivable, net of allowance for doubtful accounts of \$1,019 and \$623	10,235	6,140
Interest receivable	834	679
Inventories, net	11,516	8,694
Prepaid expenses and deposits	2,488	2,253
	<hr/>	<hr/>
Total current assets	124,835	130,231
	<hr/>	<hr/>
PROPERTY, PLANT AND EQUIPMENT, NET	21,855	15,431
	<hr/>	<hr/>
OTHER ASSETS:		
Goodwill	379	399
Intangible and other assets, net	2,789	3,964
	<hr/>	<hr/>
Other assets, net	3,168	4,363
	<hr/>	<hr/>
TOTAL ASSETS	\$ 149,858	\$ 150,025
	<hr/>	<hr/>
LIABILITIES AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable trade	\$ 2,488	\$ 7,205
Accrued expenses and other	1,644	1,098
Deferred revenue	9,923	7,889
	<hr/>	<hr/>
Total current liabilities	14,055	16,192
	<hr/>	<hr/>
DEFERRED REVENUE	32,415	37,064
	<hr/>	<hr/>
COMMITMENTS AND CONTINGENCIES (SEE NOTES 4 AND 9)		
SERIES A CONVERTIBLE EXCHANGEABLE PREFERRED STOCK, \$0.001 par value, 20,000 shares authorized; 13,787 shares issued and outstanding at December 31, 2002; liquidation preference \$14,227		
	<hr/>	14,514
	<hr/>	<hr/>
SHAREHOLDERS EQUITY:		
Series A convertible preferred stock, \$0.001 par value, 20,000 shares authorized; 14,770 shares issued and outstanding at December 31, 2003; liquidation preference \$15,240		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized Series A preferred stock, \$0.001 par value,		

Edgar Filing: ATRIX LABORATORIES INC - Form 10-K

200,000 shares authorized, none issued or outstanding		
issued or outstanding		
Common stock, \$0.001 par value; 45,000,000 shares authorized; 21,567,801 and 20,516,069 shares issued; 20,701,001 and 19,858,369 shares outstanding	22	21
Additional paid-in capital	270,157	242,699
Treasury stock, 866,800 and 657,700 shares, at cost	(13,616)	(10,740)
Accumulated other comprehensive income	1,035	1,590
Accumulated deficit	(154,210)	(151,315)
	<u> </u>	<u> </u>
Total shareholders equity	103,388	82,255
	<u> </u>	<u> </u>
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	\$ 149,858	\$ 150,025
	<u> </u>	<u> </u>

See notes to the consolidated financial statements.

F-3

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

	Year Ended December 31, 2003	Year Ended December 31, 2002	Year Ended December 31, 2001
REVENUE:			
Net sales and royalties	\$ 18,790	\$ 5,749	\$ 3,818
Contract research and development revenue	22,135	14,170	8,178
Licensing, marketing rights and milestone revenue	8,622	6,465	3,815
	<u>49,547</u>	<u>26,384</u>	<u>15,811</u>
OPERATING EXPENSE:			
Cost of sales	7,666	3,251	1,693
Research and development	36,278	32,739	25,635
Research and development license fees	150		2,985
Administrative and marketing	10,420	9,847	5,450
Administrative stock compensation	22	1,257	2,117
	<u>54,536</u>	<u>47,094</u>	<u>37,880</u>
LOSS FROM OPERATIONS	<u>(4,989)</u>	<u>(20,710)</u>	<u>(22,069)</u>
OTHER INCOME (EXPENSE):			
Equity in loss of joint venture	(83)	(972)	(3,285)
Investment income	2,877	4,795	3,965
Gain (loss) on sale and write-down of marketable securities	567	(1,071)	(831)
Interest expense		(79)	(780)
Debt conversion expense		(125)	(2,194)
Gain (loss) on extinguished debt		30	(319)
Other	(88)	(36)	(20)
	<u>3,273</u>	<u>2,542</u>	<u>(3,464)</u>
NET LOSS	<u>(1,716)</u>	<u>(18,168)</u>	<u>(25,533)</u>
Accretion of dividends and beneficial conversion feature charge on preferred stock	(1,179)	(946)	(1,171)
	<u>(2,895)</u>	<u>(19,114)</u>	<u>(26,704)</u>
NET LOSS APPLICABLE TO COMMON STOCK	<u>\$ (2,895)</u>	<u>\$ (19,114)</u>	<u>\$ (26,704)</u>
Basic and diluted loss per common share:			
Net loss	\$ (0.08)	\$ (0.90)	\$ (1.56)
Accretion of dividends and beneficial conversion feature charge on preferred stock	(0.06)	(0.05)	(0.07)
	<u>(0.14)</u>	<u>(0.95)</u>	<u>(1.63)</u>
Net loss applicable to common stock	<u>\$ (0.14)</u>	<u>\$ (0.95)</u>	<u>\$ (1.63)</u>
Basic and diluted weighted average common shares outstanding	20,102,329	20,076,999	16,348,365

See notes to the consolidated financial statements.

F-4

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

	Common Stock		Series A Convertible Preferred Stock		Additional Paid-In Capital	Treasury Shares	Treasury Stock	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Shareholders Equity
	Shares	Amount	Shares	Amount						
BALANCE, December 31, 2000	13,341,681	\$ 13		\$	\$ 101,367		\$	\$ (471)	\$ (105,497)	\$ (4,588)
Comprehensive loss:										
Net loss									(25,533)	(25,533)
Accretion of dividend on preferred stock									(1,171)	(1,171)
Other comprehensive income (loss):										
Foreign currency translation adjustments								(29)		(29)
Unrealized gain on investments								496		496
Net comprehensive loss										(26,237)
Issuance of common stock to extinguish debt	1,725,735	2			33,177					33,179
Issuance of common stock to MediGene	233,918				3,780					3,780
Non-qualified stock option compensation					2,117					2,117
Exercise of stock options and issuance of employee stock purchase plan shares	419,692	1			4,181					4,182
Issuance of restricted stock	39,031				565					565
Purchase of treasury stock						77,500	(1,558)			(1,558)
Offering of common stock, net of offering costs of \$6,574	4,099,750	4			87,716					87,720
BALANCE, December 31, 2001	19,859,807	20			232,903	77,500	(1,558)	(4)	(132,201)	99,160
Comprehensive loss:										
Net loss									(18,168)	(18,168)
Accretion of dividend on preferred stock									(946)	(946)
Other comprehensive income (loss):										
Foreign currency translation								102		102

Edgar Filing: ATRIX LABORATORIES INC - Form 10-K

adjustments										
Unrealized gain on investments						1,492				1,492
Net comprehensive loss										(17,520)
Issuance of common stock to extinguish debt	279,931				5,330					5,330
Non-qualified stock option compensation					1,257					1,257
Exercise of stock options and issuance of employee stock purchase plan shares	350,259	1			2,921					2,922
Issuance of non-qualified stock	6,000				37					37
Issuance of restricted stock	20,072				290					290
Purchase of treasury stock						580,200	(9,182)			(9,182)
Stock offering costs					(39)					(39)
BALANCE, December 31, 2002	20,516,069	21			242,699	657,700	(10,740)	1,590	(151,315)	82,255
Comprehensive loss:										
Net loss										(1,716)
Accretion of dividend on preferred stock										(1,179)
Other comprehensive income (loss):										
Foreign currency translation adjustments								207		207
Unrealized loss on investments								(762)		(762)
Net comprehensive loss										(3,450)
Restricted shares issued for stock compensation					22					22
Exercise of stock options and issuance of employee stock purchase plan shares	981,474	1			11,062					11,063
Issuance of non-qualified stock	51,499				450					450
Issuance of restricted stock	5,110				51					51
Purchase of treasury stock						209,100	(2,876)			(2,876)
Exercise of stock warrants	13,649				180					180
Reclassification of Series A Convertible Exchangeable Preferred Stock			14,770		15,693					15,693
BALANCE, December 31, 2003.	21,567,801	\$ 22	14,770	\$	\$270,157	866,800	\$(13,616)	\$ 1,035	\$(154,210)	\$ 103,388

See notes to the consolidated financial statements.

F-5

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

	Year Ended December 31, 2003	Year Ended December 31, 2002	Year Ended December 31, 2001
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	\$ (1,716)	\$ (18,168)	\$ (25,533)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Depreciation and amortization	3,680	3,188	2,480
Amortization of deferred revenue	(9,651)	(9,445)	(4,332)
Provision for inventory write-off	1,260		
Provision for doubtful accounts	653	624	69
Equity in loss of joint venture	83	972	3,285
(Gain) loss on sale and write-down of marketable securities	(567)	1,071	831
Stock compensation	22	1,257	2,117
Debt conversion expense		125	2,194
Interest expense converted to equity		110	345
(Gain) loss on extinguished debt		(30)	319
Other non-cash items	271	71	25
Net changes in operating assets and liabilities:			
Accounts receivable	(4,484)	(2,528)	(994)
Note receivable license fee			8,000
Interest receivable	(155)	316	(523)
Inventories	(3,955)	(5,281)	(1,387)
Prepaid expenses and deposits	(233)	(1,725)	479
Accounts payable	(6,146)	3,676	481
Accrued expenses and other	534	473	(144)
Deferred revenue	7,036	18,058	12,957
Net cash (used in) provided by operating activities	<u>(13,368)</u>	<u>(7,236)</u>	<u>669</u>
CASH FLOWS FROM INVESTING ACTIVITIES:			
Acquisition of property, plant and equipment	(7,861)	(9,589)	(2,069)
Investment in intangible and other assets	(602)	(1,666)	(419)
Proceeds from maturity and sale of marketable securities	38,476	69,119	23,245
Investment in marketable securities	(38,304)	(63,259)	(82,683)
Investment in joint venture	(302)	(1,500)	(2,746)
Net cash used in investing activities	<u>(8,593)</u>	<u>(6,895)</u>	<u>(64,672)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of equity securities, net of issuance costs	11,743	3,211	96,247
Payments to acquire treasury stock	(2,876)	(9,182)	(1,558)
Note receivable stock subscription			15,000
Net cash provided by (used in) financing activities	<u>8,867</u>	<u>(5,971)</u>	<u>109,689</u>
NET EFFECT OF EXCHANGE RATE ON CASH	<u>1,470</u>	<u>742</u>	<u>(112)</u>
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(11,624)	(19,360)	45,574
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	30,698	50,058	4,484

Edgar Filing: ATRIX LABORATORIES INC - Form 10-K

CASH AND CASH EQUIVALENTS, END OF YEAR	\$ 19,074	\$ 30,698	\$ 50,058
Supplemental cash flow information:			
Cash paid for interest	\$	\$	\$ 614

See notes to the consolidated financial statements.

F-6

Table of Contents

ATRIX LABORATORIES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS (Continued)

Non-cash investing and financing
activities: (amounts in 000 s)

2003

Reclassified \$15,693 of Series A Convertible Exchangeable Preferred Stock to permanent equity.
Issued restricted common stock valued at \$22 as part of employment separation agreements.
Issued preferred stock valued at \$982 to Elan for accretion of dividends.
Long-term deposits on equipment of \$869 were reclassified to property, plant and equipment.

2002

Issued common stock valued at \$5,330 in exchange for \$5,206 of the 7% Convertible Subordinated Notes.
Issued preferred stock valued at \$917 to Elan for accretion of dividends.

2001

Issued preferred stock valued at \$883 to Elan for accretion of dividends.
Issued common stock valued at \$33,177 in exchange for \$30,984 of 7% Convertible Subordinated Notes.

See notes to the consolidated financial statements.

Table of Contents

ATRIX LABORATORIES, INC. AND SUBSIDIARIES

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2003, 2002 and 2001

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Atrix Laboratories, Inc. (Atrix) was formed in August 1986 as a Delaware corporation. In November 1998, Atrix acquired ViroTex Corporation. In June 1999, Atrix organized its wholly owned subsidiary Atrix Laboratories Limited, which is based in London, England. In February 2000, Atrix organized its wholly owned subsidiary Atrix Laboratories GmbH, which is based in Bad Homburg, Germany, to conduct its European operations. Collectively, Atrix and its subsidiaries are referred to as Atrix or the Company. In June 2000, the Company entered into a research joint venture, Transmucosal Technologies Ltd. (TTL), with Elan International Services, Ltd., a wholly owned subsidiary of Elan Corporation, plc. The joint venture was terminated in September 2003.

The Company is an emerging specialty pharmaceutical company focused on advanced drug delivery. With unique patented drug delivery technologies, the Company is currently developing a diverse portfolio of products, including proprietary oncology and dermatology products. The Company also forms strategic alliances with a variety of pharmaceutical and biotechnology companies to develop products utilizing various drug delivery systems and/or to commercialize products. These strategic alliances include collaborations with, Sanofi-Synthelabo Inc., Fujisawa Healthcare, Inc., Sandoz Inc., Pfizer Inc., Sosei Co. Ltd., MediGene AG and Yamanouchi, Mayne Pharma, Tecnofarma, Han All and CollaGenex Pharmaceuticals, Inc.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of Atrix Laboratories, Inc. and its wholly owned subsidiaries Atrix Laboratories Limited and Atrix Laboratories, GmbH. All significant intercompany transactions and balances have been eliminated. While the Company initially owned 80.1% of TTL s outstanding common stock, Elan and its subsidiaries retained significant minority investor rights that were 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 TTL that were 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, prior to the Company s joint venture termination agreement with Elan in September 2003, the Company accounted for its investment in TTL under the equity method of accounting. Because the Company obtained control of TTL in September 2003, TTL has been consolidated with the Company s consolidated financial statements since that date. See Note 5 for further information related to the termination.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates include allowances for doubtful accounts, reserves for excess or obsolete inventories and the term over which deferred revenues are recognized. Actual results could differ from those estimates and the differences could be material.

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

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

Marketable Securities

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

Inventories

Inventories are stated at the lower of cost, determined by the first-in, first-out (FIFO) method, or market. Inventories consist of the cost of materials, direct labor and overhead. Inventories include preclinical and clinical products that are expensed as research and development costs, as used, if those inventories have alternative use either in products or other research and development projects. The components of inventories are as follows:

	December 31, 2003	December 31, 2002
	(In thousands)	
Raw materials	\$ 9,292	\$6,590
Work in process	1,338	1,035
Finished goods	2,146	1,069
Reserves	(1,260)	
	<u>\$ 11,516</u>	<u>\$ 8,694</u>

The Company increased its inventory reserves by \$1.3 million for the year ended December 31, 2003, as a result of its evaluation of obsolete or potential unmarketable inventory. The Company manufactured launch quantities of a generic dermatology product during the fourth quarter of 2002 and first quarter of 2003 prior to receiving FDA approval. In 2003 the Company booked a reserve allowance for this inventory in response to a non-approval letter received from the FDA. The Company believes it followed the guidelines provided by the FDA in the submission and is currently appealing the non-approval.

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

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

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:

	December 31, 2003	December 31, 2002
	(In thousands)	
Land	\$ 1,071	\$ 1,071
Building	13,252	3,921
Leasehold improvements	728	731
Furniture and fixtures	565	733
Machinery	12,159	8,306
Office equipment	2,527	2,075
Construction in progress	296	6,072
	<hr/>	<hr/>
Total property, plant and equipment	30,598	22,909
Accumulated depreciation and amortization	(8,743)	(7,478)
	<hr/>	<hr/>
Property, plant and equipment, net	\$21,855	\$15,431
	<hr/>	<hr/>

Goodwill

The Company adopted Statement of Financial Accounting Standards (SFAS) No. 142, Goodwill and Other Intangible Assets, on January 1, 2002. Goodwill is no longer amortized, but instead is tested for impairment on an annual basis or as circumstances change. As a result of impairment analysis performed in 2003, the Company recorded a \$20,000 write-down of goodwill to zero related to the Company's Biocompatible Polymer System technology.

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

	2003	2002	2001
Reported net loss applicable to common stock	\$ (2,895)	\$ (19,114)	\$ (26,704)
Add back: Goodwill amortization			208
	<hr/>	<hr/>	<hr/>
Adjusted net loss applicable to common stock	\$ (2,895)	\$ (19,114)	\$ (26,496)
	<hr/>	<hr/>	<hr/>
Basic and diluted loss per common share:			
As reported	\$ (.14)	\$ (0.95)	\$ (1.63)
Goodwill amortization			0.01
	<hr/>	<hr/>	<hr/>
Basic and diluted, as adjusted	\$ (.14)	\$ (0.95)	\$ (1.62)
	<hr/>	<hr/>	<hr/>

Intangible Assets

Edgar Filing: ATRIX LABORATORIES INC - Form 10-K

Intangible assets consist of patents and trademarks. Patents and trademarks are stated at the legal cost incurred to obtain the patents and trademarks. Upon approval, patent and trademark costs are amortized, using the straight-line method, over their estimated useful life ranging from ten to twenty years.

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

F-10

Table of Contents

ATRIX LABORATORIES, INC. AND SUBSIDIARIES

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

losses is based on the excess of the carrying amount of the asset over the fair value calculated using discounted expected future cash flows.

Fair Value of Financial Instruments

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

Concentrations of Credit Risk

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

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

Revenue Recognition

The Company recognizes revenue on product sales and contract manufacturing at the time of shipment when title to the product transfers and the customer bears risk of loss. Royalty revenue is recorded when product is shipped by licensees based on information provided by the licensee and royalty rates and formulas as specified in agreements with licensees. Generally, royalties are based on estimated net sales (gross sales less discounts, allowances and other items) of a product based on information supplied to the Company by the licensee and may require future revisions.

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. Payments received in advance of revenue recognition are recorded as deferred revenue. Revenue under other contracts is recognized based on terms as specified in the contracts, including billings for time incurred at rates as specified in the contracts and as reimbursable expenses are incurred. Such arrangements are regularly evaluated on an individual basis. Billings under these contracts are made monthly.

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

The Company has licensing agreements that generally provide for non-refundable license fees and/or milestone payments. The licensing agreements typically require a non-refundable license fee and allow the Company's partners to sell its proprietary products in a defined territory for a defined period. Non-refundable license fees are initially reported as deferred revenue and recognized as licensing revenue over the remaining contractual term or as covered by patent protection, whichever is earlier, using the straight-line method or until the agreement is terminated. A milestone payment is a payment made by a partner to the Company upon the achievement of a pre-determined event, as defined in the applicable agreement. Milestone payments are initially reported as deferred revenue and subsequently recognized using the straight-line method over the remaining contractual term or the remaining period covered by patent protection, whichever is earlier. No milestone revenue is recognized until the Company has completed the required milestone-related services.

The following table summarizes the deferred revenue to be recognized as revenue during the years ending December 31, 2004 through December 31, 2016 (amounts in thousands):

Years Ended December 31,	Amortization of Deferred Revenue
2004	\$ 9,923
2005	8,238
2006	4,698
2007	4,678
2008	4,661
Thereafter	10,140
Total	\$42,338

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, license 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 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:

	2003	2002	2001
	(In thousands)		
Research and Development			
Funded, in whole or in part	\$29,685	\$18,721	\$10,626
Atrix funded 100%	6,593	14,018	15,009
Total	\$36,278	\$32,739	\$25,635
Research and Development			
License fees Atrix funded 100%	\$ 150	\$	\$ 2,985

Table of Contents

ATRIX LABORATORIES, INC. AND SUBSIDIARIES

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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. There was no diluted effect on earnings per share computations for the assumed conversion of the Series A Convertible Preferred Stock under the if converted method. Additionally, since the Company never drew any proceeds under the convertible promissory note agreement with Elan, there was no effect on earnings per share computations pertaining to this convertible promissory note for the periods presented. Common share equivalents are excluded from the computations in loss periods, as their effect would be antidilutive. For the years ended December 31, 2003, 2002 and 2001, 1.5 million, 1.5 million and 1.7 million equivalent dilutive securities (primarily Series A convertible preferred stock and common stock options), respectively, have been excluded from the weighted-average number of common shares outstanding for the diluted net loss per share computations as they are antidilutive.

Comprehensive Income (Loss)

Items of other comprehensive income (loss) include unrealized gains and losses on available-for-sale marketable securities and foreign currency translation adjustments. Disclosure of comprehensive income (loss) for the years ended December 31, 2003, 2002 and 2001 is included in the accompanying financial statements as part of the consolidated statements of changes in shareholders' equity.

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

As permitted under Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock-Based Compensation*, the Company accounts for stock-based compensation using the intrinsic value method in accordance with Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* and related interpretations. Accordingly, no compensation expense has been recognized for fixed stock option grants to employees with an exercise price equal to market value at the date of grant. The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123, and related interpretations. At December 31, 2003, the Company has four stock-based employee, and non-employee, compensation plans, which are described more fully in Note 6. The Company accounts for those plans under the recognition and measurement principles of APB Opinion No. 25. No stock-based employee compensation cost is reflected in net income for options granted under those plans with an exercise price equal to the market value for the underlying common stock on date of grant. The following table illustrates the effect on net loss applicable to common stock and basic and diluted loss per common share if the Company had applied the fair value based method of SFAS No. 123 to stock-based compensation for the years ended, December 31:

	2003	2002	2001
	(In thousands, except per share data)		
Net loss applicable to common stock, as reported:	\$ (2,895)	\$ (19,114)	\$ (26,704)
Add: Stock based compensation expense included in reported net loss, net of related tax effects	22	1,257	2,117
Deduct: Total stock-based compensation expense determined under fair-value based method, net of related tax effects	(10,241)	(11,397)	(9,485)
Pro forma net loss applicable to common stock	\$ (13,114)	\$ (29,254)	\$ (34,072)
Basic and diluted net loss per common share:			
As reported	\$ (0.14)	\$ (0.95)	\$ (1.63)
Pro forma	\$ (0.65)	\$ (1.46)	\$ (2.08)

The weighted-average Black-Scholes fair value per option granted in 2003, 2002, and 2001 was \$10.09, \$12.50 and \$11.68, 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 2003, 2002 and 2001: no dividend yield, expected volatility of 58.1% for 2003, 60.3% for 2002, and 62.2% for 2001, risk free interest rates of 5.0% in 2003 and 2002 and 7.0% in 2001, and expected life of five years.

Income Taxes

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

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.

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

Revenue and expense accounts are translated at average exchange rates in effect during the period. Translation adjustments are recorded as a component of other comprehensive income (loss). Cumulative foreign currency translation adjustments included in accumulated other comprehensive income (loss) at December 31, 2003, 2002 and 2001 were \$292,000, \$85,000 and \$(29,000), respectively. Some of the Company's transactions and transactions of its subsidiaries are made in currencies different from their functional currency. Gains and losses from these transactions are included in other income or expense as they occur. To date, the effect on income and expenses for such amounts has been immaterial.

Derivative Instruments and Hedging Activities

In June 1998, Statement of Financial Accounting Standards (SFAS) No. 133, *Accounting for Derivative Instruments and Hedging Activities*, was issued which, as amended, was effective for all fiscal years beginning after June 15, 1999. SFAS No. 133 provides new standards for the identification, recognition and measurement of derivative financial instruments, including embedded derivatives. Historically, the Company has not entered into derivative contracts to hedge existing risks or entered into speculative derivative contracts.

New Accounting Pronouncements

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

In April 2003, the FASB issued SFAS No. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities*. SFAS No. 149 amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts (collectively referred to as derivatives) and for hedging activities. The accounting and reporting requirements is effective for contracts entered into or modified after June 30, 2003 and for hedging relationships designated after June 30, 2003. The adoption of SFAS No. 149 did not have a material impact on the Company's consolidated financial statements.

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity* (SFAS 150). SFAS 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It generally requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances), many of which were previously classified as equity. The provisions of SFAS 150 are effective for financial instruments entered into or modified after May 31, 2003 and, with one exception, are effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of SFAS 150 did not have a material effect on the Company's consolidated financial statements.

Table of Contents

ATRIX LABORATORIES, INC. AND SUBSIDIARIES

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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

In November 2002, the FASB issued Emerging Issues Task Force Issue No. 00-21 (EITF 00-21), *Accounting for Revenue Arrangements with Multiple Deliverables*. EITF 00-21 addresses how to determine whether a revenue arrangement involving multiple deliverables contains more than one unit of accounting for the purposes of revenue recognition and how the revenue arrangement consideration should be measured to the separate units of accounting. EITF 00-21 provides guidance with respect to the effect of certain customer rights due to company non-performance on the recognition of revenue allocated to delivered units of accounting. EITF 00-21 also addresses the impact on the measurement and/or allocation of arrangement consideration of customer cancellation provisions and consideration that varies as a result of future actions of the customer or the Company. Finally, EITF 00-21 provides guidance with respect to the recognition of the cost of certain deliverables that are excluded from the revenue accounting arrangement. EITF 00-21 applies to revenue arrangements that the Company enters into after June 15, 2003. The Company does not expect EITF 00-21 to have a material effect on its consolidated financial statements.

Reclassifications

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

Table of Contents**ATRIX LABORATORIES, INC. AND SUBSIDIARIES****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****2. MARKETABLE SECURITIES**

As of December 31, 2003, marketable securities available-for-sale consist of the following:

	Number of Shares or Principal Amount	Book Value	Unrealized Gains	Unrealized Losses	Fair Value
(In thousands, except share data)					
Bond Mutual Funds:					
MFS Limited Maturity Fund CL-A	1,702,572 Shares	\$ 11,647	\$	\$(138)	\$ 11,509
Pimco Total Return Fund	1,136,534 Shares	12,156	16		12,172
UBS Pace Government Securities Fund	178,198 Shares	2,310	16		2,326
Thornburg Limited Term US Government A Fund	54,738 Shares	689	29		718
Evergreen Adjustable Rate Fund Class A	584,553 Shares	5,641		(64)	5,577
Blackrock Intermediate Government Fund Class A	10,827 Shares	107	6		113
Pioneer High Yield Fund Class A	39,199 Shares	43	2		45
		<u>32,593</u>	<u>69</u>	<u>(202)</u>	<u>32,460</u>
Sub-total		<u>32,593</u>	<u>69</u>	<u>(202)</u>	<u>32,460</u>
Other Marketable Securities:					
U.S. Government and Agency Bonds	\$10,516	10,572	30		10,602
State and Municipal Bonds	\$4,935	5,308	52		5,360
Equitable Guaranteed Growth Annuity	\$1,000	1,000			1,000
Certificates of Deposit	\$1,300	1,310			1,310
Corporate Notes	\$26,380	26,931		(258)	26,673
CollaGenex Common Stock	294,989 Shares	2,231	1,052		3,283
		<u>47,352</u>	<u>1,134</u>	<u>(258)</u>	<u>48,228</u>
Sub-total		<u>47,352</u>	<u>1,134</u>	<u>(258)</u>	<u>48,228</u>
Total		<u>\$79,945</u>	<u>\$1,203</u>	<u>\$(460)</u>	<u>\$80,688</u>

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

As of December 31, 2002, marketable securities available-for-sale consist of the following:

	Number of Shares or Principal Amount	Book Value	Unrealized Gains	Unrealized Losses	Fair Value
(In thousands, except share data)					
Bond Mutual Funds:					
MFS Limited Maturity Fund CL-A	1,846,298 Shares	\$ 12,646	\$ 38	\$	\$ 12,684
Pimco Total Return Fund	1,085,830 Shares	11,612		(26)	11,586
UBS Pace Government Securities Fund	178,198 Shares	2,310	15		2,325
Thornburg Limited Term US Government A Fund	52,982 Shares	666	35		701
Sub-total		<u>27,234</u>	<u>88</u>	<u>(26)</u>	<u>27,296</u>
Other Marketable Securities:					
U.S. Government and Agency Bonds	\$25,200	25,518	540		26,058
Equitable Guaranteed Growth Annuity	\$1,000	1,000			1,000
Certificates of Deposit	\$1,300	1,300			1,300
Corporate Notes	\$23,668	22,710	266		22,976
CollaGenex Common Stock	330,556 Shares	2,500	637		3,137
Sub-total		<u>53,028</u>	<u>1,443</u>		<u>54,471</u>
Total		<u>\$ 80,262</u>	<u>\$ 1,531</u>	<u>\$ (26)</u>	<u>\$ 81,767</u>

The amount of gains and losses reclassified out of accumulated other comprehensive income into earnings was \$0.5 million net gain, \$0.1 million net loss and zero for 2003, 2002 and 2001, respectively.

Realized gains or losses on sales of securities are calculated primarily using the specific identification method. Realized gains or losses on sale of mutual funds and equity securities are calculated using the average cost method. Realized investment gains in 2003 were \$0.6 million. Realized investment losses were \$1.1 million and \$0.8 million in 2002, and 2001, respectively.

3. INTANGIBLE AND OTHER ASSETS

Intangible and other assets consist of the following as of December 31:

	2003	2002
(In thousands)		
Patents and trademarks	\$ 4,000	\$ 3,397
Purchased technology		2,800
Other assets	14	883

Edgar Filing: ATRIX LABORATORIES INC - Form 10-K

Sub-total	4,014	7,080
Less: Accumulated amortization	(1,225)	(3,116)
Total	\$ 2,789	\$ 3,964

At December 31, 2002, other assets consisted of deposits on equipment to be purchased for the Company's plant expansion. When the equipment was received, these deposits were reclassified to property plant and equipment during the year ended December 31, 2003. In 2003, the Company wrote-off the

Table of Contents

ATRIX LABORATORIES, INC. AND SUBSIDIARIES

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

purchased technology which was fully amortized as of December 31, 2003. Estimated amortization of intangibles and other assets is \$0.2 million for each year for the years ending December 31, 2004 through December 31, 2007 and \$0.1 million for the year ending December 31, 2008.

4. CONVERTIBLE SUBORDINATED NOTES PAYABLE

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

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

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

5. COLLABORATIVE ARRANGEMENTS

Sanofi-Synthelabo, Inc.

In December 2000, the Company entered into an exclusive North American marketing agreement with Sanofi-Synthelabo, Inc., a major international pharmaceutical company, for the Eligard 7.5-mg one-month, 22.5-mg three-month, and 30-mg four-month products for the treatment of prostate cancer. Additionally, in January 2002, Sanofi-Synthelabo exercised its rights under the agreement with the Company for Eligard 45.0-mg six-month product to be developed.

The Company received a license fee of \$8.0 million upon signing the agreement. The license fee was recorded as deferred revenue and is being recognized over the term of the agreement. Under the terms of the agreement, the Company will manufacture the products and receive an agreed upon transfer price from Sanofi-Synthelabo as well as royalties from sales. In addition, the agreement provides for license fees and payments for clinical, regulatory and sales milestones for the products. As part of the agreement, Sanofi-Synthelabo purchased 824,572 shares of the Company's common stock for \$15.0 million.

During the year ended December 31, 2001, the Company received \$6.0 million of milestone payments related to certain FDA filings. The milestone payments were recorded as deferred revenue and are being recognized as revenue over the remaining term of the agreement using the straight-line method.

Table of Contents

ATRIX LABORATORIES, INC. AND SUBSIDIARIES

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

During the year ended December 31, 2003, the Company received a \$6.0 million milestone payment from Sanofi-Synthelabo for the first commercial U.S. sales of Eligard 30.0-mg four-month product. The milestone payment was recorded as deferred revenue and is being recognized as revenue over the remaining term of the agreement using the straight-line method.

Fujisawa Healthcare, Inc.

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

Sandoz Inc. (formerly, Geneva Pharmaceuticals, Inc.)

In August 2000, the Company entered into a development and supply agreement with Sandoz Inc. to conduct research and development activities on a collaborative basis to develop designated generic topical prescription dermatology products. Under the terms of the agreement, Sandoz will reimburse the Company for 50% of the research and development costs the Company incurs on the products. Additionally, the Company and Sandoz will share equally in the net profits from the sales of the products.

Pfizer, Inc.

In August 2000, the Company entered into a non-exclusive comprehensive research and worldwide licensing agreement with Pfizer, Inc. to provide broad-based 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 compounds developed by Pfizer using the Company's patented drug delivery technologies. The Company will receive royalty payments from the sales of products that are successfully developed and commercialized under the agreement. As part of the agreement, Pfizer purchased 447,550 shares of the Company's common stock for \$5.0 million.

MediGene AG/ Yamanouchi

In April 2001, the Company entered into an exclusive European marketing agreement with MediGene AG, a German biotechnology company, to market the Eligard 7.5-mg one-month, Eligard 22.5-mg three-month and Eligard 30-mg four-month products. Additionally, MediGene has the right to develop the Eligard 45-mg six-month product. The Company received a license fee of \$2.0 million upon signing the agreement. The license fee was recorded as deferred revenue and is being recognized over the term of the agreement on a straight-line basis. Additionally, the Company will receive payments for certain clinical, regulatory and sales milestones, product sales and royalty payments based on MediGene's sales of Eligard products. Under the terms of the agreement, the Company will manufacture the products and will

Table of Contents

ATRIX LABORATORIES, INC. AND SUBSIDIARIES

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

receive additional payments for certain clinical, regulatory and sales milestones and royalties on sales. As part of the agreement, MediGene purchased 233,918 shares of the Company's common stock for \$3.8 million. MediGene received marketing authorization from the German regulatory authority, Bundesinstitut für Arzneimittel und Medizinprodukte, or BfArM for the Company's Eligard 7.5-mg one-month and Eligard 22.5-mg three-month products in December 2003 and January 2004, respectively.

In conjunction with the regulatory filings of the Eligard 7.5-mg one-month and Eligard 22.5-mg three-month products, the Company received a \$1.0 million milestone payment in 2002 from MediGene. This milestone payment from MediGene was recorded as deferred revenue and is being recognized as revenue over the remaining term of the agreement using the straight-line method.

CollaGenex Pharmaceuticals, Inc.

In August 2001, the Company licensed the exclusive U.S. marketing rights for Atridox, Atrisorb FreeFlow GTR Barrier and Atrisorb-D GTR Barrier products to CollaGenex Pharmaceuticals, Inc., following the reacquisition of the sales and marketing rights from Block Drug Corporation. The Company received a \$1.0 million license fee upon signing of the agreement. Additionally, the Company receives a royalty on product sales and a manufacturing margin. In connection with the transaction, the Company purchased 330,556 shares of CollaGenex's common stock for \$3.0 million, which was a \$0.5 million premium to market at the date of purchase. The Company recorded the common stock as an available-for-sale security and the premium was reflected as a reduction of the license. The net license fee was recorded as deferred revenue and is being recognized as revenue over the term of the agreement using the straight-line method.

Block Drug Corporation

In August 2001, the Company reacquired certain North American marketing rights to the dental products from Block Drug. Under the terms of the agreement, Block Drug agreed to pay the Company \$3.0 million for milestone events previously achieved by the Company and the Company agreed to pay Block Drug up to \$7.0 million, based on sales of products, over the term of the agreement, which is through August 2005. Upon execution of the termination agreement in August 2001, all previous agreements between the Company and Block Drug were terminated. The Company recorded the additional milestone payments as deferred revenue and records payments made to Block Drug as a reduction to deferred revenue. The additional milestone payments and the payments made to Block Drug are being recognized as revenue and as a reduction to revenue, respectively, over the term of the agreement under the straight-line method. As of December 31, 2003, the Company has paid Block Drug \$4.3 million under this agreement.

Elan International Services, Ltd.

In July 2000, the Company formed a joint venture, Transmucosal Technologies Ltd., with Elan International Services, Ltd., a wholly owned subsidiary of Elan Corporation, plc. The purpose of the joint venture was to develop and commercialize oncology and pain management products. On September 10, 2003, the Company entered into a termination agreement with Elan for the termination of the Company's joint venture, Transmucosal Technologies, Ltd. Pursuant to the terms of the agreement, the Company acquired Elan's preferred shares in Transmucosal Technologies, Ltd. in exchange for a royalty interest on certain future revenues and payments to the Company, if any, related to certain technology rights retained by the Company. The Company now owns 100% of Transmucosal Technologies, Ltd. The Company estimated that the fair value of the future contingent royalty payments is not material and, accordingly, no liability has been reflected in the Company's financial statements.

Table of Contents

ATRIX LABORATORIES, INC. AND SUBSIDIARIES

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In connection with the formation of Transmucosal Technologies Ltd., the Company issued to Elan 12,015 shares of its Series A convertible exchangeable preferred stock (Series A), valued at \$12.0 million in exchange for 6,000 shares of common stock and 3,612 shares of preferred stock of Transmucosal Technologies Ltd., representing an initial ownership in the joint venture of 80.1%. Series A bears a 7% annual dividend, accruing semi-annually, payable in-kind. During the year ended December 31, 2001, the Company issued 856 shares of Series A stock in payment of accreted dividends of \$0.9 million. When the Series A stock was issued in payment of these dividends, the trading price of the Company's common stock was in excess of the conversion rate of the Series A. As a result, the Company recorded a charge of \$0.3 million for the beneficial conversion feature related to this issuance, which was recorded as an additional dividend on preferred stock. During the year ended December 31, 2002, the Company issued 917 shares of Series A stock in payment of accreted dividends of \$0.9 million. No beneficial conversion feature charges were recorded in 2002 because the trading price of the Company's common stock was less than the conversion rate of the Series A at the time the shares were issued. During the year ended December 31, 2003, the Company issued 983 shares of Series A stock in payment of accreted dividends of \$1.0 million. When the Series A stock was issued in payment of these dividends, the trading price of the Company's common stock was in excess of the conversion rate of the Series A. As a result, the Company recorded a charge of \$0.2 million 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, 2003 and 2002 were \$0.5 million and \$0.4 million, respectively.

Series A is convertible as of July 2002, at Elan's option, into the Company's common stock at \$18.00 per common share, subject to anti-dilution adjustments. The Series A stock must be redeemed by the Company in July 2006, either in cash or in the Company's common stock at Atrix's option, in an amount equal to the liquidation preference. The liquidation preference of Series A is its stated value plus accreted and unpaid dividends. In connection with the formation of the joint venture, Elan purchased 442,478 shares of the Company's common stock for \$5.0 million and the Company issued Elan a warrant to purchase up to 1,000,000 shares of the Company's common stock at \$18.00 per share. The warrant was exercisable at issuance and expires in July 2005.

Because of the exchange feature, the Series A was presented outside of stockholders' equity. In connection with the termination, Elan and its affiliates agreed to forego the exchange right included in the Series A stock of the Company (which is held by a wholly-owned subsidiary of Elan). Accordingly, the Company reclassified the Series A stock to permanent equity, which increased equity by \$15.7 million.

The joint venture contracted with Atrix and Elan to perform certain research and development activities. During the years ended December 31, 2003, 2002, and 2001, the Company earned contract research and development revenues of \$0.1 million, \$1.2 million, and \$4.1 million, respectively, and had receivables from the joint venture at December 31, 2003 and 2002 of \$0 and \$0.3 million, respectively. Additionally, the Company had payables to the joint venture at December 31, 2003 and 2002 of \$0 and \$0.2 million, respectively. During 2003, 2002 and 2001, the Company recognized \$0.1 million, \$1.0 million and \$3.3 million, respectively, for its share of the losses of Transmucosal Technologies Ltd.

Other Collaborations

The Company has other various individually less significant collaborative agreements that may provide for license fees, milestone payments and/or research and development payments. During the years ended December 31, 2003, 2002, and 2001, the Company received license fees and milestone payments of \$1.0 million, \$1.0 million, and \$0.1 million, respectively from other collaborations. These payments are being recognized as revenue over the terms of the related contracts using the straight-line method.

Table of Contents**ATRIX LABORATORIES, INC. AND SUBSIDIARIES****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****6. STOCK OPTION PLANS**

As of December 31, 2003, 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 2.5 million of its authorized but unissued common stock for stock options to be granted under the 1987 Plan. Under the terms of the 1987 Plan, options generally vest ratably over a period of three years from the date of grant and expire after ten years. The exercise price of all options is the closing bid price of the stock on the date of grant. The 1987 Plan expired in May 2002 and no stock options will be granted under this plan after expiration. However, all currently outstanding options will vest and will be exercisable pursuant to their terms at grant.

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, 2000	1,510,524	\$ 5.38 - 20.75	\$ 9.61
Options granted	86,390	5.50 - 25.99	16.12
Options canceled or expired	(88,277)	5.50 - 17.25	8.10
Options exercised	(393,980)	5.50 - 20.75	9.98
Options outstanding, December 31, 2001	1,114,657	5.38 - 25.99	10.11
Options granted	7,000	22.25 - 22.99	22.46
Options canceled or expired	(6,386)	5.50 - 17.25	11.31
Options exercised	(240,073)	5.50 - 17.25	9.07
Options outstanding, December 31, 2002	875,198	5.38 - 25.99	10.48
Options canceled or expired	(15,300)	5.50 - 25.99	12.83
Options exercised	(538,959)	5.50 - 25.99	8.99
Options outstanding, December 31, 2003	320,939	\$ 5.50 - 25.99	\$ 12.50
Options outstanding were available for exercise as follows:			
Exercisable at December 31, 2003	298,244		\$ 11.99
Exercisable at December 31, 2002	753,152		\$ 9.95
Exercisable at December 31, 2001	816,999		\$ 9.76

Range of Exercise Prices	Number Outstanding at December 31, 2003	Weighted- Average Remaining Contractual Life	Weighted- Average Exercise Price	Number Exercisable at December 31, 2003	Weighted- Average Exercise Price Exercisable
\$ 5.50 - 6.88	38,548	3 years	\$ 6.45	38,548	\$ 6.45
9.00 - 9.94	134,333	1 year	9.60	134,333	9.60
10.00 - 11.75	47,410	4 years	10.75	38,910	10.89

Edgar Filing: ATRIX LABORATORIES INC - Form 10-K

16.50 - 17.25	65,804	4 years	16.59	65,804	16.59
19.00 - 25.99	34,844	8 years	25.07	20,650	25.29
<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
\$ 5.50 - 25.99	320,939	5 years	\$12.50	298,245	\$11.99
<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>

F-23

Table of Contents**ATRIX LABORATORIES, INC. AND SUBSIDIARIES****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****2000 Stock Incentive Plan (the 2000 Plan)**

The Company has reserved 4,250,000 of its authorized but unissued common stock for stock options to be granted under the 2000 Plan. In April 2003, the shareholders voted to approve an increase to the number of shares authorized for issuance from 2,750,000 to 4,250,000. Under the terms of the 2000 Plan, options 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 981,147 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. All options awarded under this portion of the plan are made under the 2000 Plan. Only the Company's chief executive officer and chairman of the board is eligible to receive awards under the 2001 Program. Grants may be made under the 2001 Program at any time prior to August 5, 2004. The exercise price of the options is determined by the Board of Directors or a designated committee. The aggregate value of awards that may be granted under the 2001 Program, at the time of grant, is \$7.0 million. Awards 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 the closing bid price of the stock on the date of the grant. All of these options granted to the Chief Executive Officer were fully vested at the date of the grant. As a result, the Company recognized \$2.0 million of compensation expense in the year ended December 31, 2001. In 2002, the Company granted the Chief Executive Officer 100,000 options at market and above. In 2003, the Company granted the Chief Executive Officer 150,000 options at market price.

In 2002, in connection with the retirement of an officer of the Company, the Company accelerated the vesting of 100,500 options held by that officer. As a result, the Company recognized a one-time charge of \$1.3 million.

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

	Number of Shares	Exercise Price Per Share	Weighted- Average Exercise Price
Options outstanding, December 31, 2000	1,060,485	\$ 9.00 - 18.88	\$ 12.09
Options granted	1,047,238	5.00 - 28.19	18.48
Options canceled or expired	(173,969)	9.00 - 25.99	17.59
Options exercised	(17,385)	9.00 - 17.63	10.43
Options outstanding, December 31, 2001	1,916,369	5.00 - 28.19	15.21
Options granted	820,400	12.88 - 30.00	22.29
Options canceled or expired	(122,452)	9.00 - 28.19	20.13
Options exercised	(149,448)	9.00 - 18.63	10.97
Options outstanding, December 31, 2002	2,464,869	5.00 - 30.00	17.58
Options granted	1,092,100	10.53 - 30.75	18.46

F-24

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

	Number of Shares	Exercise Price Per Share	Weighted- Average Exercise Price
Options canceled or expired	(454,949)	9.00 - 26.14	19.98
Options exercised	(471,609)	9.00 - 25.99	13.48
Options outstanding, December 31, 2003	2,630,411	\$ 5.00 - 30.75	\$ 18.28

Options outstanding were available for exercise as follows:

Exercisable at December 31, 2003	1,085,404	\$ 16.26
Exercisable at December 31, 2002	887,558	\$ 13.75
Exercisable at December 31, 2001	412,233	\$ 10.49

Range of Exercise Prices	Number Outstanding at December 31, 2003	Weighted- Average Remaining Contractual Life	Weighted- Average Exercise Price	Number Exercisable at December 31, 2003	Weighted- Average Exercise Price Exercisable
\$ 5.00	100,503	8 years	\$ 5.00	100,503	\$ 5.00
9.00 - 9.75	221,630	6 years	9.60	221,630	9.60
10.06 - 14.50	236,122	7 years	11.64	132,656	11.88
15.00 - 19.95	921,503	9 years	16.66	257,801	16.82
20.25 - 25.00	769,399	8 years	22.34	170,771	22.56
25.00 - 30.75	381,254	8 years	26.68	202,043	26.02
\$ 5.00 - 30.75	2,630,411	8 years	\$ 18.28	1,085,404	\$ 16.26

1999 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. The Company has reserved 25,000 shares of its authorized but unissued common stock for issuance to non-employee directors under the DSI Plan. This DSI Plan is comprised of two components: an Automatic Option Grant Program and a Stock Fee Program. The board of directors amended the non-employee director compensation policy in November 2002.

Automatic Option Grant Program

Immediately following each annual meeting of the Company's stockholders, commencing with the 1999 Annual Stockholders Meeting, each non-employee director is granted a Non-Qualified Stock Option to purchase 4,000 shares of the Company's common stock. These options vest ratably over a period of three years and expire ten years after grant. The exercise price of each option is equal to the market price of the Company's common stock on the date of the grant. All options awarded under this portion of the plan are made under the 2000 Stock Incentive Plan. For the year ended December 31, 2003, 72,000 stock options were issued at a price of \$16.47 and none were exercised under this program.

Edgar Filing: ATRIX LABORATORIES INC - Form 10-K

Stock Fee Program

Each non-employee director receives an annual retainer fee of \$12,000, per meeting fees of \$1,750 and an annual grant of 15,000 options. Upon reelection, directors receive an additional 18,000 options. The retainer fee and per meeting fees are paid in cash, restricted shares of common stock or a combination

F-25

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

thereof at the director's election. The number of shares issued is determined based on the fair value of the company's common stock on the date paid. The options vest ratably over a period of three years. The exercise price of each stock option, which as 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. All options awarded under this portion of the plan are made under the 2000 Stock Incentive Plan. During the years ended December 31, 2003, 2002 and 2001, the Non-Employee Directors elected to have 3,112, 1,871, and 932 shares of Restricted Common Stock issued, respectively. As of December 31, 2003, there are 13,519 shares that remain available to be issued under this program.

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

The Company has reserved 150,000 shares of its authorized but unissued common stock for stock options to be granted to outside consultants under the Non-Qualified Plan. The Compensation Committee sets the option price and exercise terms granted under the Non-Qualified Plan. The exercise price of all options granted under the Non-Qualified Plan currently outstanding has been the closing market price at the date of grant. There are 42,020 shares as of December 31, 2003, which remain available under the Non-Qualified Plan for future stock option grants.

The Company accounts for grants under the Non-Qualified Plan at fair value. The fair value of options granted under the Non-Qualified Plan was estimated on the grant date using the Black-Scholes option-pricing model and included as compensation expense. The stock compensation recorded under the Non-Qualified Plan was not material for the years ended December 31, 2003, 2002 and 2001. The following weighted-average assumptions were used in 2003, 2002, and 2001: no dividend yield, expected volatility of 58.1% for 2003, 60.3% for 2002, and 62.2% for 2001, risk free interest rates of 5.0% in 2003 and 2002 and 7.0% in 2001, 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, 2000	49,000	\$ 5.13 - 16.50	\$ 9.21
Options granted	10,000	20.31	20.31
Options exercised	(5,000)	6.00	6.00
Options outstanding, December 31, 2001	54,000	5.13 - 20.31	11.56
Options exercised	(6,000)	6.00 - 7.00	6.17
Options outstanding, December 31, 2002	48,000	5.13 - 20.31	12.24
Options exercised	(19,000)	7.00 - 12.28	9.87
Options outstanding, December 31, 2003	29,000	\$ 5.13 - 20.31	\$ 13.79

Options outstanding were available for exercise as follows:

Exercisable at December 31, 2003	29,000	\$ 13.79
Exercisable at December 31, 2002	48,000	\$ 12.24
Exercisable at December 31, 2001	54,000	\$ 11.56

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

Range of Exercise Prices	Number Outstanding at December 31, 2003	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable at December 31, 2003	Weighted-Average Exercise Price Exercisable
\$ 5.13	7,000	2 years	\$ 5.13	7,000	\$ 5.13
10.88	6,000	3 years	10.88	6,000	10.88
15.38 - 16.50	6,000	4 years	15.94	6,000	15.94
20.31	10,000	7 years	20.31	10,000	20.31
\$ 5.13 - 20.31	29,000	4 years	\$ 12.20	29,000	\$ 12.20

7. INCOME TAXES

Net deferred tax assets as of December 31, consist of:

	2003	2002
	<u> </u>	<u> </u>
	(In thousands)	
Deferred tax assets:		
Net operating loss carryforwards	\$ 40,836	\$ 34,671
Research and development tax credit carryforwards	4,063	3,836
Amortization of intangibles	1,535	1,649
Deferred revenue	15,606	16,581
Depreciation	760	462
Stock compensation	789	789
Loss on write-down of marketable security		557
Inventory reserves	470	
Allowance for doubtful accounts reserves	378	
Other items	191	410
	<u> </u>	<u> </u>
Net deferred tax assets	64,628	58,955
Less valuation allowance	(64,628)	(58,955)
	<u> </u>	<u> </u>
Total	\$	\$
	<u> </u>	<u> </u>

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

At December 31, 2003, the Company had approximately \$108.5 million of income tax net operating loss carryforwards, of which \$6.2 million relates to foreign losses available for carryforward. The Company has research and development credits of \$4.1 million, which expire through 2023. At December 31, 2003 and 2002, the Company has \$4.7 million and \$1.0 million of deferred tax assets included in the total deferred tax asset for net operating loss carryforwards that resulted from the benefits from the exercise of employee stock options of \$12.6 million and \$3.0 million for the years ended December 31, 2003 and 2002, 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 occur.

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

A reconciliation of the differences in income tax benefit from loss computed at the federal statutory rate and income tax benefit as recorded for the years ended December 31 is as follows:

	<u>2003</u>	<u>2002</u>	<u>2001</u>
	(In thousands)		
Income tax benefit computed at federal statutory rate	\$ (583)	\$ (6,177)	\$ (8,681)
State income taxes net of federal taxes	(57)	(599)	(843)
Equity in loss of joint venture	28	330	1,117
Research and development	(464)	(701)	(565)
Amortization of intangibles	181	230	314
Other	(480)	(146)	32
Change in valuation allowance	1,375	7,063	8,626
	<u> </u>	<u> </u>	<u> </u>
Income tax expense	\$	\$	\$
	<u> </u>	<u> </u>	<u> </u>

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:

	<u>2003</u>	<u>2002</u>	<u>2001</u>
	(In thousands)		
Eligard products	\$ 14,127	\$ 2,079	\$
Dental products	4,225	2,631	2,436
Generic dermatology products	314		
Contract manufacturing	4	848	1,092
Other	120	191	290
	<u> </u>	<u> </u>	<u> </u>
Net sales and royalties	\$ 18,790	\$ 5,749	\$ 3,818
	<u> </u>	<u> </u>	<u> </u>

Revenues by geographic area consisted of the following for the years ended December 31:

	<u>2003</u>	<u>2002</u>	<u>2001</u>
	(In thousands)		
United States	\$ 45,078	\$ 23,289	\$ 10,306
Foreign countries	5,295	3,819	5,950
Less intercompany	(826)	(724)	(445)
	<u> </u>	<u> </u>	<u> </u>

Edgar Filing: ATRIX LABORATORIES INC - Form 10-K

Total revenue	\$49,547	\$26,384	\$15,811
---------------	----------	----------	----------

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

For the year ended December 31, 2003, revenue from two customers accounted for 43%, and 24% of total revenue. For the year ended December 31, 2002, revenue from four customers accounted for 26%,

F-28

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

17%, 14% and 14% of total revenue. For the year ended December 31, 2001, revenue from two customers accounted for 26% and 22% of total revenue.

At December 31, 2003, amounts due from three customers each exceeded 10% of accounts receivable and accounted for 60% of total accounts receivable. At December 31, 2002, amounts due from two customers each exceeded 10% of accounts receivable and accounted for 52% of total accounts receivable.

9. COMMITMENTS AND CONTINGENCIES

As of December 31, 2003, minimum rental commitments for future years under non-cancelable operating leases of one year or more are as follows:

Years Ended December 31,	Minimum Rental Commitments
	(In thousands)
2004	\$ 502
2005	499
2006	228
2007	47
	—
Total	\$1,276

Rent expenses were \$0.7 million, \$0.6 million and \$0.4 million for the years ended December 31, 2003, 2002 and 2001, respectively.

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

The Company has entered into various commitments for the purchase of research services and studies of \$8.6 million in 2004, marketing programs with certain collaborative partners of \$2.3 million in 2004 and supply agreements and issued purchase orders we have entered into for the supply of raw materials for the years ending December 31, 2004 of \$5.6 million; 2005 through 2007 of \$2.4 million in each year and \$0.1 million in 2008 and 2009. These research services and studies are for both internally and externally funded research projects. Marketing programs are amounts we have committed to spend in conjunction with our marketing partners in advertising campaigns. The amounts presented for supply agreements represent minimum quantities at fixed prices. Commitments under certain of the agreements are contingent upon regulatory approval of the raw material to be supplied. We believe the minimum quantities in the supply agreements are not in excess of the anticipated demand for the raw material.

The Company offers a 401(k) Employee Savings Plan, or the Savings Plan, which allows eligible employees to contribute from 1% to 17% of their income to the Savings Plan. Effective January 1, 2002, the Company amended the Savings Plan Company match from 50% of the first 6% of the employees' contributions to 100% company match on the first 6% of employees' 401(k) contributions and 50% company match of the next 6% of the employees' contributions. The Company's matching contributions to the Savings Plan, which vest immediately, were \$0.5 million, \$0.4 million and \$0.1 million for the years ended December 31, 2003, 2002 and 2001, respectively.

The Company offers 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

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

unissued common stock for issuance under the ESPP, of which 268,014 shares remain available as of December 31, 2003.

We have a revolving line of credit with a bank that expires in May 2004. Under the terms of the line of credit, we may borrow up to \$1.0 million. Borrowings under the line of credit bear interest at the prime rate and are subject to financial covenants requiring us to maintain certain levels of net worth and liquidity. Additionally, in July 2003, we renewed a second \$1.0 million line of credit with another bank. The second line of credit expires in June 2004. Borrowings under the second line of credit bear interest at the prime rate plus 1/2%. As of December 31, 2003, there was no obligation outstanding under either of these lines of credit.

In November 2002, the Company's Board of Directors amended the September 17, 2001 stock repurchase program to provide that the Company may acquire up to a maximum of \$20.0 million of Atrix common stock in the open market or in privately negotiated transactions under this program. The program terminated on December 31, 2003. Since the inception of the stock repurchase program on September 17, 2001 through December 31, 2003, the Company repurchased a total of 866,800 shares of its common stock in the open market for \$13.6 million, or an average price per share of \$15.71. During the year ended December 31, 2003, the Company repurchased 209,100 shares of its common stock in the open market for \$2.9 million, or an average price per share of \$13.75 under the program.

On November 3, 2003, TAP Pharmaceutical Products, Inc. and two additional plaintiffs filed suit in U.S. District Court, Northern District of Illinois, Eastern Division, Tap Pharmaceutical Products, Inc., et al v. Atrix Laboratories, Inc., et al, alleging that the Eligard delivery system infringes a patent that claims, among other things, a biodegradable high molecular polymer, which patent is licensed to TAP Pharmaceuticals by the two other plaintiffs. The plaintiffs seek an injunction and unspecified damages. We believe the claims are without merit and intend to defend against them vigorously.

The Company is a party to certain other legal proceedings arising in the ordinary course of business. It is the opinion of management that their ultimate disposition will not have a material adverse effect upon the Company's financial position, results of operations or liquidity.

10. SELECTED QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

The following table summarizes the quarterly financial information for the year ended December 31, 2003:

	2003 Fiscal Quarters			
	First	Second	Third	Fourth
	(In thousands)			
Total revenue	\$ 9,460	\$ 12,343	\$ 13,639	\$ 14,105
Total operating expense	12,997	13,775	14,026	13,738
Net other income	786	969	764	754
Net income (loss)	(2,751)	(463)	377	1,121
Net income (loss) applicable to common stock	(2,995)	(712)	(47)	859
Basic and diluted earnings (loss) per common share	(0.14)	(0.02)	0.02	0.05
Basic and diluted earnings (loss) per common share applicable to common stock	(0.15)	(0.04)		0.04

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

The following table summarizes the quarterly financial information for the year ended December 31, 2002:

	2002 Fiscal Quarters			
	First	Second	Third	Fourth
	(In thousands)			
Total revenue	\$ 5,017	\$ 6,484	\$ 7,624	\$ 7,259
Total operating expense	10,171	10,711	12,353	13,859
Net other income (expense)	607	(148)	810	1,273
Net loss	(4,547)	(4,375)	(3,919)	(5,327)
Net loss applicable to common stock	(4,775)	(4,608)	(4,161)	(5,570)
Basic and diluted earnings per common share for net loss	(0.23)	(0.22)	(0.20)	(0.27)
Basic and diluted earnings per common share for net loss applicable to common stock	(0.24)	(0.23)	(0.21)	(0.28)

F-31

Table of Contents**EXHIBIT INDEX**

Exhibit Number	Description	Location
2.1	Agreement and Plan of Reorganization dated November 24, 1998 by and among Atrix Laboratories, Inc., Atrix Acquisition Corporation and ViroTex Corporation.	Incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K, dated November 24, 1998, as filed with the Securities and Exchange Commission on December 9, 1998 (File No. 000-18231).
2.2	Certificate of Merger of Atrix Acquisition Corporation into ViroTex Corporation dated November 24, 1998.	Incorporated by reference to Exhibit 10.2 to Registrant's Current Report on Form 8-K, dated November 24, 1998, as filed with the Securities and Exchange Commission on December 9, 1998 (File No. 000-18231).
3.1	Amended and Restated Certificate of Incorporation.	Incorporated by reference to Exhibit 3.1 to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1998 (File No. 000-18231).
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation.	Incorporated by reference to Exhibit 4.2 to Registrant's Registration Statement on Form S-3 (File No. 333-55634), filed with the Securities and Exchange Commission on June 5, 2001.
3.3	Certificate of Designation of the Series A Preferred Stock filed with the State of Delaware on September 25, 1998.	Incorporated by reference to Exhibit 3.1 to Registrant's Registration Statement on Form 8-A (File No. 000-18231), filed with the Securities and Exchange Commission on October 1, 1998.
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.	Incorporated by reference to Exhibit 99.9 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. 000-18231).
3.5	Ninth Amended and Restated Bylaws.	Incorporated by reference to Exhibit 3.5 to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2001 (File No. 000-18231).
4.1	Form of Common Stock Certificate.	Incorporated by reference to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1993 (File No. 000-18231).
4.2	Amended and Restated Rights Agreement (including form of Right Certificate, as Exhibit A, and form of Summary of Rights, as Exhibit B).	Incorporated by reference to Exhibit 4.1 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).
4.3	Registration Rights Agreement, dated as of July 18, 2000, between Registrant and Elan International Services, Ltd., or EIS.	Incorporated by reference to Exhibit 99.2 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. 000-18231).
4.4	Warrant dated as of July 18, 2000, issued by Registrant to EIS.	Incorporated by reference to Exhibit 99.4 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. 000-18231).

Table of Contents

Exhibit Number	Description	Location
4.5	Convertible Promissory Note, dated as of July 18, 2000, issued by Registrant to EIS.	Incorporated by reference to Exhibit 99.6 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. 000-18231).
4.6	Warrant, dated as of April 4, 2001, issued by Atrix Laboratories, Inc. to Ferghana Partners, Inc.	Incorporated by reference to Exhibit 4.15 to Registrant's Registration Statement on Form S-3 (File No. 333-82250), filed with the Securities and Exchange Commission on February 6, 2002.
10.1	Lease Agreement dated May 11, 1991 between the Registrant and GB Ventures.	Incorporated by reference to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1993 (File No. 000-18231).
10.2	Agreement dated December 16, 1996 between the Registrant and Block Drug Corporation (Block Agreement).**	Incorporated by reference to Exhibit 10 to Registrant's Current Report on Form 8-K, dated December 16, 1996, as filed with the Securities and Exchange Commission on May 20, 1998 (File No. 000-18231).
10.2A	First Amendment to Block Agreement dated June 10, 1997.**	Incorporated by reference to Exhibit 10.3A to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1998 (File No. 000-18231).
10.2B	Second Amendment to Block Agreement dated July 31, 1997.**	Incorporated by reference to Exhibit 10.3B to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1998 (File No. 000-18231).
10.2C	Third Amendment to Block Agreement dated February 4, 1998.**	Incorporated by reference to Exhibit 10.3C to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1998 (File No. 000-18231).
10.2D	Fourth Amendment to Block Agreement dated January 12, 1999.**	Incorporated by reference to Exhibit 10.3D to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1998 (File No. 000-18231).
10.2E	Fifth Amendment to Block Agreement dated January 27, 1999.**	Incorporated by reference to Exhibit 10.3E to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1998 (File No. 000-18231).
10.2F	Sixth Amendment to Block Agreement dated September 24, 1999.**	Incorporated by reference to Exhibit 10.3F to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1999 (File No. 000-18231).
10.2G	Eighth Amendment to Block Agreement dated as of August 24, 2001.**	Incorporated by reference to Exhibit 10.01 to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2001 (File No. 000-18231).
10.3	Amended and Restated Performance Stock Option Plan, as amended.(M)	Incorporated by reference to Exhibit 10.5 to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1998 (File No. 000-18231).

Table of Contents

Exhibit Number	Description	Location
10.4	Non-Qualified Stock Option Plan, as amended.(M)	Incorporated by reference to Exhibit 10.6 to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1998 (File No. 000-18231).
10.5	Non-Employee Director Stock Incentive Plan.(M)	Incorporated by reference to Exhibit 10.7 to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1999 (File No. 000-18231).
10.6	Employment Agreement between Registrant and Dr. J. Steven Garrett dated April 17, 1995.(M)	Incorporated by reference to Exhibit 10.7 to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1998 (File No. 000-18231).
10.7	Employment Agreement between Registrant and Dr. David W. Osborne dated November 24, 1998.(M)	Incorporated by reference to Exhibit 10.9 to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1998 (File No. 000-18231).
10.8	Personal Services Agreement between Registrant and David R. Bethune dated August 10, 1999.(M)	Incorporated by reference to Exhibit 10.12 to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1999 (File No. 000-18231).
10.9	Stock Purchase Agreement, dated as of August 8, 2000, by and between Registrant and Pfizer Inc.	Incorporated by reference to Exhibit 99.1 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. 000-18231).
10.10	Collaborative Research Agreement, dated as of August 8, 2000, by and between Registrant and Pfizer Inc.**	Incorporated by reference to Exhibit 99.2 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. 000-18231).
10.11	License and Royalty Agreement, dated as of August 8, 2000, by and between Registrant and Pfizer Inc.**	Incorporated by reference to Exhibit 99.3 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. 000-18231).
10.12	Collaboration, Development and Supply Agreement dated as of August 28, 2000 between Registrant and Sandoz, Inc (formerly, Geneva Pharmaceuticals, Inc.)**	Incorporated by reference to Exhibit 10.13 to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2000 (File No. 000-18231).
10.13	Securities Purchase Agreement, dated as of July 18, 2000, between Registrant and EIS.**	Incorporated by reference to Exhibit 99.1 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. 000-18231).
10.14	Newco Registration Rights Agreement, dated as of July 18, 2000, among Registrant, Atrix Newco Ltd., or Newco, and EIS.	Incorporated by reference to Exhibit 99.3 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. 000-18231).
10.15	Subscription, Joint Development and Operating Agreement, dated as of July 18, 2000, among EIS, Registrant, Newco and Elan Pharma International Limited, or EPIL.**	Incorporated by reference to Exhibit 99.5 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. 000-18231).

Table of Contents

Exhibit Number	Description	Location
10.16	Company License Agreement, dated as of July 18, 2000, among Registrant, Newco and Elan Corporation plc, or Elan.**	Incorporated by reference to Exhibit 99.7 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. 000-18231).
10.17	EPIL License Agreement, dated as of July 18, 2000 among Elan, EPIL, Newco and Registrant.**	Incorporated by reference to Exhibit 99.8 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. 000-18231).
10.18	Collaboration, License and Supply Agreement, dated as of December 8, 2000, by and between Registrant and Sanofi-Synthelabo Inc.**	Incorporated by reference to Exhibit 99.1 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).
10.19	Termination Agreement, dated as of September 10, 2003, by and between Registrant, Elan Pharma International Limited, Elan International Service, Ltd., and Transmucosal Technologies Ltd.	Incorporated by reference to Exhibit 10.1 to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003 (File No. 000-18231).
10.20	Stock Purchase Agreement, dated as of December 29, 2000, by and between Registrant and Sanofi-Synthelabo.	Incorporated by reference to Exhibit 99.2 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).
10.21	2000 Stock Incentive Plan.(M)	Incorporated by reference to Exhibit 10.25 to Registrant's Annual Report on Form 10-K for the year ended December 31, 2000 (File No. 000-18231).
10.22	License Agreement by and between Registrant and CollaGenex Pharmaceuticals, Inc. dated as of August 24, 2001.**	Incorporated by reference to Exhibit 10.02 to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2001 (File No. 000-18231).
10.23	Stock Purchase Agreement by and between Registrant and CollaGenex Pharmaceuticals, Inc. dated as of August 24, 2001.**	Incorporated by reference to Exhibit 10.03 to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2001 (File No. 000-18231).
10.24	Collaboration, License and Supply Agreement by and between Registrant and Fujisawa Healthcare, Inc., dated October 15, 2001.**	Incorporated by reference to Exhibit 10.04 to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2001 (File No. 000-18231).
10.25	Collaboration, License and Supply Agreement, dated as of April 4, 2001, by and between Registrant and MediGene.**	Incorporated by reference to Exhibit 99.1 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).
10.26	Stock Purchase Agreement, dated as of April 4, 2001, by and between Registrant and MediGene.**	Incorporated by reference to Exhibit 99.2 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).
10.27	2001 Executive Long Term Incentive Compensation Program.(M)	Incorporated by reference to Exhibit 10.28 to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2001 (File No. 000-18231).

Table of Contents

Exhibit Number	Description	Location
21	Subsidiaries of the Registrant.	Incorporated by reference to Exhibit 21 to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000 (File No. 000-18231).
23	Consent of Deloitte & Touche LLP	Filed herewith.
31.1	Rule 13a-14(a) Certification of the Chief Executive Officer	Filed herewith.
31.2	Rule 13a-14(a) Certification of the Chief Financial Officer	Filed herewith.
32.1	Section 1350 Certification of Chief Executive Officer	Filed herewith.
32.2	Section 1350 Certification of Chief Financial Officer	Filed herewith.

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

(M) This item is a management compensatory plan or arrangement required to be filed as an exhibit to this report.