

2003



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COLLAGENEX
PHARMACEUTICALS

2003 Annual Report

Financial Highlights

Consolidated Statement of Operations Data

	Year ended December 31,		
	2003	2002	2001
<i>Amounts in millions</i>			
Revenues:			
Net product sales	\$ 49,038	\$ 42,111	\$ 31,358
Total revenues	\$ 52,859	\$ 44,619	\$ 35,232
Operating expenses:			
Cost of product sales	7,362	6,713	5,825
Research and development	5,462	4,394	3,764
Selling, general and administrative	33,668	32,699	34,010
Net income (loss) allocable to common stockholders	\$ 4,827	\$ (727)	\$ (9,824)
Basic net income (loss) per share allocable to common stockholders	\$ 0.40	\$ (0.06)	\$ (0.94)
Diluted net income (loss) per share allocable to common stockholders	\$ 0.38	\$ (0.06)	\$ (0.94)

Consolidated Balance Sheet Data

	Year ended December 31,		
	2003	2002	2001
<i>Amounts in millions</i>			
Cash, cash equivalents and short-term investments	\$ 32,670	\$ 10,112	\$ 6,171
Working capital	32,010	5,992	6,194
Total assets	43,305	17,634	14,698
Total stockholders' equity	33,956	8,352	7,127

Revenues	\$52,859
	\$44,619
(in thousands)	\$35,232
	\$21,771
	\$16,081

Net Income (Loss)	\$4,827
Allocable to	\$(727)
Common	\$(9,824)
Stockholders	\$(10,519)
(in thousands)	\$(715,683)

Earnings	\$0.38
(Loss)	\$(0.06)
Per Share	\$(0.94)
	\$(1.27)
	\$(71.82)



Corporate Profile

Who We Are

CollaGenex Pharmaceuticals is a specialty pharmaceutical company focused on developing and providing innovative medical therapies for targeted diseases in high potential markets. We currently serve two sectors: dentistry, where we are the leader in the periodontal market with the largest pharmaceutical brand; and dermatology, where we are poised for significant growth.

Marketed Products

Today, CollaGenex markets five products through our professional pharmaceutical sales force. Four of these are differentiated products for use by dentists and periodontists to effectively treat various aspects of periodontal disease; our fifth product marks our entry into dermatology:

- Periostat®, the first and only systemic pharmaceutical for periodontal disease
- Atridox®, a locally-applied, anti-microbial for periodontitis
- Atrisorb FreeFlow®, a guided tissue regeneration (GTR) product
- Atrisorb-D FreeFlow®, a GTR barrier product with doxycycline
- Pandel®, a mid-potency corticosteroid for atopic dermatitis and psoriasis

Investing in the Future

Product development is the cornerstone of our efforts to invest in the future of CollaGenex. We have two strong, proprietary platform technologies, IMPACS® and Restoraderm®, from which we can identify, develop and commercialize additional products.

Our IMPACS technology encompasses several compounds, including Periostat, that inhibit multiple proteases and cytokines. These properties could offer broad utility in treating many inflammatory and degenerative diseases. We continue to screen additional IMPACS compounds for potential efficacy in treating a variety of disease conditions and will pursue development partnerships for indications that fall outside the Company's areas of focus. This is the basis of our collaboration with the National Cancer Institute (NCI) to develop Metastat® for the treatment of Kaposi's sarcoma and other metastatic cancers.

Our Restoraderm technology is a unique drug delivery system that enables us to develop topical prescription pharmaceuticals for the treatment of dermatologic conditions. The first two products under development will be for acne and psoriasis and will consolidate our entry into dermatology.

Our investments in new products build on the momentum we have created in the dental market and will fuel the next phase of the Company's growth. With our experienced development team, our proven ability to bring products through regulatory review and the potential to build brands through our established sales and marketing infrastructure, CollaGenex is well positioned to continue providing innovative products that advance the care of our patients.



Letter to Our Shareholders

“We completed the largest clinical study ever conducted for evaluating a systemic treatment for rosacea when we successfully concluded our Phase III study in Periostat.”

Dear Shareholders,

2003 was a strong and rewarding year for CollaGenex. We continued to see increasing acceptance of our products, particularly Periostat, across the dental community, and we maintained our momentum in the dermatology market with the accelerating penetration of Pandel.

Net product sales increased 16.4% to \$49.0 million and total revenues grew 18.5% to \$52.9 million in 2003. The Company also achieved its first full year of profitability with net income allocable to common stockholders in 2003 of \$4.8 million, or \$0.38 per diluted share, compared to a net loss allocable to common stockholders of \$727,000, or \$0.06 per diluted share, in 2002.

We made considerable progress on our pipeline in 2003, particularly with the development of Periostat to treat dermatological indications. In fact, we successfully completed the largest Phase III clinical study ever, evaluating a systemic treatment for rosacea with Periostat. The highly positive data from this large-scale trial enables us to move forward with confidence as we further develop the franchise with our new, once-daily formulation of Periostat.

Research on Periostat as a potential treatment for rosacea and acne also received national attention in 2003 with the publication of favorable data in two peer-reviewed journals. *Archives of Dermatology* highlighted the successful outcome of a Phase II clinical trial of Periostat in the treatment of moderate facial acne, while *Skin Med* featured the use of sub-antimicrobial dose doxycycline in acne and rosacea. This article also included a report describing the positive results of a physician-sponsored, open-label clinical study of Periostat as a monotherapy in treating rosacea. In addition, results of a Phase II clinical study evaluating Periostat as adjunctive therapy to MetroLotion® (metronidazole) in treating rosacea demonstrated that patients treated with a combination of these two products experienced significantly better clinical outcomes than those treated with MetroLotion alone.



The Company took decisive steps in 2003 to resolve outstanding legal issues affecting the proprietary position of Periostat. CollaGenex was granted a preliminary injunction preventing the FDA from approving generic versions of Periostat until a federal court judge decides on our claim that Periostat was denied the protection of the Hatch-Waxman Act when the FDA approved the product in 1998. Though we expected this case would be heard in January 2004, a date has not yet been set.

In addition, CollaGenex settled all litigation with West-ward Pharmaceuticals Corporation. Under the terms of the settlement, West-ward agreed that the Periostat patents are valid and that they were infringed by the filing of West-ward's ANDA, and that they would be further infringed by the manufacture and sale of a generic version of Periostat. We believe West-ward's action strengthens our patent infringement case against United Research Laboratories, Inc./Mutual Pharmaceutical Company, Inc. which is scheduled to be heard in the Eastern District Court of New York in mid-2005.

We also significantly advanced the development of Periostat MR™, our "once-a-day" formulation, to extend the franchise beyond the expiration of the last critical patent covering the current twice-a-day formulation in 2007. We completed the necessary pharmacokinetic studies and confirmed that the lead formulation falls within our pre-defined criteria for maximum serum concentration and total dose delivered. This enables us to begin Phase III clinical trials with Periostat MR in periodontitis and rosacea patients during the first and second quarters of 2004, respectively, and keeps us on target to achieve our goal of approval for both indications during 2005, with subsequent launches in 2006.

As we focus on CollaGenex's continuing growth and success, we will address the unique needs of each of our markets. Accordingly, we will realign the Company's sales and marketing team into two dedicated units, one focused on dentistry and the other on dermatology. We believe this will increase the yield from our sales force for current products and accelerate the market penetration of new products. We will further leverage this new structure by continuing to in-license or acquire additional dental and dermatology products and expedite the use of Periostat MR in periodontitis, rosacea and, potentially, acne.



Letter to Our Shareholders (continued)

“We have compiled an extensive body of clinical data and are demonstrating the proven clinical benefits of Periostat through multiple education programs for dentists and periodontists.”

In our specialty dental pharmaceutical business, we are concentrating on driving organic growth of current products through our “evidence-based” marketing initiative. We have compiled an extensive body of clinical data and are demonstrating the proven clinical benefits of Periostat through multiple education programs for dentists and periodontists.

We believe these efforts will be greatly enhanced by the recent findings of the American Academy of Periodontology 2003 Workshop on Contemporary Sciences in Clinical Periodontics. The workshop proceeding found that, based on the clinical data available, there was a “strong” level of evidence supporting the use of Periostat as an adjunct to conventional therapy in the management of chronic periodontitis. We are pleased to report this was the highest ranking possible.

Our Phase IV program for Periostat will be expanded, specifically targeting “at risk” patients, such as smokers and diabetics, who are particularly difficult to treat. We will also use the findings of other recently completed Phase IV trials to demonstrate the efficacy and utility of Periostat in managing periodontal disease while encouraging the concomitant and synergistic use of Atridox, a locally-applied, anti-microbial product that we market to dentists under an exclusive license from Atrix Laboratories.

As we build our dermatology business by increasing sales of Pandel, adding other prescription dermatology brands and advancing Periostat MR, we are also aggressively working to leverage our IMPACS and Restoraderm technologies to develop new pharmaceutical products. In the near-term, we are working on two Restoraderm products, one to treat acne and the second for psoriasis. The launch dates of these prescription products are planned for 2005 and 2007, respectively.

We are also expediting the screening of other IMPACS compounds, initially for dermatological use, as we maintain our drive to build the pipeline, broaden our proprietary product base and secure longer-term growth opportunities.

Essential to our continued success is the strength of our management team. In January 2004, we added a chief medical officer to lead our development activities on current and future products. We also plan to recruit a senior business development executive in 2004 to achieve the dual goals of expanding our marketed dental and dermatology portfolios while forging out-licensing and co-development partnerships.



The conclusion of 2003 marked the end of an era at CollaGenex with Dr. Brian Gallagher's retirement as Chairman, President and Chief Executive Officer of CollaGenex after nine years of leadership. He will continue to serve on the Board as a Director. During his tenure, Dr. Gallagher led the development and launch of Periostat, the most successful systemic pharmaceutical ever introduced to the dental market, and established the foundation for the Company's future growth.

My decision to join CollaGenex in December 2003 was due to the strength of the Company's currently marketed products, the quality of its pipeline, the depth of the IMPACS and Restoraderm technologies and the significant opportunity to commercialize these assets through an established infrastructure.

I firmly believe that by continuing to invest in the future of CollaGenex we can successfully build on that base and maximize the opportunities presented to us. We must, however, closely monitor, scrutinize and evaluate the returns from all of our investments in product development, infrastructure and marketing to ensure that we also build the long-term value of CollaGenex for our shareholders.

I am confident that CollaGenex has the right combination of people, products and technologies to become a major diversified specialty pharmaceutical company. I look forward to leading the Company to the next level of its corporate development and to the exciting times that lie ahead.

Sincerely,

President and Chief Executive Officer



Colin W. Stewart
President & Chief Executive Officer

Product Pipeline

	PRE-CLINICAL	PHASE I	PHASE II	PHASE III	APPROVED & MARKETED	PHASE IV
Dentistry						
PERIOSTAT Adult periodontitis; systemic treatment approved as adjunctive therapy to SRP						
ATRIDOX Chronic adult periodontitis; locally-applied antimicrobial						
ATRISORB FREEFLOW Periodontal disease; used during GTR surgery						
ATRISORB-D FREEFLOW Periodontal disease; used during GTR surgery						
PERIOSTAT MR Periodontal disease; once-daily formulation					2006 est.	
Dermatology						
PANDEL Atopic dermatitis and psoriasis						
PERIOSTAT Rosacea						
RESTORADERM-ACNE Topical proprietary acne product						2005 est.
RESTORADERM-PSORIASIS Topical proprietary psoriasis product						2007 est.
PERIOSTAT MR Rosacea; once-daily formulation						2006 est.
COL-3 Rosacea						
Other						
METASTAT Kaposi's sarcoma						
PERIOSTAT Meibomianitis (ocular rosacea)						Pilot
COL-308 Dermatologic and other indications						
COL-1002 Dermatologic and other indications						

2003



Market Overview

Dentistry

CollaGenex is the leading specialty pharmaceutical company serving the needs of the periodontal and dental communities. Our flagship product, Periostat (doxycycline hyclate tablets, 20 mg), is the first and only systemic treatment for adult periodontitis. At this sub-antimicrobial dose, Periostat works by suppressing the enzymes that destroy periodontal support tissue and stimulating bone protein synthesis. It is prescribed as an adjunct to scaling and root planing (SRP), which involves the mechanical removal of hardened bacterial plaque above and below the gum line.

Since Periostat's approval in October 1998, we have worked diligently to build the market for it through evidence-based promotional and educational initiatives that focus on the significant body of science behind this product. Today, Periostat is the largest pharmaceutical brand in the dental market. More than three million prescriptions have been filled since its launch, and more than two million patients have benefited from treatment with Periostat. We continue to increase our market penetration of Periostat and see significant opportunities for further growth among the more than 15 million U.S. patients who seek treatment for this disease annually. Today, over 100 million people have access to Periostat at nominal co-pay levels through their HMOs, managed health plans and pharmacy benefit managers, and Periostat is reimbursed on nearly all state Medicaid plans.

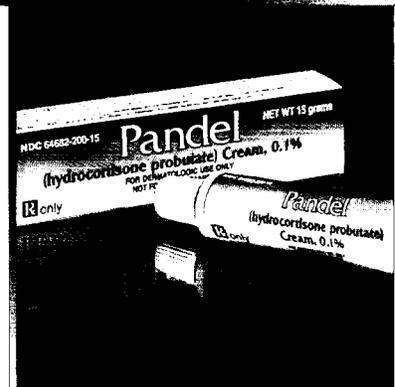
Furthermore, in recent findings from the American Academy of Periodontology 2003 Workshop on Contemporary Sciences in Clinical Periodontics, the use of Periostat as an adjunct to conventional therapy in the management of chronic periodontitis received a "strong" ranking, the highest score it could achieve. Moreover, this ranking was determined by a distinguished panel of leading periodontal clinicians and researchers which was given the task of analyzing the evidence as part of a rigorous systematic review for the use of adjunctive host-modulating agents in the treatment of periodontitis. The CollaGenex dental sales force will educate the periodontists and dentists on the clinical value of this important finding throughout 2004.

While CollaGenex's focus is predominantly on the U.S. market, we are pleased to report that Periostat is now commercially available in seven countries throughout North America and Europe. Consistent with our global marketing strategy, we expanded its distribution by entering into exclusive marketing and distribution agreements with a Zurich-based company, Karr Dental Ltd., to market Periostat to the Swiss market, and Pharmascience Inc. in Canada, where approximately 12,000 dentists routinely prescribe pharmaceuticals. We currently market Periostat directly to dentists in the United Kingdom through our local subsidiary, CollaGenex International Limited, which is also responsible for the management of our other European distribution partners.



We continue to **SUCCESSFULLY**
BUILD our two core franchises,
DENTISTRY AND DERMATOLOGY,
by **TARGETING HIGH-POTENTIAL**
PRESCRIBING DOCTORS in the
dental and dermatology communities
across the United States.





Our second product in the dental market is Atridox (doxycycline hyclate 10%). This locally-applied, slow-release gel delivers antibiotic levels of doxycycline into periodontal pockets, addressing the need for site-specific bacterial reduction. Atridox is FDA-approved to increase clinical attachment, reduce pocket depth and reduce probing-related bleeding in patients with chronic adult periodontitis. A single unit of Atridox can be used to treat multiple sites, making it an economically attractive therapy to other locally-applied anti-microbials. In 2003, CollaGenex initiated several new marketing programs designed to highlight Atridox's strong clinical efficacy and cost-effectiveness.

The number of dental professionals adopting a dual-pronged approach to treating periodontal disease by suppressing elevated enzymes and eradicating harmful bacteria continued to grow in 2003. Many of these dentists are using a combined therapy of Periostat and Atridox to achieve optimal results. To validate this combination therapy, we initiated a 180-patient, multi-center, double-blinded, placebo-controlled trial evaluating the combined use of Periostat and Atridox in treating adult periodontitis. This study combined full-mouth SRP at baseline, followed by six months of treatment with Periostat or placebo. Atridox was applied to selected tooth sites in the active group at baseline and at three months. This trial was completed in late 2003 and we anticipate the results will be published during 2004.

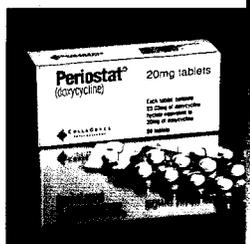
Our sales force also markets Atrisorb FreeFlow and Atrisorb-D FreeFlow, two bioadhesive, bioabsorbable barriers used to enhance healing during and after Guided Tissue Regeneration (GTR) procedures. Both products facilitate the regeneration and integration of tissue components by promoting the synthesis of new bone. Atrisorb-D also incorporates an antibiotic, doxycycline, to reduce bacterial colonization of the barrier at the site of GTR surgery, thereby reducing the incidence of infection and improving recovery times.

Dermatology

Our decision in 2003 to enter the dermatology market was based on the large market opportunity and compelling reports that patients treated with Periostat for periodontal disease experienced a reduction in the symptoms of various inflammatory skin diseases, including acne and rosacea. Clinical studies to confirm the efficacy of Periostat in dermatologic indications are ongoing and other development products from our IMPACS and Restoraderm platforms are being formulated and studied. These will all contribute to a tangible, near-term opportunity to penetrate the \$5.6 billion dermatology market.

As part of our entry strategy, we launched Pandel (hydrocortisone probutate cream, 0.1%) in late 2002. This product is a mid-potency, topical corticosteroid indicated for the relief of mild-to-moderate inflammatory skin disorders, such as atopic dermatitis and psoriasis. As a result of our marketing efforts to approximately 4,000 dermatologists, Pandel is now the fastest growing product within the \$125 million, branded mid-potency steroid market.

“Our R&D strategy is prioritized to strengthen and expand our dental and dermatology product lines...”



Future

We will continue to drive our business through a combination of organic growth from our existing brands and proprietary launches from our IMPACS and Restoraderm technologies, augmented by targeted, in-licensing opportunities. Although our near-term focus will remain in dentistry and dermatology, we are assessing our pipeline potential for other specialty pharmaceutical sectors.

Our R&D strategy is prioritized to strengthen and expand our dental and dermatology product lines, as well as to identify new indications for our pipeline compounds in other inflammatory and degenerative conditions that could be developed alone by Collegenex, or in partnership with another company. Klaus Theobald, M.D., Ph.D., our new Chief Medical Officer, is leading the clinical development team and will ensure that time-to-market is minimized for all candidate compounds.

Currently, our lead programs include the development of a once-daily formulation of Periostat to treat adult periodontitis and rosacea, development of the Restoraderm delivery system for differentiated topical dermatology products and the development of next-generation IMPACS compounds.

Periostat: Extending the Franchise

Collegenex is rapidly advancing the development of Periostat MR, a novel, once-daily version of Periostat based on a patented controlled release delivery technology that we licensed from Shire Laboratories.

In 2003, we completed initial Phase I clinical studies, thereby establishing the pharmacokinetics of our lead formulation for this product. These studies confirmed that it falls within our pre-defined criteria for maximum plasma concentration and total dose delivered. With this stage complete, we will initiate Phase III clinical trials of Periostat MR in periodontitis and rosacea patients by mid-2004.

Building on anecdotal and subsequent clinical evidence that Periostat's anti-inflammatory activity has broad potential utility beyond the dental arena, we have evaluated and continue to assess this product in several indications involving inflammation and degradation of the connective tissues, notably acne, rosacea and meibomianitis. Of these, Collegenex has advanced our research farthest in rosacea. We now have developed an impressive body of positive clinical data to demonstrate the utility of Periostat to position the product to meet the large, unsatisfied need for a safe and effective systemic treatment.

For example, a physician-sponsored, open-label, 50-patient study indicated that the use of Periostat resulted in a significant clearing of inflammatory lesions as well as a reduction in erythema and telangiectatic vessels. An article describing these results was subsequently published in the peer-reviewed journal *Skin Med*.

2003



During 2003, CollaGenex also completed the largest clinical trial ever conducted to evaluate a systemic treatment for rosacea. This 134-patient, multi-center, double-blinded, placebo-controlled Phase III clinical trial demonstrated that Periostat offers significant benefits to rosacea patients.

Patients treated with Periostat showed a continuous improvement during the 16-week course of the study compared to patients on placebo. Patients on Periostat also had a significantly greater reduction in the number of inflammatory lesions (papules and pustules) compared to patients on placebo. In this primary efficacy analysis, the improvement vs. baseline was both clinically and statistically highly significant ($P = 0.009$).

Also in this study, overall clinical disease severity as measured using the Clinician's Global Severity Assessment Scale declined significantly in the group of patients treated with Periostat compared to placebo. A greater number of patients on Periostat showed a complete clearing of the disease at 16 weeks compared to those patients on placebo ($P = 0.014$).

Erythema scores are a more difficult endpoint to interpret because erythema (skin redness) is episodic and measurements are highly subjective. Nonetheless, erythema scores in patients receiving Periostat showed an overall response towards improvement compared with patients in the placebo group ($P = 0.08$).

This positive data validate our commitment to developing Periostat for the dermatology market. In line with CollaGenex's plan to extend the indications for this product based on our once-daily formulation, we will aim to initiate pivotal Phase III trials by mid-2004 following agreement on the final program with the FDA.

Other studies indicate that Periostat is also a potential treatment for acne. In April 2003, the journal *Archives of Dermatology* published favorable data from a multi-center, randomized, placebo-controlled Phase II clinical trial of Periostat in the treatment of this common skin condition. Periostat significantly reduced the number of inflammatory and non-inflammatory lesions in patients with moderate facial acne without significant side effects. Notably, the use of Periostat did not result in an increase in resistant organisms or an overgrowth of opportunistic pathogens, effects often observed with the chronic use of higher doses of tetracycline antibiotics.



PRODUCT DEVELOPMENT and a

STRONG PIPELINE are cornerstones

of **CollaGenex's** growth strategy.

RESEARCH EXPERTISE we

derive from our technology license

and longstanding relationship with

scientists at **SUNY** will support the

development of new products based

on our **IMPACS TECHNOLOGY,**

while our **RESTORADERM**

TECHNOLOGY will be a source of

differentiated topical products to augment

our **DERMATOLOGY** franchise.





In addition, data were reported from a double-blinded, placebo-controlled clinical study evaluating the combined use of Periostat and MetroLotion (metronidazole) in treating rosacea, reflecting the common practice of prescribing combination therapies in treating skin diseases. Treatment with the combination regimen resulted in significantly improved clinical outcomes versus MetroLotion alone. At all time points during the course of the study, patients receiving Periostat had significantly fewer inflammatory lesions than those on placebo ($p < 0.05$). In addition, there was a trend towards improvement in patients' erythema scores.

Leveraging the IMPACS Platform

CollaGenex is pursuing a number of strategies to capitalize on the benefits of our IMPACS platform technology. In addition to advancing the study of sub-antimicrobial doses of commercially available tetracyclines, e.g. Periostat, we are developing novel, proprietary IMPACS compounds based on non-antimicrobial, chemically modified tetracycline derivatives. The most advanced compound of this product group, COL-3, is being studied at various doses for a variety of indications, including Kaposi's sarcoma and rosacea.

The key advantages to our IMPACS platform technology are its broad-spectrum, anti-inflammatory activity, preservation of connective tissue and oral bioavailability. IMPACS products are derived from CollaGenex's perpetual technology license with the State University of New York (SUNY).

Metastat

Metastat is the trade name for our orally administered angiogenesis inhibitor based on our compound, COL-3. We are collaborating with the NCI under a Cooperative Research and Development Agreement to develop Metastat as a potential treatment for HIV-related Kaposi's sarcoma. The NCI is sponsoring an ongoing 75-patient Phase II study evaluating Metastat in this indication, for which there is a significant unmet need. This multi-center, open-label study, which is being conducted by the AIDS Malignancy Consortium, was fully enrolled in 2003. Primary endpoints of the study are tumor response rate and response duration as well as serum levels of pro-angiogenic mediators, which are measures of biologic activity.

This study builds on encouraging results from a Phase I/II dose-escalation study of Metastat in 18 patients with recurrent HIV-related Kaposi's sarcoma. Data from this study, which were published in the *Journal of Clinical Oncology*, demonstrated a 44% clinical response rate and indicated that Metastat was generally well tolerated. It is anticipated that data from the ongoing Phase II study will help establish an appropriate dose for an NDA-directed Phase III study, the design of which is currently in development with the NCI.



Restoraderm Drug Delivery Technology

Our second platform technology, Restoraderm, is an advanced lipid delivery system. It has broad potential applications, including the treatment of disrupted skin barrier and the dermal and transdermal delivery of drugs. CollaGenex holds the exclusive worldwide license to this technology from its originator.

Restoraderm's unique, water-based composition mimics the body's natural skin lipids and contains both ceramides and lipid precursors. This composition promotes synthesis of cholesterol and is suitable for both water- and fat-soluble drugs. A differentiated micro-carrier system within the formulation allows for control of release and penetration depth.

As part of our strategy to build a diversified portfolio of dermatology products, CollaGenex is developing a line of topical pharmaceuticals that leverage the Restoraderm technology. We are currently formulating the first two Restoraderm candidates for the topical delivery of approved prescription dermatological pharmaceuticals and plan to launch these two products in 2005 and 2007.

Pursuing Out-Licensing Opportunities

As with Metastat, our other products and technologies have potential utility in therapeutic areas beyond the dentistry and dermatology markets where CollaGenex is presently focused. We have established strategic alliances with a number of companies, including Medtronic and EpiTan, for specific indications outside our core markets. We will continue to explore and enter into licensing agreements for additional non-core indications.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549



FORM 10-K
FOR ANNUAL AND TRANSITION REPORTS
PURSUANT TO SECTIONS 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

(Mark One)

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2003

OR

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 0-28308

COLLAGENEX PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

52-1758016
(I.R.S. Employer Identification No.)

41 University Drive,
Newtown, Pennsylvania
(Address of Principal Executive Offices)

18940
(Zip Code)

Registrant's telephone number, including area code (215) 579-7388

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

Title of each class	Name of Each Exchange on Which Registered
None	

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

Common Stock, \$0.01 par value
(Title of Class)

Preferred Stock Purchase Rights, \$0.01 par value
(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 twelve (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 ninety (90) days. Yes: No:

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

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

The aggregate market value of the registrant's voting shares of common stock held by non-affiliates of the registrant on June 30, 2003, based on \$13.26 per share, the last reported sale price on the NASDAQ National Market on that date, was \$130.6 million.

The number of shares outstanding of each of the registrant's classes of common stock, as of March 11, 2004:

Class	Number of Shares
Common Stock, \$0.01 par value	14,121,677

The following documents are incorporated by reference into the Annual Report on Form 10-K: Portions of the registrant's definitive Proxy Statement for its 2004 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report.

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PART I

Item 1. *Business.*

General

CollaGenex Pharmaceuticals, Inc. and subsidiaries is a specialty pharmaceutical company currently focused on providing innovative medical therapies to the dental and dermatology markets. Our first product, Periostat®, is an orally administered, prescription pharmaceutical product that was approved by the United States Food and Drug Administration in September 1998 and is the first and only dental pharmaceutical to treat adult periodontitis by inhibiting the enzymes that destroy periodontal support tissues. Periostat is indicated as an adjunct to scaling and root planing, or SRP, the most prevalent therapy for adult periodontitis, to promote attachment level gain and to reduce pocket depth in patients with adult periodontitis. Adult periodontitis, a chronic disease characterized by the progressive loss of attachment between the tooth root and the surrounding periodontal structures, may result in tooth loss if untreated.

We currently market Periostat and other pharmaceutical products to the dental and dermatology communities through our own professional pharmaceutical sales force of approximately 115 sales representatives and managers. Pursuant to an exclusive License and Marketing Agreement with Atrix Laboratories, Inc., we began, in October 2001, to actively market Atrix's proprietary dental products, Atridox® and Atrisorb FreeFlow®, and Atrisorb-D®, to the United States dental market. In May 2002, we executed a sublicense agreement with Altana Inc. to market and distribute Pandel®, a prescription mid-potency topical corticosteroid product developed by Altana Inc. to dermatologists in the United States and Puerto Rico. We distribute Periostat and Pandel exclusively through drug wholesalers in the United States. Periostat is also sold through wholesalers and direct to dentists in the United Kingdom through our wholly-owned subsidiary, CollaGenex International, Ltd., and by distributors and licensees in certain other overseas markets. The Atrix dental products are distributed through a specialty distributor who sells these products directly to dental practitioners in the United States and Puerto Rico.

Research has shown that certain unique properties of the tetracyclines discovered during the development of Periostat may be applicable to other diseases involving inflammation and/or destruction of the body's connective tissues, including acne, rosacea, meibomianitis and cancer metastasis, among others. CollaGenex is further evaluating Periostat and a series of novel, proprietary compounds known as IMPACS® (Inhibitors of Multiple Proteases and Cytokines), to assess whether they are safe and effective in these applications. Phase I clinical trials for Metastat®, our lead compound for the treatment of metastatic cancer, were initiated under the sponsorship of the National Cancer Institute, or NCI. In Phase I clinical trials, Metastat demonstrated an overall tumor response rate of 44% in patients with Kaposi's sarcoma, and the NCI is sponsoring a Phase II clinical trial to continue to evaluate the safety and efficacy of Metastat in HIV-related Kaposi's sarcoma. We anticipate that the results of this trial will be available during the second quarter of 2004.

In 2003, we continued to implement our plans to expand into the dermatology market. A growing number of studies have shown the safety and efficacy of Periostat to treat dermatological conditions and diseases, and two of these studies have been published in peer-reviewed medical journals. There is no FDA or other regulatory approval for the use of Periostat to treat any dermatological condition or disease. In September 2001, we announced the results of a 59-patient, double-blinded, placebo-controlled clinical trial designed to evaluate the efficacy of Periostat to treat adult patients with acne. The results from this trial revealed that the patients who were administered Periostat experienced a greater than 50% reduction in the number of comedones, inflammatory lesions and total lesions relative to baseline lesion counts, a statistically significant improvement compared to the patients in the placebo group.

During 2002 and 2003, we conducted a double-blinded, placebo-controlled, 134-patient Phase III clinical trial to evaluate the safety and efficacy of Periostat in the treatment of rosacea, a dermatological condition that affects approximately 15 to 20 million patients in the United States. In February 2004, we announced the positive

outcome of that study. Preliminary data analysis indicated that patients treated with Periostat showed a continuous improvement during the 16-week course of the study compared to patients on placebo. In the study, patients on Periostat had a significantly greater reduction in the number of inflammatory lesions (papules and pustules) compared to patients on placebo. This improvement was both clinically and statistically highly significant. Overall clinical disease severity based on the Clinician's Global Severity Assessment Scale declined significantly in the group of patients treated with Periostat compared to placebo, with a greater number of patients on Periostat showing a complete clearing of the disease at 16 weeks compared to those patients on placebo. In addition, the erythema, or persistent redness of the skin, in patients in the Periostat group showed a trend towards greater improvement compared to patients in the placebo group.

In February 2002, we announced that we had licensed a new dermal and transdermal drug delivery technology called Restoraderm™, which we intend to develop for dermatological applications. Several products based on the Restoraderm technology have completed preliminary stability studies, and we are developing plans to launch two products based on this technology by 2007. Manufacturing arrangements are currently being pursued for the first of these products, which we expect to launch in 2005. We are actively seeking additional product licensing opportunities to augment our near-term offerings to the dermatology market.

In May 2002, we executed a sublicense Agreement with Altana Inc. with respect to the marketing and distribution of Pandel. Our sales force has been promoting Pandel to the dermatological community since July 2002.

Our core IMPACS technology is licensed on a perpetual basis from the Research Foundation of the State University of New York at Stony Brook, or SUNY. SUNY also conducts research and development on other potential applications of the core technology on a project basis.

We are a Delaware corporation. We were incorporated and began operations in 1992 under the name CollaGenex, Inc. and changed our name to CollaGenex Pharmaceuticals, Inc. in April 1996. Our principal executive offices are located at 41 University Drive, Suite 200, Newtown, Pennsylvania 18940, and our telephone number is (215) 579-7388.

In this Annual Report on Form 10-K, the terms "CollaGenex," "we," "us" and "our" includes CollaGenex Pharmaceuticals, Inc. and its subsidiaries.

Periostat®, Metastat®, Dermostat®, Nephrostat®, Osteostat®, Arthrostat®, Rheumastat®, Corneostat®, Gingistat®, IMPACS™, PS20®, The Whole Mouth Treatment®, Restoraderm™, Dentaplex®, Lytra™, Periostat-MR™ and Xerostat™ are United States trademarks of CollaGenex Pharmaceuticals, Inc. Periostat®, Nephrostat®, Optistat®, Xerostat® and IMPACS™ are European Community trademarks of CollaGenex Pharmaceuticals, Inc. Periostat®, Nephrostat®, Optistat®, Xerostat®, IMPACS®, Dentaplex®, Restoraderm™, Pericycline®, Periostat® and Periostat-SR® are United Kingdom trademarks of our wholly-owned subsidiary, CollaGenex International Ltd. CollaGenex®, PS20®, Dermastat®, Periostan®, "C" Logo® and "The Whole Mouth Treatment" Logo® are European Community and United Kingdom trademarks of CollaGenex International Ltd. Pericycline™, Restoraderm™ and Periostat-SR™ are European Community Trademarks of CollaGenex International Ltd. All other trade names, trademarks or service marks appearing in this Annual Report are the property of their respective owners and are not property of CollaGenex Pharmaceuticals, Inc. or any of our subsidiaries.

Products and Product Agreements

Our Current Marketed Products

Our current proprietary and licensed products are summarized below:

<u>Products</u>	<u>Territory Where Marketed</u>	<u>Marketing Partner</u>
Periostat	United States and Puerto Rico	Not applicable
Periostat	United Kingdom	CollaGenex International Ltd.
Periostat	Israel	Taro Pharmaceuticals, Inc
Periostat	Portugal	ISDIN S.A
Periostat	Austria	Willovonseder & Marchesani Ges.m.b.H & Co. KG
Periostat	Switzerland	Karr Dental, Inc.
Periostat	Canada	Pharmascience, Inc.
Atridox	United States and Puerto Rico	Atrix Laboratories, Inc.
Atrisorb FreeFlow	United States and Puerto Rico	Atrix Laboratories, Inc.
Atrisorb-D	United States and Puerto Rico	Atrix Laboratories, Inc.
Pandel	United States and Puerto Rico	Altana, Inc.

Periostat

Adult periodontitis is a chronic disease characterized by the progressive loss of attachment between the periodontal ligament and the surrounding alveolar bone, ultimately resulting in tooth loss. According to industry data, in the United States alone, an estimated one-third of all adults, or approximately 67 million people, suffer from some form of periodontal disease. Approximately 13 million people seek professional treatment annually for periodontal disease, resulting in over 15 million periodontal procedures and annual expenditures of approximately \$6.0 billion, primarily for procedures and surgeries performed by a periodontist or a dental professional.

The most prevalent therapy for adult periodontitis is SRP, a mechanical procedure that removes bacteria deposits called plaque from tooth and root surfaces above and below the gum line. Periostat is the first orally administered, systemically delivered pharmaceutical indicated as an adjunct to SRP to promote attachment level gain and to reduce pocket depth in patients with adult periodontitis. The Proceedings of the American Academy of Periodontology 2003 Workshop on Contemporary Sciences in Clinical Periodontics, published January 22, 2004, set forth a detailed report and summary by leading United States academic and clinical periodontology experts who concluded that the peer-reviewed scientific evidence strongly supports the use of Periostat as an adjunct to conventional therapy, such as SRP, in the management of chronic periodontitis.

Periostat, a 20 mg dose of doxycycline hyclate, is a unique sub-anti-microbial dosage strength that suppresses the chronic and progressive tissue degradation characteristic of periodontitis without exerting any anti-microbial effect. Doxycycline is an active ingredient of several FDA approved drugs and has been in use, at higher dosages, for approximately 35 years, for the treatment of microbial infections and, along with other tetracyclines, has a well established safety record. Periostat is intended to be taken orally by the patient between dental visits. Periostat's mechanism of action is believed in part to be through the down-regulation of the activity of collagenases, enzymes that belong to a broad class of enzymes known as matrix metalloproteinases. Collagenase is excessively produced as a result of inflammation resulting from bacterial infection in the gums. In September 1998, the FDA granted United States marketing approval for Periostat as an adjunct to SRP to promote attachment level gain and reduce pocket depth in patients with adult periodontitis. Periostat was made available for prescription use in November 1998 and was fully launched commercially in January 1999. Since

January 1999, more than 3.0 million Periostat prescriptions have been filled and over 40,000 dentists have written a Periostat prescription. Periostat tablets are manufactured for us by Pharmaceutical Manufacturing Research Services, Inc., a contract manufacturing company. We intend to supply Periostat tablets to our foreign marketing partners upon receipt of requisite regulatory approvals, if at all, for distribution in countries other than the United States and the United Kingdom.

We currently actively sell Periostat in the United States and the United Kingdom and our partners have begun initial sales of Periostat in Israel, Portugal, Austria, Switzerland and Canada. We also have other marketing and distribution partnerships for the sale of Periostat in various foreign countries, subject to regulatory approval.

Atridox, Atrisorb FreeFlow and Atrisorb-D

Pursuant to the terms of an exclusive License and Marketing Agreement that we executed with Atrix Laboratories, Inc. in August 2001, we obtained the right to market, sell and distribute Atrix's proprietary dental products, Atridox, Atrisorb FreeFlow and Atrisorb-D to the United States dental community. We believe that these products generally complement Periostat in the treatment of adult periodontitis.

Atridox is a locally-applied, anti-microbial therapy for the treatment of chronic adult periodontitis. Atridox uses Atrix's patented drug delivery technology, Atrigel[®], for the targeted delivery of doxycycline, which has been shown to reduce the levels of bacteria in the periodontal pocket. Atridox is a gel that is placed into affected periodontal pockets by a dental professional and resorbs over a two week period. In pivotal double-blinded, placebo-controlled clinical trials conducted by Atrix, the administration of Atridox was shown to increase attachment level between the gums and the teeth and decrease periodontal pocket depth in patients with adult periodontitis.

Atrisorb FreeFlow is a guided tissue regeneration, or GTR, barrier product used in the surgical treatment of periodontal defects to help regenerate tissue. In periodontal surgery, a section of the gums called a flap is cut away from the underlying bone structure to allow the periodontist to repair the periodontal support structure. When the flap is subsequently repositioned, a membrane barrier product such as Atrisorb FreeFlow is placed between the flap and the bone to prevent the downgrowth of epithelial tissues, which interferes with the re-attachment of the gums to the teeth.

Atrisorb-D is the first GTR barrier product to incorporate an antibiotic, which has been shown to reduce the incidence of infections during GTR procedures.

Under the terms of our License and Marketing Agreement with Atrix, we committed to: (i) expend no less than \$2.0 million in advertising and selling expenses related to the Atrix products during the fiscal year beginning January 1, 2002, during which year we met this requirement; (ii) maintain, for a period of 24 months, a force of no less than 90 full time dental consultants and divisional and regional managers to make sales and product recommendation calls on dental professionals (which requirement we have fulfilled); and (iii) making the Atrix products the subject of a specific number of detail calls in the United States during 2002, which we achieved. We are also required to make certain annual minimum expenditures for advertising and promotional activities over the term of the agreement beginning January 1, 2003, including: (i) the lesser of \$4.0 million or 30% of our contribution margin, as defined in the agreement, relating to a specific Atrix product that we market, and (ii) the lesser of \$2.0 million or 30% of our contribution margin, as defined in the agreement, relating to a separate Atrix product that we market. These annual requirements were met by us in 2003. In 2003, we and Atrix agreed to share funding for training and maintaining a corps of dental hygienists who would serve as part-time, professional sales associates in the dental market, with a specific focus on the Atrix products. This 2003 addendum will terminate on December 31, 2004, unless extended by Atrix and us.

The License and Marketing Agreement terminates incrementally with respect to each Atrix product, upon each successive expiration date of the patent protection afforded to such product. We may terminate the License

and Marketing Agreement at any time, with or without cause, upon twelve (12) months prior written notice to Atrix. Furthermore, either party may terminate the agreement upon the occurrence of certain conditions, as more fully set forth in the License and Marketing Agreement.

Pandel

On May 24, 2002, we executed a Sublicense Agreement with Altana Inc., the United States subsidiary of Altana Pharma AG, pursuant to which we were granted the exclusive right to market, advertise, promote, distribute, offer for sale and sell, in the United States and Puerto Rico, Pandel Cream, a mid-potency topical corticosteroid that is indicated for the relief of mild-to-moderate inflammatory disorders of the skin in adults, such as atopic dermatitis and psoriasis. We had detailed Pandel on a co-promotional basis with Altana since October 2001. Altana currently licenses such rights from Taisho Pharmaceutical Co., Ltd., a company organized and existing under the laws of Japan. Pursuant to the terms of such agreement, we agreed to pay Altana an aggregate sublicense fee of \$1.7 million, \$800,000 of which was paid in June 2002 and \$900,000 of which was paid in May 2003. We purchase from Altana all Pandel products to be sold and are required to pay Altana a royalty fee equal to a percentage of the net sales of Pandel.

Vioxx

Pursuant to a Co-Promotion Agreement we executed with Merck in September 1999, we received the exclusive right to co-promote Vioxx, a prescription strength non-steroidal anti-inflammatory drug that was approved by the FDA on May 20, 1999 to relieve osteoarthritis and manage acute pain in adults, including dental pain. The agreement provided for certain payments by Merck to us upon sales of Vioxx to the dental community. On September 23, 2002, we executed an amendment, extension and restatement of our Co-Promotion Agreement with Merck with respect to Vioxx. In accordance with that amendment, extension and restatement, our agreement with Merck automatically expired on December 31, 2003. We will continue to earn residual contract revenues under the co-promotion agreement with Merck through December 2005.

AVAR

In March 2003, we executed co-promotion agreements with Sirius Laboratories, Inc. pursuant to which we jointly marketed Sirius' AVAR™ product line and Pandel to dermatologists in the United States. These agreements were mutually terminated on December 31, 2003. We do not expect contract revenues from AVAR beyond this date.

Denavir

Denavir is an FDA-approved topical antiviral cream used for the treatment of recurrent cold sores in adults. We marketed Denavir to the dental community under a Co-Promotion Agreement that we executed with SmithKline Beecham Consumer Healthcare in October 1998, that provided for certain payments by SmithKline Beecham to us. Following the acquisition of SmithKline Beecham by Novartis Consumer Health, Inc., Novartis terminated this Co-Promotion Agreement effective April 13, 2001.

On October 1, 2002, we entered into a Product Detailing Agreement with Novartis Consumer Health, Inc. pursuant to which we co-promoted Denavir to our target dentists in the United States and received detailing fees and performance incentives from Novartis Consumer Health, Inc. Our agreement with Novartis to co-promote Denavir expired on September 30, 2003, and we and Novartis decided not to renew our arrangement with respect to Denavir. We do not expect to earn contract revenues for Denavir beyond 2003.

Sales and Marketing

We market and sell our dental and dermatological products in the United States through a dedicated sales force comprised of approximately 115 sales representatives and managers. We currently market Periostat in

certain foreign markets, either through our wholly-owned subsidiary, CollaGenex International Ltd., or through marketing and distribution partnerships with companies in these markets, and we intend to market Periostat in additional foreign markets upon receipt of all requisite regulatory approvals. We currently actively sell Periostat in the United States and the United Kingdom and our partners have begun initial sales of Periostat in Israel, Portugal, Austria, Switzerland and Canada. We currently have such agreements with foreign companies, subject to requisite regulatory approvals, covering Japan, Spain and Greece.

Typically, our foreign marketing and distribution agreements provide for milestone payments upon the achievement of various regulatory and commercial events as well as supply agreements for manufactured product.

United States

Our field sales organization is currently comprised of one regional manager, eleven district managers and approximately 103 full-time equivalent sales representatives. Each full-time equivalent sales representative is responsible for covering a territory that includes approximately 100 dentists and periodontists that are believed to be potential high volume prescribers of Periostat based on the estimated number of scaling and root planings performed in their respective practices. Additionally, each representative calls on approximately 50 dermatology offices that have high potential for prescribing Pandel. In accordance with legal and regulatory requirements, our representatives also provide peer-reviewed scientific literature about the safety and use of Periostat to treat dermatological conditions and diseases.

Our field sales organization currently details Periostat, Atridox, Atrisorb FreeFlow and Atrisorb-D, to dental professionals, and Pandel to dermatological professionals.

We believe that our dental sales effort is distinguished from typical dental promotion by our focus on education and the clinical benefits of pharmaceutical dentistry, a new approach to treating dental diseases. Accordingly, we produce educational marketing materials, detail aids and product samples that are used extensively by our representatives in their presentations to dentists. Clinical reprints and video presentations are also provided. We believe that peer-to-peer communications are vital to increasing the acceptance of Periostat and, therefore, we arrange speaking engagements and teleconferences where Periostat advocates share their experiences with other dental professionals.

Sales training is an important component of our sales and marketing efforts. New representatives receive four weeks of field training and two weeks of intensive office training in periodontal disease, host response, dermatology, territory management and selling skills. Training continues at district-level meetings throughout the year. In order to provide an integrated dental and dermatology product line and leverage our sales and marketing organization, we are actively seeking to in-license or acquire other high-quality therapeutic dental and dermatology products.

International

We are establishing relationships with key partners to market and sell Periostat internationally, upon receipt of the requisite foreign regulatory approvals. In 1996, we executed a manufacturing and distribution agreement with Roche S.P.A. (formerly Boehringer Mannheim Italia) pursuant to which Roche S.P.A. had the exclusive right to market Periostat in Italy, San Marino and The Vatican City pending requisite regulatory approval. In 1997, we announced that a Marketing Authorization for Approval was filed for Periostat by Roche S.P.A. with the Italian Ministry of Health. Due to delays incurred in the review of national filings, Roche S.P.A. withdrew the Marketing Authorization for Approval in Italy, and Italy was included under the pan-European Mutual Recognition Procedure, which we filed in June 2001. In February 2002, we received provisional approval to market Periostat in Italy. In June 2002, we received final approval to market Periostat in Italy. Subsequent to this approval, we were notified by Roche that due to changes in Roche's local market strategy, Roche was not going

to launch Periostat in the Italian market. In January 2003, we attempted to reach agreement with Roche regarding compensation for outstanding milestone payments. In March 2003, we terminated our agreement with Roche and notified them of our intent to take the matter to arbitration as is provided for in our agreement with Roche. In June 2003 we received \$425,000 in outstanding milestone payments which settled all outstanding obligations due from Roche. We currently do not have a licensing partner for Periostat in Italy.

In October 1998, we announced that a Marketing Authorization Application had been filed with the United Kingdom Medicines Control Agency with respect to Periostat. A capsule formulation of Periostat was approved by the United Kingdom Medicines Control Agency in February 2000, and we launched a modest direct marketing effort in the United Kingdom to dentists through our United Kingdom subsidiary, CollaGenex International Limited. Sales of Periostat capsules commenced in the United Kingdom in September 2000. In December 2000, the United Kingdom Medicines Control Agency approved a tablet formulation of Periostat, and in June 2001, we applied for the registration of Periostat tablets with the European Union Member States and Norway under the Mutual Recognition Procedure, with the United Kingdom Medicines Control Agency acting as our Reference Member State.

Under the Mutual Recognition Procedure, once marketing approval for a pharmaceutical is granted by one European Member State, such state then acts as a Reference Member State, and assists in expediting the review and approval of the pharmaceutical in other European Member States.

In February 2002, we received provisional approval for the marketing of Periostat from seven European Member States including Austria, Finland, Ireland, Italy, Luxembourg, the Netherlands and Portugal. In April 2002, we announced that we received the final Marketing Authorizations from the Ministries of Health in Austria and Finland. In June 2002, we announced that we had received final Marketing Authorizations from the Ministries of Health in the Netherlands and Portugal. In June 2002 we received final approval to market Periostat in Ireland and Italy.

We cannot be certain that we will achieve other foreign regulatory approvals or will be successful in marketing Periostat in the United Kingdom or other European countries.

We executed a licensing agreement with Pharmascience Inc. in June 1999 pursuant to which Pharmascience will market and distribute Periostat in Canada. In the fourth quarter of 1999, Pharmascience submitted an application to the Canadian Therapeutic Products Program of Health Canada for Canadian marketing approval of a capsule formulation of Periostat which was approved in March 2003. In August 2003, Pharmascience launched Periostat in Canada and accordingly, we began recognizing royalty income on Pharmascience net product sales. Future milestone fees will be due from Pharmascience upon individual provincial formulary approval expected in 2004.

On May 2, 2000, we announced that we had executed an exclusive marketing and distribution agreement with ISDIN S.A., a joint venture between the Spanish companies Laboratorios del Dr. Esteve S^{OA}. and Antonio Puig S.A, for the marketing and distribution of Periostat tablets in Spain, pending requisite regulatory approval, and Portugal, where we have received such regulatory approval and began recording sales in June 2003. Such agreement was subsequently extended, granting ISDIN S.A. the right to market and distribute Periostat in Greece, pending requisite regulatory approval.

On June 9, 2000, we announced that we had executed marketing and distribution agreements with Willvonseder & Marchesani Ges.m.b.H & Co. KG, a Vienna-based company and Karr Dental Ltd., a Zurich-based company, with respect to the marketing and distribution of Periostat tablets in Austria and Switzerland, respectively. In April 2002, Periostat received regulatory approval under the Mutual Recognition Procedure for marketing in Austria. In December 2002, we made our first sales of Periostat to Willvonseder & Marchesani Ges.m.b.H and the product was launched in Austria by them in April 2003. The regulatory authorities in Switzerland granted final approval for Periostat in October 2003 and we have made our first shipment of product to Karr Dental in January 2004.

On August 9, 2000, we announced that we had executed an exclusive marketing and supply agreement with Showa Yakuhin Kako Co. Ltd., a Japanese company, with respect to the marketing and supply of Periostat tablets in Japan, pending requisite regulatory approval. Showa continues to work with the regulatory authorities in Japan to establish the appropriate clinical development program in order to gain regulatory approval for Periostat in Japan.

On August 24, 2000, we announced that we had executed an agreement for the marketing and distribution of Periostat in Israel with Taro International Ltd., a wholly-owned subsidiary of Taro Pharmaceutical Industries Limited, an Israeli company. This agreement provides for the payment of milestone fees to us associated with the regulatory approvals of Periostat. In February 2002, the Israeli authorities notified Taro with respect to the provisional approval of Periostat in Israel. In May 2002, we announced that the Israeli Ministry of Health had granted a Marketing Authorization to Taro. In October 2002, we made initial sales of Periostat and Taro formerly launched the product in Israel in January 2003. We have made additional sales to Taro in 2003.

On January 30, 2001, we announced that we had signed an exclusive Middle East Export Marketing Agreement with Pharma Med Inc. to distribute and manage the introduction of Periostat in certain Middle Eastern countries, pending requisite regulatory approval. In January 2004, we informed Pharma Med that we elected not to renew such arrangement.

In November 2001, we terminated our distribution and marketing agreement for Germany with Hain Diagnostika GmbH due to Hain's failure to fulfill its obligations under the agreement. We signed a settlement agreement with Hain in November 2002 with respect to Hain's non-payment of milestone fees due to CollaGenex. We currently do not have a licensing partner for Periostat in Germany.

In February 2002, we announced that we had contracted with Dexcel-Dental, a division of Dexcel-Pharma Limited, to promote Periostat to the dental profession in the United Kingdom and, upon receipt of final regulatory approval, the Republic of Ireland. In October 2002, we provided Dexcel-Dental with a formal termination notice of our agreement. During 2003, we and Dexcel-Pharma commenced non-binding mediation to resolve their dispute regarding the termination of the agreement. In March, 2004, we and Dexcel-Pharma agreed to settle the dispute and resolve outstanding invoices from Dexcel-Pharma. We continue to market Periostat in the United Kingdom through our wholly-owned subsidiary, CollaGenex International Ltd.

Manufacturing, Distribution and Suppliers

In 1995, we entered into a supply agreement with Hovione International Limited pursuant to which the active ingredient in Periostat, doxycycline hyclate, is supplied to us by Hovione from its offshore facilities. Hovione supplies a substantial portion of the doxycycline used in the United States from two independent facilities, providing for a back-up supply in the event that one facility is unable to manufacture. The initial term of the supply agreement expired on January 25, 2000 and, pursuant to an addendum to that agreement, the term was extended to May 14, 2006 and thereafter automatically renews for successive two-year periods unless, 90 days prior to the expiration of any such periods, either party gives the other party written notice of termination. In addition, in the event of a default that remains uncured for 90 days, the non-defaulting party can terminate the supply agreement effective immediately at the end of such ninety-day period. We rely on Hovione as our sole supplier of doxycycline, and have no back-up supplier at this time.

On September 26, 2000, we entered into a Service and Supply Agreement with a contract manufacturer, Pharmaceutical Manufacturing Research Services, Inc., for the tablet formulation of Periostat. Our current arrangement with Pharmaceutical Manufacturing Research Services has been extended until the earlier of March 30, 2007 or until a generic 20 mg doxycycline hyclate tablet is available on the market. Currently, Pharmaceutical Manufacturing Research Services is the sole third-party contract manufacturer to supply a tablet formulation of Periostat to us. We intend to contract with additional manufacturers for the commercial manufacture of Periostat tablets. Pharmaceutical Manufacturing Research Services is required to comply with current good manufacturing practices, or cGMP, requirements.

In November 1998, we executed a Distribution Services Agreement with Cardinal Health Specialty Pharmaceutical Services, or SPS, pursuant to which SPS acts as our exclusive logistics provider for Periostat in the United States and Puerto Rico. Under this agreement, SPS warehouses and ships Periostat and Pandel from its central distribution facility near Nashville, Tennessee to wholesalers that distribute our products to pharmacies throughout the United States for prescription sale to patients. SPS also provides various customer and financial support services to us, including billing and collections, contract pricing maintenance, cash application, chargeback processing and related reporting services. The Distribution Services Agreement had an initial term of three years with automatic renewal for successive one-year periods unless notice of termination was provided by either party 90 days prior to expiration. We negotiated a three-year extension of such agreement having similar terms to the original agreement with an effective date of March 1, 2002.

In February 2002, we executed a Wholesale Service Agreement effective November 2001 with National Specialty Services, Inc., now known as Cardinal Health Specialty Pharmaceutical Distribution, or SPD, pursuant to which SPD acts as our non-exclusive authorized distributor of Atridox, Atrisorb FreeFlow and Atrisorb-D. Under this agreement, SPD will also provide certain additional services, including marketing, sales detail report production, contract administration and chargeback processing. The Wholesale Service Agreement has an initial term of three years and shall renew automatically for successive one-year periods unless notice of termination is provided by either party 90 days prior to expiration.

We do not have the resources, facilities or capabilities to manufacture any of our products or product candidates. We have no current plans to establish a manufacturing facility. We expect that we will be dependent, to a significant extent, on contract manufacturers for commercial scale manufacturing of our products or product candidates in accordance with regulatory standards.

We cannot be certain that we will be able to enter into additional, or maintain existing manufacturing, distribution or supply agreements on acceptable terms, if at all. In the event that we are unable to obtain sufficient quantities of doxycycline hyclate or Periostat on commercially reasonable terms, or in a timely manner, or if our suppliers fail to comply with cGMP or if our distributors are unable to ship or support our products, our business, financial condition and results of operations may be materially adversely affected.

Customers/Backlog

During 2003, net product sales to each of Cardinal Health, Inc., McKesson Corporation and Amerisource-Bergen Corporation accounted for 43%, 31% and 20%, respectively, of our aggregate net product sales. As is common practice in the pharmaceutical industry, wholesalers may become very speculative in their purchasing practices in anticipation of product price increases. Accordingly, we may limit, fulfill or delay shipment of customer purchase orders depending on the availability of product and other factors necessary to operate our business efficiently. At December 31, 2003, there were open customer purchase orders with an aggregate value of approximately \$800,000. These orders were shipped complete during January 2004.

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Research and Development

Overview

Our research and development activities are conducted primarily by third parties including contract research organizations and academic and government institutions. The main focus of these activities is the identification and development of novel tetracycline-based compounds for application in a variety of inflammatory and tissue-destructive disorders. Other than Periostat, the most advanced program involves Metastat, our lead compound for treating metastatic cancer.

Major research programs currently being conducted by us include: (i) the clinical development of the sub-antimicrobial dose of doxycycline for the treatment of rosacea, perioral dermatitis (a skin condition characterized by inflammatory lesions and redness around the mouth frequently associated with the use of topical steroids) and

meibomianitis (a disorder characterized by “dry eye”); (ii) the development of a “once-a-day” formulation of Periostat (Periostat MR); and (iii) limited support for the conduct of exploratory studies in the utility of Metastat (COL-3) as a treatment for soft tissue sarcoma, periodontitis and rosacea.

As of December 31, 2003, we had five products or product candidates in various stages of clinical trials. Completion of clinical trials may take several years or more, but the length of time can vary substantially according to the type, complexity, novelty and intended use of a product candidate. Because of this, it is very difficult to estimate the cost of completing these trials. We continue to study Periostat in a series of clinical studies in order to determine its usefulness in certain patient types or in conjunction with procedures other than SRP. For example, data on the use of Periostat in diabetic patients was published in 2003 and suggested that the drug may provide benefits not only in improved periodontal outcomes but also in improved diabetic control. Extensive additional studies are required before this finding can be confirmed, if at all. We intend to continue the Phase IV development of Periostat in 2004.

If a particular indication proves promising during early stage clinical development, and the commercial opportunity justifies the investment, the next stage of development typically involves more extensive Phase II trials to determine the appropriate dose and dosing regimen. Based on our assessment of the data obtained, we may then decide to conduct Phase III clinical trials involving the indication and use positive results from the Phase III trials, if any, to support a New Drug Application, or NDA, to the FDA. However, we cannot be certain that any of our products will prove to be safe or effective, will receive regulatory approvals, or will be successfully commercialized.

The duration and the cost relating to preclinical testing and clinical trials may vary significantly over the life of a project. Our joint development arrangement for Metastat with the NCI, may also result in variability in our development costs. We closely monitor our research and development costs in order to ensure that our investment is consistent with the return we predict from each project.

Technology

Our core technology involves the use of pharmaceutical products to inhibit the destruction of the connective tissues of the body and to down-regulate the pathological host response to a variety of external and internal mediators of inflammation and tissue destruction.

The technology works in part by modulating the activity of matrix metalloproteinases. Matrix metalloproteinases are responsible for the normal turnover of collagen and other proteins that are integral components of a variety of connective tissues such as skin, bone, cartilage and ligaments.

Under normal physiological conditions, the natural breakdown of collagen is in part regulated by the interaction between the degradative properties of matrix metalloproteinases and a group of naturally occurring biomolecules called tissue inhibitors of metalloproteinases, which modulate the level of matrix metalloproteinase activity. In many pathological conditions, however, the balance between collagen production and degradation is disrupted resulting in excessive loss of tissue collagen, a process called collagenolysis. One such example is the progressive destruction of the periodontal ligament and alveolar bone in adult periodontitis. Similar degradative activity is associated with other disorders and conditions such as cancer metastasis, wounds, osteoarthritis, osteoporosis, rheumatoid arthritis and diabetic nephropathy.

Elements of our core technology are licensed on an exclusive basis from SUNY and results from the research of Drs. Lorne M. Golub and Thomas F. McNamara and their colleagues at SUNY. These researchers demonstrated that tetracyclines can significantly reduce the pathologically excessive collagen degradation associated with periodontitis. They also were able to demonstrate that this result was unrelated to the antibiotic properties of tetracyclines. Furthermore, they demonstrated that the administration of doses of antibiotic tetracyclines well below the dosage levels necessary to destroy microbes (sub-antimicrobial doses) was effective

in preventing the loss of connective tissue in models of periodontitis. Studies published in scientific journals support the hypothesis that the mechanism of action for this activity is the result, in part, of the direct binding of tetracyclines to certain metal binding sites associated with the matrix metalloproteinase structure.

Additional research suggests that tetracyclines also have the ability to stimulate new bone protein synthesis by a variety of mechanisms. These properties, which are independent from the anticollagenolytic properties of the compounds, are particularly important during the development of certain types of bone deficiency disorders, including periodontitis. Particularly in patients with concomitant disorders, such as diabetic osteopenia and peri- or post-menopausal osteoporosis, periodontitis can occur in the absence of inflammatory-mediated elevated collagenolytic activity and is primarily a function of alterations in the balance of osteoblast and osteoclast mediated resorption and bone formation (in particular a reduction of bone formation). In these and other circumstances during development of the bony lesion characterizing adult periodontitis, the property of tetracyclines to stimulate new bone formation is the means by which the compounds are able to effectively treat periodontitis.

Other commercially available antibiotic tetracyclines show effective anti-collagenolytic and independent bone protein synthesis stimulating potential. Long-term administration of these compounds at normal antibiotic doses, however, can result in well-known complications of antibiotic therapy, such as gastrointestinal disturbance, overgrowth of yeast and fungi, and the emergence of antibiotic-resistant bacteria. Our Phase III clinical trials with Periostat demonstrated that the administration of sub-antimicrobial doses of doxycycline over a twelve-month period exerted no anti-microbial effects. Thus, the use of this dosage strength provides the anti-collagenolytic and bone protein synthesis effects without the complications of long-term antibiotic therapies. In pharmacokinetic studies, Periostat MR, our once-daily, modified release formulation of Periostat, showed similar blood concentration levels (bio availability) as Periostat, and we believe Periostat MR will show similar safety and efficacy as Periostat.

Our license from SUNY also covers the uses of a broad class of compounds (IMPACS) that have been chemically modified to retain and enhance their anti-collagenolytic and other properties but which may have the structural elements responsible for their antibiotic activity removed. These compounds have shown potential in a number of pre-clinical models of excessive connective tissue breakdown. Our current research and development programs focus on the potential use of Periostat as well as the use of IMPACS for a variety of disorders characterized by inflammation and connective tissue destruction.

Additional research has been conducted to identify, synthesize and characterize a new generation of IMPACS compounds, and we have filed patent applications on these compounds. The first of these compounds, called COL-1002, recently issued in the United States. We have also filed patent applications on other IMPACS compounds, which are pending.

Periostat

We have completed various clinical trials that evaluate the use of Periostat for other therapeutic indications. Studies that evaluated Periostat's ability to promote attachment level, decrease pocket depth and promote healing in patients undergoing periodontal flap surgery are complete and data are awaiting final analysis, which is expected to be completed during the first half of 2004. Preliminary data from this study were presented at the American Academy of Periodontology meeting in 2002 and suggested that Periostat significantly improved certain clinical and biochemical parameters that are key to the successful outcome of periodontal surgery. Other Phase IV clinical trials are being conducted or are planned to evaluate Periostat as an adjunct to SRP in institutionalized geriatric patients, in patients with Type I and Type II diabetes and in a population of smokers. Two of the studies in diabetic patients reported encouraging preliminary data at the American Association for Dental Research meeting in March 2003, suggesting that Periostat had the potential to improve periodontal clinical outcomes and possibly contribute to improvements in diabetic control in these patients. In January 2003, we announced that the first patients had entered a multi-center, double-blinded, placebo-controlled Phase IV

clinical study to evaluate the combined efficacy of Periostat and Atridox (doxycycline hyclate) 10%, a locally-applied antimicrobial gel, in the treatment of adult periodontitis. This study is fully enrolled and results are expected to be reported during 2004. We have incurred approximately \$300,000 in expenses to date for this project and expect to incur approximately \$100,000 in 2004 to complete the study.

To extend the possible therapeutic use of Periostat beyond the oral cavity, we and our collaborators are planning, conducting or have completed clinical trials in other indications. Of these studies, only the study in meibomianitis (dry eye) is being fully funded by us, although we support additional studies through the provision of active drug and placebo without charge.

A study carried out in 2002 focused on the use of Periostat to treat moderate acne. The Periostat acne clinical trial was a multi-center, placebo-controlled, double-blind study chaired by Dr. Robert Skidmore, Chief of Dermatology at the University of Florida Medical Center. The results revealed statistically and clinically significant benefits to patients receiving Periostat for all three of the pre-established primary endpoints: change in total comedones, total inflammatory lesions and total lesion counts.

Rosacea

In May 2003, we announced the results of a double-blinded, placebo-controlled clinical study designed to evaluate the efficacy of Periostat when combined with MetroLotion® (metronidazole) Topical Lotion, 0.75%, for the treatment of rosacea. The study was conducted by Jorge Sanchez, M.D., Professor of Dermatology at the University of Puerto Rico. Forty patients were randomized to receive either MetroLotion and Periostat tablets or MetroLotion and placebo tablets for 12 weeks. After week 12, patients discontinued the use of MetroLotion and were maintained on either Periostat or placebo for an additional 4 weeks. Lesion counts, along with an assessment of erythema, or persistent redness, and overall clinical disease severity were recorded. The project was completed in 2003 at a total cost of approximately \$50,000.

At all points during the course of the study, patients receiving Periostat had significantly fewer inflammatory lesions than those on placebo. At week 12 there was a 59% reduction in lesion count in the group receiving MetroLotion and Periostat, compared with a 34% reduction in the group receiving MetroLotion and placebo, a clinically significant difference. The Clinician's Global Severity Assessment Scale, which is a numerical scoring system that evaluates a patient's overall disease severity, was also significantly improved in the Periostat group, and there was a trend towards improvement in the erythema scores. Patients who were maintained on Periostat for an additional four weeks maintained the improvements observed at week 12, which was not true for those patients on placebo.

In July 2003, we announced that the July/August issue of the peer-reviewed dermatology journal, *Skin Med*, featured an article describing the positive outcome of a physician-sponsored clinical study of Periostat in the treatment of rosacea. This open-label, 50-patient study was designed to determine whether monotherapy with Periostat improved the symptoms associated with various stages of rosacea. Joseph B. Bikowski, M.D., Department of Dermatology, University of Pittsburgh School of Medicine, and author of the article, concluded that treatment with Periostat resulted in a significant clearing of inflammatory lesions as well as a reduction in erythema and telangiectatic vessels. Patients were treated for up to eight weeks with Periostat. After an average of four weeks treatment, patients experienced an 80% to 100% clearing of inflammatory lesions and a 50% reduction in erythema. Periostat was well tolerated by the patients in the study, with no reports of nausea, vomiting, headache, diarrhea, vaginitis or photosensitivity, effects often observed with the chronic use of higher doses of tetracycline antibiotics.

In February 2004, we announced the positive outcome of a Phase 3 double-blinded, placebo-controlled clinical study designed to evaluate the safety and efficacy of Periostat for the treatment of rosacea. The study enrolled 134 patients and is the largest clinical trial ever conducted to evaluate a systemic therapy for rosacea. The detailed study data will be presented at the Skin Disease Education Foundation's Dermatology Open Seminar on March 21, 2004.

Preliminary data analysis indicated that patients treated with Periostat showed a continuous improvement during the 16-week course of the study compared to patients on placebo. In the study, patients that were administered Periostat had a significantly greater reduction in the number of inflammatory lesions (papules and pustules) compared to patients on placebo. This improvement was both clinically and statistically significant.

Overall clinical disease severity based on the Clinician's Global Severity Assessment Scale declined significantly in the group of patients treated with Periostat compared to placebo, with a greater number of patients on Periostat showing a complete clearing of the disease at 16 weeks compared to those patients on placebo. The erythema in patients in the Periostat group showed a trend toward greater improvement compared to patients in the placebo group. The total expenses incurred to date on this project were \$880,000. We expect to incur an additional \$500,000 in 2004 to complete this trial.

Periostat MR Once-A-Day Formulation

The development of a once-a-day formulation, Periostat MR, is being conducted through a development agreement with Shire Laboratories. Formulations arising from this research were administered to human volunteers during 2002 and exhibited promising results, leading to the selection of a formulation for more complete clinical testing in 2003. In October 2003, we announced that these tests had shown that we had a suitable formulation and planned to enter Phase III clinical trials with this new once-a-day formulation in the second quarter of 2004. We also expect to launch a Phase III clinical trial in periodontitis patients and two Phase III clinical trials in roseacea patients by mid-2004. We have incurred approximately \$3.3 million in expenses through December 31, 2003. The total anticipated expenses, through commercialization, including various milestones to Shire, is estimated to be between \$16.0 million and \$18.0 million.

Metastat

Cancer metastasis is the spread of cancer cells from a diseased organ to the lymphatic or circulatory system, where such cells then migrate throughout the body causing tumor growth in other organs. Tumor cell invasion is a complex process that involves the destruction of the basement membrane, or structural support tissue, of the lymphatic or circulatory system, and the migration of tumor cells to secondary sites, followed by proliferation of these cells. Data from pre-clinical studies sponsored by us at two major universities suggest that several of our IMPACS drug candidates have potent activity in models of cancer invasion, including prostate, breast, lung, colon and melanoma.

These studies also demonstrated that the down-regulation of the invasive phenotype by conventional tetracyclines and IMPACS results in a decreased ability of tumor cells to invade the lung in models of metastasis. For example, IMPACS have been shown to modulate the specific type of matrix metalloproteinases isolated from human lung cancer cells, the activity of which has been correlated with the metastatic potential of tumors. In animal models involving a variety of human cancer cell types, including prostate, breast, lung, colon and melanoma, IMPACS developed by us exhibited an ability to inhibit metastasis.

In 2001, at their cost, the NCI initiated an open-label, two-dose study to establish clinical efficacy of Metastat in patients with HIV-related Kaposi's sarcoma. This multi-center Phase 2 study enrolled 77 patients with HIV-related Kaposi's sarcoma by March 2003. Patients received one of two different doses of Metastat for six months. The primary objectives of the study were to evaluate the tumor response rate and duration as well as to evaluate the biologic activity of Metastat by measuring serum levels of pro-angiogenic mediators.

Due to the unexpected finding that patients on Metastat continued to improve over the course of their therapy, the AIDS Malignancy Consortium and the NCI did not undertake an interim analysis of this database until January 2004. We believe the analysis will be finalized in the second quarter of 2004. Early reports of this open-label study suggest that certain patients obtained significant relief (both partial responses and complete responses) of their clinical symptoms during the course of the study, but we cannot be certain until the data is formally analyzed.

COL-3

A Phase I, ascending dose trial with COL-3 in normal human volunteers succeeded in establishing the maximum tolerated dose that could be supported in investigational new drug, or IND-based, exploratory studies. During 2003, we set up clinical studies with COL-3, the active ingredient in Metastat, in the treatment of adult periodontitis and rosacea. The rosacea study began recruiting patients in 2003 and the periodontitis study will begin recruiting patients during 2004. However, we do not know whether the drug will exhibit sufficient efficacy in the treatment of rosacea or periodontitis to justify further clinical investigation.

We have not developed forecasts for the sale of products arising from the commercialization of COL-3, nor do we anticipate spending significant resources on the development of COL-3 until it is clear from the currently conducted studies with the NCI or other sources of external funding that the drug has a tolerable safety profile and a high likelihood of clinical and commercial success.

Preclinical and Other Research and Development Activities

A preclinical program has identified and characterized IMPACS that exhibit the potential for enhanced biological activities compared to Periostat and Metastat. In collaboration with the University of Rochester, we have synthesized a number of new IMPACS. These novel compounds underwent preliminary evaluation in a variety of *in vitro* and *in vivo* assay systems. In March 2003, we announced the issuance of the first United States patent claiming a compound that was discovered as a result of these efforts. Further patents for other compounds in the series have issued in 2003, and we anticipate that others will issue in 2004 and beyond.

We receive certain proprietary rights to inventions or discoveries that arise as a result of this research. Our current research and development objective is to develop additional products utilizing our IMPACS technology, preferably in conjunction with development partners.

In October 2002, we announced with Discovery Laboratories, Inc. the formation of a research collaboration to evaluate the combination of Discovery's platform technologies for the development of novel respiratory disease therapeutics. Due to changed priorities at Discovery, this agreement was terminated in September 2003.

In October 2002, we also announced the execution of a license agreement with Medtronic, Inc. involving our IMPACS compounds, pursuant to which Medtronic obtained an exclusive, worldwide license to technology relating to the use of the compounds to treat aortic aneurysms and other forms of vascular disease with medical devices. This program is still underway.

In February 2002 we announced that we had licensed a dermal and transdermal drug delivery technology named Restoraderm from its inventor. Restoraderm is designed to enhance the dermal delivery of a variety of active ingredients and we intend to develop it into a portfolio of topical dermatological pharmaceuticals.

The Restoraderm technology is based on the ability of certain lipid compositions to enhance the natural skin barrier and facilitate the dermal and transdermal delivery of therapeutic active ingredients. The Restoraderm technology is currently still under development, and we anticipate that the first products to be developed using the technology will be available in early 2005. We have acquired exclusive rights to the technology and will pay the inventor milestone fees upon the achievement of certain objectives as well as royalties on future sales of products based on the technology. To date, we have spent \$1.2 million in development costs for the Restoraderm technology. This amount includes \$930,000 in milestone payments to the inventor. We anticipate spending approximately \$8.2 million in development expenses through commercialization.

Our research and development expenditures were approximately \$5.5 million, \$4.4 million and \$3.8 million in 2003, 2002 and 2001, respectively. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations." We expect to significantly increase our investment in research and development in 2004.

Patents, Trade Secrets and Licenses

Our success will depend in part on patent and trade secret protection for our technologies, products and processes, and on our ability to operate without infringement of proprietary rights of other parties both in the United States and in foreign countries. Because of the substantial length of time and expense associated with bringing new products through development to the marketplace, the pharmaceutical industry places considerable importance on obtaining and maintaining patent and trade secret protection for new technologies, products and processes.

We depend on our license from SUNY for all of our core technology. The SUNY License grants us an exclusive worldwide license to make and sell products employing tetracyclines that are designed or utilized to alter a biological process. Thirty one United States patents and five United States patent applications held by SUNY are licensed to us under the SUNY License. Three of the 31 patents have been co-assigned to the University of Miami, Florida, and another patent has been co-assigned to Washington University. Other institutions are co-owners with SUNY as follows: one patent is co-owned with the Hospital for Joint Diseases in New York City; three patents are co-owned with the University of Helsinki; and one patent is co-owned with the University of Rochester.

The primary United States patent claims methods of use of conventional tetracyclines to inhibit pathologically excessive collagenolytic activity (the "Primary Patent"), while a related United States patent claims methods of use of tetracyclines which have no antibiotic activity (the "Secondary Patent"). The 29 other United States patents relate to chemically modified tetracyclines, or CMTs, and compositions of certain CMTs with anti-proteinase properties, including anti-gelatinase, anti-membrane-type metalloproteinase, anti-collagenase, and anti-elastase properties and methods of use of tetracyclines to reduce bone loss and skeletal muscle wasting; and methods of use of tetracyclines to enhance bone growth and promote synthesis in skeletal muscle, inhibit protein glycosylation, inhibit excess phospholipase A₂ activity/production, inhibit endogenous production of nitric oxide, or NO, enhance endogenous production of interleukin 10, reduce dental plaque adhesion, and inhibit or reduce pulmonary neutrophil infiltration (or accumulation). SUNY did not apply in foreign countries for patents corresponding to the Primary Patent, but has obtained patents that correspond to the Secondary Patent in Australia, Canada and certain European countries. One of the Secondary Patents has also been issued in Japan. SUNY also has obtained patents in certain European countries, Canada and Japan, and has pending patent applications in certain other foreign countries which correspond to its United States patents relating to methods of use of tetracyclines to reduce bone loss. Eighty seven patents have been issued in foreign countries. All of SUNY's United States and foreign patents expire between 2004 and 2019. Our rights under the SUNY License are subject to certain statutory rights of the United States government resulting from federal support of research activities at SUNY. The failure to obtain and maintain patent protection may mean that we will face increased competition in the United States and in foreign countries. The SUNY License is terminable by SUNY on 90 days prior notice only upon our failure to make timely payments, reimbursements or reports, if the failure is not cured by us within 90 days. The termination of the SUNY License, or the failure to obtain and maintain patent protection for our technologies, would have a material adverse effect on our business, financial condition and results of operations.

One of the United States patents and a corresponding Japanese patent application licensed to us under the SUNY License are owned jointly by SUNY and a Japanese company. These patent rights, which expire in 2012, cover particular CMTs (the "Jointly Owned CMTs") that were involved in research activities between SUNY and the Japanese company. The Japanese company may have exclusive rights to these Jointly Owned CMTs in Asia, Australia and New Zealand and may have a non-exclusive right to exploit these Jointly Owned CMTs in other territories. These Jointly Owned CMTs are not involved in our Periostat product but could, in the future, prove to be important for one or more of our other potential applications of its technology. If we incorporate the Jointly Owned CMTs in any future product, we may be precluded from marketing these products in Asia, Australia and New Zealand and could experience increased competition in other markets from the joint owner.

In consideration of the license granted to us, we: (i) issued to SUNY 78,948 shares of common stock in 1992; and (ii) have agreed to pay SUNY royalties on the net sales of products employing tetracyclines, with

minimum annual royalty payments of \$50,000 per year. The term of the license is: (i) until the expiration of the last to expire of the licensed patents in each country; or (ii) until November 18, 2018, at which time we have a fully paid, non-exclusive license.

In addition to the patents and patent applications licensed from SUNY which represent the core technology, we own additional technology for which applications for United States patents have been filed and have been issued. In this regard, we report the existence of an issued patent for a toothpaste/mouthwash formulation for the amelioration of dentin hypersensitivity. A second patent was issued which covers one of the novel compounds discovered by us and its use to treat abdominal aortic aneurysm, ulceration of the cornea, periodontal disease, diabetes, diabetes mellitus, scleroderma, progeria, lung disease (such as ARDS, cystic fibrosis, emphysema or acute lung injury resulting from inhalation of toxicants), cancer, graft versus host disease, disease of depressed bone marrow function, thrombocytopenia, prosthetic joint loosening, spondyloarthropathies, osteoporosis, Paget's disease, autoimmune disease, systemic lupus erythematosus, acute or chronic inflammatory condition (such as inflammatory bowel disease, arthritis, osteoarthritis, rheumatoid arthritis, pancreatitis, nephritis, glomerulonephritis, sepsis, septic shock, lipopolysaccharide endotoxin shock, multisystem organ failure or psoriasis), renal disease (such as chronic renal failure, acute renal failure, nephritis or glomerulonephritis), connective tissue disease, and neurological or neurodegenerative condition (such as Alzheimer's disease, Guillain-Barré Syndrome, Krabbe's disease, adrenoleukodystrophy, Parkinson's disease, Huntington's disease, multiple sclerosis, amyotrophic lateral sclerosis or an encephalopathy, e.g., spongiform encephalopathy). Furthermore, we report pending applications covering other new tetracycline derivatives, and, among other things, methods of treating acne, rosacea, meibomianitis and Kaposi's sarcoma.

On June 10, 2002, we executed a Development and Licensing Agreement with Shire Laboratories, Inc. pursuant to which we were granted an exclusive worldwide license (including the right to sublicense) to develop, make, have made, use, supply, export, import, register and sell products for the treatment of various inflammatory disorders. In addition, under the agreement, certain product development functions shall be performed for us. Also under the agreement, we have committed to payments, in cash or at our option, a combination of cash and our common stock, upon the achievement of certain clinical and regulatory milestones in the event we pursue certain applications of the technology which could total up to \$7.9 million in the aggregate. Pursuant to the terms of such agreement, we shall also pay a percentage of certain net sales of products, if any, utilizing any part of the technology. We may terminate the agreement upon sixty days notice.

We intend to enforce our patent rights against third-party infringers. Due to the general availability of generic tetracyclines for use as antibiotics, we could become involved in infringement actions, which could entail substantial costs to us. Regardless of the outcome, defense or prosecution of patent claims is expensive and time consuming, and results in the diversion of substantial financial, management and other resources from our other activities.

During 2003, we announced that we had settled all pending litigations between CollaGenex and West-ward Pharmaceutical Corporation, or West-ward, a generic pharmaceutical company that had filed an ANDA for a generic version of Periostat. We sued West-ward and other defendants in the United States District Court for the Eastern District of New York, alleging that West-ward infringes our patents for Periostat for the treatment of adult periodontitis. Our complaint also alleged that West-ward infringed our patent rights under the Hatch-Waxman act by submitting an ANDA with the FDA, seeking FDA approval to market a generic capsule version of Periostat.

In a separate action in the United States District Court for the District of Columbia, we sought and, on July 23, 2003, were granted a preliminary injunction preventing the FDA from approving generic versions of Periostat, including West-ward's version. West-ward intervened in that case.

In the settlement, West-ward agreed and confessed to judgment that our Periostat patents are valid and infringed by the filing of West-ward's ANDA. West-ward also agreed and confessed to judgment that our

Periostat patents would be infringed by the manufacture and sale of a generic version of Periostat. West-ward consented to a judgment enjoining West-ward and any party acting in concert with West-ward from making and selling a generic version of Periostat until our patents expire or are declared invalid or unenforceable by a court of competent jurisdiction. Finally, West-ward agreed to withdraw from the FDA case in the District of Columbia. We agreed to pay a portion of West-ward's actual legal expenses in the amount of \$700,000.

In a related case, we have separately sued United Research Laboratories/Mutual Pharmaceutical Company, or Mutual, in the United States District Court for the Eastern District of New York, claiming that Mutual infringes the claims of our Periostat patents. Mutual has sued us in the United States District Court for the Eastern District of Pennsylvania, alleging that we engaged in tortious and anticompetitive behavior to prevent Mutual from commercializing a generic version of Periostat. Mutual has also intervened in the FDA action in the United States District Court for the District of Columbia.

In addition, on July 14, 2003 we submitted a Citizen Petition to the FDA requesting that it refuse to approve any generic version of Periostat, submitted by Mutual on the ground that the bioequivalence studies Mutual submitted are insufficient to show that the Mutual product is bioequivalent to Periostat. The FDA has not reached a decision on our Citizen Petition. The resolution of the West-ward cases does not resolve any of the pending Mutual litigations or administrative proceedings. We cannot predict the outcome of these matters.

Our patent positions, like those of other pharmaceutical firms, are generally uncertain and involve complex legal and factual questions. Consequently, as to the patent applications licensed to us, even though we currently prosecute such patent applications with United States and foreign patent offices, we do not know whether any of such applications will result in the issuance of any additional patents or, if any additional patents are issued, whether they will provide significant proprietary protection or will be circumvented or invalidated. Since patent applications in the United States are maintained in secrecy until published or until patents issue, and since publication of discoveries in the scientific and patent literature tends to lag behind actual discoveries by several months, we cannot be certain that we were the first creator of inventions covered by pending patent applications or that we were the first to file patent applications for such inventions.

There can be no assurance that patent applications to which we hold rights will result in the issuance of patents, that any patents issued or licensed to us will not be challenged and held to be invalid, or that any such patents will provide commercially significant protection to our technology, products and processes. In addition, there can be no assurance that others will not independently develop substantially equivalent proprietary information not covered by patents to which we own rights or obtain access to our know-how, or that others will not be issued patents which may prevent the sale of one or more of our products, or require licensing and the payment of significant fees or royalties by us to third parties in order to enable us to conduct our business. In the event that any relevant claims of third-party patents are upheld as valid and enforceable, we could be prevented from selling our products or could be required to obtain licenses from the owners of such patents. There can be no assurance that such licenses would be available or, if available, would be on terms acceptable to us. Our failure to obtain these licenses would have a material adverse effect on our business, financial condition and results of operations.

Our success is also dependent upon know-how, trade secrets, and the skills, knowledge and experience of our scientific and technical personnel. We require all employees to enter into confidentiality agreements that prohibit the disclosure of confidential information to anyone outside CollaGenex. In addition, we seek to obtain such agreements from our consultants, advisors and research collaborators. There can be no assurance that adequate protection will be provided for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure. We occasionally provide information and chemical compounds to research collaborators in academic institutions, and request that the collaborators conduct tests in order to investigate certain properties of the compounds. There can be no assurance that the academic institutions will not assert intellectual property rights in the results of the tests conducted by the research collaborators, or that the academic institutions will grant licenses under such intellectual property rights to us on acceptable terms. If the

assertion of intellectual property rights by an academic institution can be substantiated, failure of the academic institution to grant intellectual property rights to us could have a material adverse effect on our business, financial condition and results of operations.

Government Regulation

Government authorities in the United States and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution, and marketing of the products we develop and market. In the United States, the FDA regulates Atridox, Pandel, Periostat and our products in development as drugs under the Federal Food, Drug, and Cosmetic Act and implementing regulations. The FDA regulates Atrisorb FreeFlow and Atrisorb-D as medical devices under the Food, Drug and Cosmetic Act and implementing regulations. Failure to comply with FDA requirements may subject us to administrative or judicial sanctions, such as the FDA's refusal to approve pending applications or warning letters, product recalls, product seizures, total or partial suspension of production or distribution, withdrawal of approvals, import detentions, injunctions, and/or criminal prosecution.

Our products in development are drugs. The steps required before a drug may be marketed in the United States include:

- pre-clinical laboratory tests, animal studies, and formulation studies;
- submission to the FDA of an investigational new drug exemption for human clinical testing, which must become effective before human clinical trials may begin;
- adequate and well-controlled clinical trials to establish the safety and efficacy of the drug for each indication;
- submission to the FDA of an NDA for approval;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMP; and
- FDA review and approval of the NDA.

Pre-clinical tests include laboratory evaluations of product chemistry, toxicity, and formulation, as well as animal studies. The results of the pre-clinical tests, together with manufacturing information, analytical data, and a plan for studying the product in humans, are submitted to the FDA as part of an investigational new drug exemption, which must become effective before human clinical trials may begin. An investigational new drug exemption automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials outlined in the investigational new drug exemption. In that case, the investigational new drug exemption is placed on clinical hold and the sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. Submission of an investigational new drug exemption does not always result in the FDA allowing clinical trials to commence.

Clinical trials involve administration of the investigational drug to human subjects under the supervision of qualified investigators and are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the investigational new drug exemption process, and must be reviewed and approved by an independent Institutional Review Board before it can begin. Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Phase I usually involves the initial introduction of the investigational drug into people to evaluate its safety, dosage tolerance, pharmacodynamics, and, if possible, to gain an early indication of its effectiveness. Phase II usually involves trials in a limited patient population to evaluate dosage tolerance and appropriate dosage, identify possible adverse effects and safety risks and evaluate preliminarily the efficacy of the drug for specific indications. Phase III trials usually further evaluate clinical

efficacy and test further for safety by using the drug in its final form in an expanded patient population. We cannot guarantee that Phase I, Phase II, or Phase III testing for our products in development will be completed successfully within any specified period of time, if at all. Many products that initially appear promising are found, after clinical evaluation, not to be safe and effective. Also, we, or the FDA, may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Assuming successful completion of the required clinical testing, the results of the preclinical studies and of the clinical studies, together with other detailed information, including information on the manufacture and composition of the drug, are submitted to the FDA in the form of a new drug application requesting approval to market the product for one or more indications. Before approving an application, the FDA usually will inspect the facility or the facilities at which the drug is manufactured, and will not approve the product unless compliance with cGMP is satisfactory. If the FDA determines the application and the manufacturing facilities are acceptable, the FDA will issue an approval letter. If the FDA determines the application or manufacturing facilities are not acceptable, the FDA will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. The FDA approved our NDA for Periostat in 1998, however, we cannot be sure that any additional approvals will be granted on a timely basis, if at all. After approval, certain changes to the approved product, such as adding new indications, manufacturing changes, or additional labeling claims are subject to further FDA review and approval. For example, before we can market Periostat for additional indications now being evaluated, we will be required to obtain an additional FDA approval.

As a condition of approval of an application, the FDA may require postmarketing testing and surveillance to monitor the drug's safety or efficacy. As part of the NDA for Periostat, the FDA has requested a postmarket animal study related to long-term dosing and carcinogenicity, which was completed in 2000.

In some circumstances, approved drugs are provided protection from competitive versions of the approved drug for specified time periods. For example, the law provides for patent extension or market exclusivity in certain circumstances. The FDA has not provided such protection to Periostat.

Approved and cleared drugs and medical devices remain subject to comprehensive regulation by the FDA while they are being marketed. The drug and medical device regulatory schemes differ in detail, but they are essentially similar. For example, marketers of approved and cleared drugs and medical devices are required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with requirements concerning advertising and promotional labeling for their products. Also, the FDA does not permit a manufacturer to market or promote an approved or cleared drug product or medical device for an unapproved or uncleared use. Also, quality control and manufacturing procedures must continue to conform to the FDA's requirements for current Good Manufacturing Practices (for drugs) or Quality Systems Regulation (for medical devices) after approval. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with these and other aspects of regulatory compliance. The FDA periodically inspects manufacturers to assess compliance with manufacturing and other requirements. We buy bulk active ingredient for Periostat and our products in development from third party suppliers and finish the products in third party manufacturing facilities. The other products we market, Atridox, Atrisorb FreeFlow, Atrisorb-D and Pandel are provided by suppliers. Our failure, or the failure of our suppliers, to comply with FDA requirements could disrupt production and subject us to administrative or judicial sanctions.

In addition to the applicable FDA requirements, we are subject to foreign regulatory authorities governing clinical trials and drug sales. Whether or not FDA approval has been obtained, approval of a pharmaceutical product by the comparable regulatory authorities of foreign countries must be obtained prior to the commencement of marketing of the product in those countries. The approval process varies from country to country and the time required may be longer or shorter than that required for FDA approval.

Competition

The pharmaceutical industry is subject to intense competition as well as rapid and significant technological change.

We expect that competition in the periodontal area will be based on a variety of factors, including product efficacy, safety, cost-effectiveness, ease of use, patient discomfort, availability, price, patent position and effective product promotion. We believe that Periostat is distinguished from other existing and known periodontitis treatments in that it is the only treatment that is directed to suppression of the enzymes that degrade periodontal support tissues. We believe that all other therapies of which we are aware focus on temporarily removing the bacteria associated with periodontitis. Periostat is a prescription pharmaceutical tablet indicated as an adjunct to SRP to promote attachment level gain and to reduce pocket depth in patients with adult periodontitis that is taken by the patient between dental visits. We believe that the following chart summarizes the pharmacotherapies available in the United States and indicated for the treatment of adult periodontitis:

<u>Product Name</u>	<u>Product Manufacturer/ Marketer</u>	<u>Dental Procedure</u>	<u>Delivery Route</u>	<u>Patient Administered</u>	<u>Treatment Focus</u>	<u>Indication</u>
Periostat	CollaGenex Pharmaceuticals, Inc.	No	Systemic	Yes	Tissue degradation	As an adjunct to SRP to promote attachment level gain and to reduce pocket depth in patients with adult periodontitis
*Atridox	Atrix Laboratories/ CollaGenex Pharmaceuticals, Inc.	Yes	Local	No	Bacteria	For treatment of chronic adult periodontitis for a gain in clinical attachment, reduction in probing depth and reduction in bleeding on probing
Periochip	Vendent on behalf of Dexcel	Yes	Local	No	Bacteria	As an adjunct to SRP procedures for reduction of pocket depth in patients with adult periodontitis
Arestin	Orapharma, a Division of Johnson & Johnson, Inc.	Yes	Local	No	Bacteria	As an adjunct to SRP procedures for reduction of pocket depth in patients with adult periodontitis

* In August 2001, we entered into a License and Marketing Agreement with Atrix Laboratories, Inc. pursuant to which we market Atridox, Atrisorb FreeFlow and Atrisorb-D to the United States dental community. See—"Item 1. Business"

Many of the companies participating in the periodontal area have substantially greater financial, technical and human resources than we do, and may be better equipped to develop, manufacture and market products. These companies may develop and introduce products and processes competitive with or superior to ours.

In addition, we may face competition from generic competitors. If one or more generic versions of Periostat are approved and marketed, our revenues from Periostat would significantly decrease. We cannot be certain that parties will not receive FDA approval to introduce a competitive generic version of Periostat.

Employees

We have historically outsourced our manufacturing, clinical trials, new drug application preparation, warehousing, distribution and other activities. We intend to continue to outsource many of the activities which we have historically outsourced. As of December 31, 2003, we employed 156 persons. Each of our management personnel has had extensive prior experience with pharmaceutical, biotechnology or medical products companies. We cannot be certain that we will be able to recruit and retain qualified inside sales and marketing personnel, additional foreign sub-licensees or distributors or marketing partners or that our marketing and sales efforts will be successful. Currently, none of our employees are covered by collective bargaining agreements. In general, our employees are covered by confidentiality agreements. We consider relations with our employees to be excellent.

Additional Factors That May Affect Future Results

We Rely on Periostat for Most of Our Revenue.

During the years ended December 31, 2003, 2002 and 2001, Periostat accounted for approximately 82%, 82% and 87% of our total net revenues, respectively. Although we currently derive additional revenue from marketing and/or selling other products (Atridox, Atrisorb FreeFlow, Atrisorb-D and Pandel) and from licensing fees from foreign marketing partners, our revenue and profitability in the near future will depend on our ability to successfully market and sell Periostat.

Although we recently settled our litigation with West-ward, Mutual submitted an application to the FDA for approval of a generic version of Periostat. Other companies may also have submitted applications for approval of generic versions of Periostat. We have filed suits to enforce our patent rights and to compel the FDA to award patent and exclusivity protections that would prevent a generic drug application from being approved now. On July 23, 2003, we announced that the United States District Court for the District of Columbia had granted a preliminary injunction temporarily restraining the FDA from approving any ANDAs submitted for any generic version of Periostat. Until the Court has made a final ruling on our complaint, the FDA cannot approve the ANDAs on file for Mutual's 20 mg. doxycycline hyclate tablet or any other ANDA for a generic version of Periostat. The Court could make a final ruling at any time. If the Court decides in favor of the FDA, the FDA could begin to approve generic drugs immediately thereafter.

As a result of the ruling in the District Court of the District of Columbia, we have withdrawn our motion for a temporary restraining order and preliminary injunction in our patent infringement suit against Mutual, which was filed in the District Court of the Eastern District of New York. Our suit against Mutual, however, remains on file and a motion for injunctive relief can be filed immediately if required. We cannot predict the outcome of these matters. In addition, we cannot be sure that one or more generic versions of Periostat will not be approved and marketed. If one or more generic versions of Periostat are approved and marketed, our revenues from Periostat would significantly decrease and, as a result, our business, financial condition, cash flows and results of operations would be materially adversely affected.

We May Not Be Able to Maintain Profitability.

From our founding in 1992 through the commercial launch of Periostat in November, 1998, we had no revenue from sales of our own products. As of December 31, 2003, we have an accumulated deficit of \$69.9 million. Our historical losses have resulted primarily from the expenses associated with our pharmaceutical development program, clinical trials, the regulatory approval process associated with Periostat and sales and marketing activities relating to Periostat and our other products. Although we achieved net income of \$6.4 million and \$902,000 for the years ended December 31, 2003 and 2002, respectively, we expect to incur significant future expenses, particularly with respect to the sales and marketing of our existing products, new products and continuing clinical and manufacturing development for other indications and formulations of Periostat, and therefore, we cannot be certain that we will be able to maintain our profitability in the future, if at all.

Our Competitive Position in the Marketplace Depends on Enforcing and Successfully Defending Our Intellectual Property Rights.

In order to be competitive in the pharmaceutical industry, it is important to establish, enforce, and successfully defend patent and trade secret protection for our established and new technologies. We must also avoid liability from infringing the proprietary rights of others.

Our core technology is licensed from SUNY, and other academic and research institutions collaborating with SUNY. Under the license agreement with SUNY, or the SUNY License, we have an exclusive worldwide license to SUNY's rights in certain patents and patent applications to make and sell products employing tetracyclines to treat certain disease conditions. The SUNY License imposes various payment and reporting obligations on us, and our failure to comply with these requirements permits SUNY to terminate the SUNY License. If the SUNY License is terminated, we would lose our right to exclude competitors from commercializing similar products, and we could be excluded from marketing the same products if SUNY licensed the underlying technology to a competitor after terminating the SUNY License.

SUNY owns 31 United States patents and six United States patent applications that are licensed to us. The patents licensed from SUNY expire between 2004 and 2019. Two of the patents are related to Periostat and expire in 2004 and 2007. Technology covered by these patents becomes available to competitors as the patents expire.

Since many of our patent rights cover new treatments using tetracyclines, we may be required to bring expensive infringement actions to enforce our patents and protect our technology. Although federal law prohibits making and selling pharmaceuticals for infringing use, competitors and/or practitioners may provide generic forms of tetracycline for treatment(s) which infringe our patents, rather than prescribe our Periostat product. Enforcement of patents can be expensive and time consuming.

We are currently enforcing our patent rights against Mutual, a generic drug company. Mutual has submitted a request for listing a generic tablet replacement for Periostat on the New Jersey Formulary. In keeping with our patent enforcement policy, we have initiated a patent infringement action in the Eastern District of New York to prevent Mutual from introducing a generic version of Periostat. A motion for preliminary injunction was filed and served to prevent Mutual from introducing a generic version of Periostat to the marketplace. As a result of our litigation against the FDA, we have withdrawn our motion for a temporary restraining order and preliminary injunction in our patent infringement suit against Mutual, although our complaint against Mutual remains outstanding. Mutual has filed various claims against us relating to these matters. We cannot be certain that Mutual or other third parties will not receive FDA approval and introduce a competitive generic version of Periostat. Any infringement or related action involving Mutual or any third party will likely result in significant expenditures, even if such actions are settled, require substantial management time and may not be resolved in our favor.

Our success also depends upon know-how, trade secrets, and the skills, knowledge and experience of our scientific and technical personnel. To that end, we require all of our employees and, to the extent possible, all consultants, advisors and research collaborators, to enter into confidentiality agreements prohibiting unauthorized disclosure. With respect to information and chemical compounds we provide for testing to collaborators in academic institutions, we cannot guarantee that the institutions will not assert property rights in the results of such tests nor that a license can be reasonably obtained from such institutions which assert such rights. Failure to obtain the benefit of such testing could adversely affect our commercial position and, consequently, our financial condition.

If We Lose Our Sole Supplier of Doxycycline Hyclate or Our Current Manufacturer of Periostat, Our Commercialization of Periostat Will be Interrupted, Halted or Less Profitable.

We rely on a single supplier, Hovione International Limited, or Hovione, for doxycycline, the active ingredient in Periostat. There are relatively few alternative suppliers of doxycycline and Hovione produces the

majority of the doxycycline used in the United States. Our current supply agreement with Hovione expires on May 14, 2006 and thereafter automatically renews for successive two-year periods unless, 90 days prior to the expiration of any such periods, either party gives the other party written notice of termination. In addition, in the event of a default, uncured for 90 days, the non-defaulting party can terminate the supply agreement effective immediately at the end of such ninety-day period. We rely on Hovione as our sole supplier of doxycycline and have no back-up supplier at this time. If we are unable to procure a commercial quantity of doxycycline from Hovione on an ongoing basis at a competitive price, or if we cannot find a replacement supplier in a timely manner or with favorable pricing terms, our costs may increase significantly and we may experience delays in the supply of Periostat.

We have entered into an agreement with a contract manufacturer, Pharmaceutical Manufacturing Research Services, Inc., or PMRS, for our tablet formulation for Periostat. Our current arrangement with PMRS has been extended until the earlier of March 30, 2007 or until a generic 20 mg doxycycline hyclate tablet is available on the market. Currently, PMRS is the sole third-party contract manufacturer to supply a tablet formulation of Periostat to us. Any inability of PMRS to produce and supply product on agreed upon terms could result in delays in the supply of Periostat. The introduction of a generic 20 mg doxycycline hyclate tablet could leave us without a manufacturer or force us to negotiate a new arrangement, possibly on less favorable terms. We intend to contract with additional manufacturers for the commercial manufacture of Periostat tablets. We believe, however, that it could take up to one year to successfully transition from PMRS to a new manufacturer.

Our Products are Subject to Extensive Regulation by the FDA.

Drugs and medical devices generally require approval or clearance from the FDA before they can be marketed in the United States. Periostat, Pandel and Atridox have been approved by the FDA as drugs. Atrisorb FreeFlow and Atrisorb-D have been cleared by the FDA as medical devices. Our drug products under development, however, will have to be approved by the FDA before they can be marketed in the United States. Also, we cannot market our approved products for new indications until FDA approves the product for that indication. If the FDA does not approve our products under development or additional indications for marketed products in a timely fashion, or does not approve them at all, our financial condition may be adversely affected.

In addition, drug and medical device products remain subject to comprehensive regulation by the FDA while they are being marketed. The drug and medical device regulatory schemes differ in detail, but they are essentially similar. The FDA regulates, for example, the safety, manufacturing, labeling, and promotion of both drug and medical device products. If we or our partners who manufacture our products fail to comply with regulatory requirements, various adverse consequences can result, including recalls, civil penalties, withdrawal of the product from the market and/or the imposition of civil or criminal sanctions.

We are, and will increasingly be, subject to a variety of foreign regulatory regimes governing clinical trials and sales of our products. Other than Periostat, which has been approved by the Medicines Control Agency for marketing in the United Kingdom and approved for marketing in Austria, Finland, Switzerland, Ireland, Israel, Italy, Luxembourg, the Netherlands, Portugal and Canada, our products in development have not been approved in any foreign country. Whether or not FDA approval has been obtained, approval of drug products by the comparable regulatory authorities of foreign countries must be obtained prior to the commencement of marketing of those products in those countries. The approval process varies from country to country, and other countries may also impose post-approval requirements.

A Small Number of Wholesale Customers Account for the Majority of Our Sales, and the Loss of One of Them, or Changes in Their Purchasing Patterns, Could Result in Reduced Sales, Thereby Adversely Affecting Our Operating Results.

We sell most of our products to a small number of wholesale drug distributors. For the year ended December 31, 2003, sales to Cardinal Health, Inc., McKesson Corporation and Amerisource-Bergen Corporation,

represented approximately 43%, 31% and 20%, respectively, of our aggregate net product sales. The small number of wholesale drug distributors, consolidation in this industry or financial difficulties of these distributors could result in the combination or elimination of warehouses, which could temporarily increase returns of our products or, as a result of distributors reducing inventory levels, delay the purchase of our products. In addition, wholesalers may increase purchase levels in anticipation of future price increases or may capitalize on volume discounts to acquire inventory. This may cause an unexpected increase in the level of trade inventories normally maintained by wholesalers. Although we have developed a plan to manage our products trade inventory level, this plan may not be effective. If trade inventory levels become too high, or if prescription growth of our products are lower than expected by the trade, wholesalers and large retail chains could reduce their orders for our products, which could result in reduced sales of our products and adversely affect our operating results.

We Cannot Assure You that Our Pursuit of Business in the Dermatology Market will be Successful.

During 2003, we began to implement our plans to expand into the dermatology market. We have completed and announced the preliminary results of a double-blind, placebo-controlled 134-patient Phase III clinical trial to evaluate the safety and efficacy of Periostat to treat rosacea, we have licensed a new dermal and transdermal drug delivery technology called Restoraderm and we executed a sublicense Agreement with Altana Inc. with respect to the marketing and distribution of Pandel. In addition, we continue to actively seek product licensing opportunities to enhance our near-term offerings to the dermatology market. Our future success will depend on, among other things, our ability to: (i) achieve market acceptance for any of these or future dermatological offerings; (ii) hire and retain personnel with experience in the dermatology market; (iii) execute our business plan with respect to this market segment; and (iv) adapt to technical or regulatory changes once operational. Furthermore, while we have experience in the sales and marketing of dental products, we have limited experience in this market. This market is very competitive and some of our competitors have substantially greater resources than we have. New product development is a lengthy, complex and uncertain process that will require significant attention and resources from management. A product candidate can fail at any stage of the development process due to, among other things, efficacy or safety concerns, the inability to obtain necessary regulatory approvals, the difficulty or excessive cost to manufacture and/or the infringement of patents or intellectual property rights of others. Furthermore, the sales of new products may prove to be disappointing and fail to reach anticipated levels. We therefore cannot assure you that we will be successful in our pursuit of business in the dermatology market, or that we can sustain any business in which we achieve initial success.

If Our Products Cause Injuries, We May Incur Significant Expense and Liability.

Our business may be adversely affected by potential product liability risks inherent in the testing, manufacturing and marketing of Periostat and other products developed by or for us or for which we have licensing or co-promotion rights. We have an aggregate of \$10.0 million in product liability insurance for Periostat, our product candidates and products for which we have licensing or co-promotion rights. This level of insurance may not adequately protect us against product liability claims. Insufficient insurance coverage or the failure to obtain indemnification from third parties for their respective liabilities may expose us to product liability claims and/or recalls and could cause our business, financial condition and results of operations to decline.

Because Our Executive Officers, Directors and Affiliated Entities Own Approximately 23.3% of Our Capital Stock, They Could Influence Our Actions in a Manner That Conflicts With Our Interests and the Interests of Our Other Stockholders.

Currently, our executive officers, directors and affiliated entities together beneficially own approximately 23.3% of the outstanding shares of our common stock or equity securities convertible into common stock. As a result, these stockholders, acting together, or in the case of our preferred stockholders, in certain instances, as a class, will be able to influence corporate actions requiring stockholder approval, including the election of

directors. This concentration of ownership may have the effect of delaying or preventing a change in control, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices.

Our Stock Price is Highly Volatile and, Therefore, the Value of Your Investment May Fluctuate Significantly.

The market price of our common stock has fluctuated and may continue to fluctuate as a result of variations in our quarterly operating results. These fluctuations may be exaggerated if the trading volume of our common stock is low. In addition, the stock market in general has experienced dramatic price and volume fluctuations from time to time. These fluctuations may or may not be based upon any business or operating results. Our common stock may experience similar or even more dramatic price and volume fluctuations that may continue indefinitely.

The following table sets forth the high and low closing market price per share for our common stock for each of the quarters in the period beginning January 1, 2000 through December 31, 2003, as reported on the Nasdaq National Market:

<u>Quarter Ended</u>	<u>High</u>	<u>Low</u>
March 31, 2000	\$27.13	\$12.63
June 30, 2000	\$15.50	\$ 8.25
September 30, 2000	\$ 9.88	\$ 8.06
December 31, 2000	\$ 7.88	\$ 3.13
March 31, 2001	\$ 6.00	\$ 4.47
June 30, 2001	\$ 8.80	\$ 5.06
September 30, 2001	\$10.00	\$ 7.25
December 31, 2001	\$ 9.50	\$ 7.50
March 31, 2002	\$12.00	\$ 7.72
June 30, 2002	\$11.65	\$ 5.75
September 30, 2002	\$ 7.34	\$ 4.70
December 31, 2002	\$ 9.93	\$ 4.05
March 31, 2003	\$11.03	\$ 6.66
June 30, 2003	\$13.27	\$ 8.62
September 30, 2003	\$15.84	\$10.50
December 31, 2003	\$11.82	\$ 8.90

Item 2. Properties.

We own no real property. Our principal executive offices, located at 41 University Drive, Suite 200, Newtown, Pennsylvania, consist of approximately 14,204 square feet. Our lease for such premises continues through April 2009.

Item 3. Legal Proceedings.

In November 2002, we commenced an action in the United States District Court for the Eastern District of New York seeking to prevent West-ward Pharmaceutical Corporation, or West-ward, from selling 20 mg. capsules of doxycycline hyclate to treat periodontal disease, which we believe would infringe patents covering our Periostat product. As discussed below, we have settled all pending litigation with West-ward.

In July 2003, we commenced an action against Mutual in the United States District Court for the Eastern District of New York seeking to prevent Mutual from introducing 20 mg. tablets of doxycycline hyclate into the market in the United States. Our suit alleges infringement of patents to which we are the exclusive licensee.

In July 2003, Mutual commenced an action against us in the United States District Court for the Eastern District of Pennsylvania. Mutual alleges that we have engaged in an overall scheme to monopolize the market for low-dose doxycycline products. In addition, the suit alleges that we have engaged in exclusionary, unfair, and anticompetitive practices. Mutual seeks an award of treble damages, injunctive relief, compensatory, punitive and exemplary damages and reasonable attorneys' fees. In January 2004, the Court stayed all proceedings in this case.

In June 2003, we commenced an action and filed a motion for a preliminary injunction in the United States District Court for the District of Columbia challenging FDA's decision to treat Periostat as an antibiotic drug, thus denying Periostat certain protections afforded non-antibiotic drugs under the Food, Drug, and Cosmetic Act and against FDA approval of generic copies of Periostat. West-ward and Mutual intervened in this action. On July 22, 2003, the Court granted a preliminary injunction temporarily restraining the FDA from approving any ANDA submitted for a generic version of Periostat (doxycycline hyclate) 20 mg.

Until the United States District Court for the District of Columbia has made a final ruling on the regulatory status of Periostat, the FDA cannot approve the ANDAs for West-ward's 20 mg. doxycycline hyclate capsule, Mutual's 20 mg. doxycycline hyclate tablet or any other ANDA for a generic version of Periostat. Cross motions for summary judgment are pending.

As a result of the ruling in the United States District Court for the District of Columbia, we withdrew our then pending motion for a temporary restraining order and preliminary injunction in our patent infringement suit against Mutual, which was filed in the United States District Court for the Eastern District of New York, although our complaint remains outstanding. In November, 2003 the proceedings in the patent infringement case were stayed pending a determination by the United States Patent and Trademark Office of its re-examination of the patents-in-suit, subject to the parties' right to conduct limited discovery related to the potential re-instatement of our motion for a temporary restraining order and preliminary injunction. We cannot predict the outcome of these matters.

On November 7, 2003, we settled all pending litigation between us and West-ward. In the settlement, West-ward agreed and confessed to judgment that our Periostat patents are valid and infringed by the filing of West-ward's ANDA. West-ward also agreed and confessed to judgment that our Periostat patents would be infringed by the manufacture and sale of a generic version of Periostat. West-ward consented to a judgment enjoining West-ward and any party acting in concert with West-ward from making and selling a generic version of Periostat until our patents expire or are declared invalid or unenforceable by a court of competent jurisdiction. Finally, West-ward agreed to withdraw from the FDA case in the District of Columbia. In connection with this settlement, we agreed to pay a portion of West-ward's actual legal expenses in the amount of \$700,000.

We anticipate that our future legal costs in these matters relating to patent infringement and defense will be reimbursed by SUNY pursuant to our Technology License Agreement with SUNY to the extent that these legal expenses do not exceed royalties earned by SUNY during that period. During 2002 and 2003, we incurred \$129,000 and \$3.8 million respectively, in legal defense, litigation and settlement costs for the aforementioned law suits with West-ward and Mutual, \$129,000 and \$1.7 million respectively, of which were deducted from royalties payable to SUNY during those periods. In the event such cumulative legal costs exceed the amount of the royalties payable to SUNY, we will not be able to recover such legal costs from SUNY. As of December 31, 2003, we have \$1.7 million in previously recorded legal expenses available to offset future royalties which may become payable to SUNY.

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

Not applicable.

PART II

Item 5. Market for the Company's Common Equity and Related Stockholder Matters.

Prior to June 1996, there was no established market for our common stock. Since June 20, 1996, our common stock has traded on the Nasdaq National Market under the symbol "CGPI."

The following table sets forth the high and low per share sales prices for our common stock for each of the quarters in the period beginning January 1, 2002 through December 31, 2003 as reported on the Nasdaq National Market.

<u>Quarter Ended</u>	<u>High</u>	<u>Low</u>
March 31, 2002	\$12.00	\$ 7.72
June 30, 2002	\$11.65	\$ 5.75
September 30, 2002	\$ 7.34	\$ 4.70
December 31, 2002	\$ 9.93	\$ 4.05
March 31, 2003	\$11.03	\$ 6.66
June 30, 2003	\$13.27	\$ 8.62
September 30, 2003	\$15.84	\$10.50
December 31, 2003	\$11.82	\$ 8.90

As of March 11, 2004, the approximate number of holders of record of our common stock was 114 and the approximate number of beneficial holders of our common stock was 4,406.

We have never declared or paid any cash dividends on our common stock. Except as set forth below, we intend to retain earnings, if any, to fund future growth and the operation of our business. On May 12, 1999, we consummated a \$20.0 million financing through the issuance of our Series D cumulative convertible preferred stock. As a result of such financing, we had certain common stock dividend obligations and continue to have certain cumulative cash dividend obligations to the holders of the Series D preferred stock. Such financing arrangement also limits our ability to generally declare dividends to our common stockholders. In addition, our ability to generally declare dividends to our common stockholders is further limited by the terms of our credit facility with Silicon Valley Bank for which we are currently negotiating a two-year renewal upon expiration. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources."

The following information relates to all securities of the Company sold by us during the year ended December 31, 2003 which were not registered under the securities laws at the time of grant, issuance and/or sale (and which were not previously reported on a Quarterly Report on Form 10-Q):

Option Grants

During the fourth quarter of 2003, we granted stock options pursuant to our 1996 Stock Plan and outside of our 1996 Stock Plan which were not registered under the Securities Act of 1933, as amended (the "Securities Act"). All of such option grants were granted at the then current fair value of the common stock. The following table sets forth certain information regarding such grants during the quarter:

<u>Number of Options Granted</u>	<u>Weighted Average Exercise Price</u>
309,650	\$10.15

We did not employ an underwriter in connection with the issuance of the securities described above. We believe that the issuance of the foregoing securities was exempt from registration under either (i) Section 4(2) of the Securities Act as transactions not involving any public offering and such securities having been acquired for investment and not with a view to distribution, or (ii) Rule 701 under the Securities Act as transactions made pursuant to a written compensatory benefit plan or pursuant to a written contract relating to compensation. All recipients had adequate access to information about us. On February 6, 2004, we filed a registration statement on Form S-8 with the Securities and Exchange Commission with respect to the foregoing securities.

Item 6. Selected Consolidated Financial Data.

The selected consolidated financial data set forth below with respect to our consolidated statement of operations data for each of the years in the three-year period ended December 31, 2003, and with respect to the consolidated balance sheet data as of December 31, 2003 and 2002 are derived from and are qualified by reference to our audited consolidated financial statements and the related notes thereto found at "Item 15. Exhibits, Financial Statement Schedules, and Reports on Form 8-K" herein. The consolidated statement of operations data for the years ended December 31, 2000 and 1999 and with respect to the consolidated balance sheet data as of December 31, 2001, 2000 and 1999 are derived from our audited consolidated financial statements not included in this Annual Report on Form 10-K. The selected consolidated financial data set forth below should be read in conjunction with and is qualified in its entirety by our audited consolidated financial statements and related notes thereto found at "Item 15. Exhibits, Financial Statement Schedules, and Reports on Form 8-K" and "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" which are included elsewhere in this Annual Report on Form 10-K.

	Years Ended December 31,				
	<u>2003</u>	<u>2002</u>	<u>2001</u>	<u>2000</u>	<u>1999</u>
	(In thousands except for per share data)				
Consolidated Statement of Operations Data:					
Revenues:					
Net product sales	\$ 49,038	\$ 42,111	\$ 31,358	\$ 20,501	\$ 15,211
Contract revenues	3,122	2,332	3,386	3,240	770
License revenues	699	176	488	530	100
Total revenues	<u>52,859</u>	<u>44,619</u>	<u>35,232</u>	<u>24,271</u>	<u>16,081</u>
Operating expenses:					
Cost of product sales	7,362	6,713	5,825	4,070	3,139
Research and development	5,462	4,394	3,764	3,128	5,005
Selling, general and administrative	33,668	32,699	34,010	25,746	23,180
Operating income (loss)	6,367	813	(8,367)	(8,673)	(15,243)
Interest income	148	77	232	613	851
Interest expense	—	(5)	(17)	(15)	(197)
Other (expense) income	(3)	17	8	9	(2)
Income (loss) before income taxes and cumulative effect of change in accounting principle	6,512	902	(8,144)	(8,066)	(14,591)
Income taxes	85	—	—	—	—
Cumulative effect of change in accounting principle(1)	—	—	—	(764)	—
Net income (loss)	<u>\$ 6,427</u>	<u>\$ 902</u>	<u>\$ (8,144)</u>	<u>\$ (8,830)</u>	<u>\$ (14,591)</u>
Net income (loss) allocable to common stockholders	<u>\$ 4,827</u>	<u>\$ (727)</u>	<u>\$ (9,824)</u>	<u>\$ (10,519)</u>	<u>\$ (15,683)</u>
Basic net income (loss) per share allocable to common stockholders before cumulative effect of change in accounting principle(1)(2)	<u>\$ 0.40</u>	<u>\$ (0.06)</u>	<u>\$ (0.94)</u>	<u>\$ (1.12)</u>	<u>\$ (1.82)</u>
Diluted net income (loss) per share allocable to common stockholders before cumulative effect of change in accounting principle(1)(2)	<u>\$ 0.38</u>	<u>\$ (0.06)</u>	<u>\$ (0.94)</u>	<u>\$ (1.12)</u>	<u>\$ (1.82)</u>
Basic net income (loss) per share allocable to common stockholders(2)	<u>\$ 0.40</u>	<u>\$ (0.06)</u>	<u>\$ (0.94)</u>	<u>\$ (1.21)</u>	<u>\$ (1.82)</u>
Diluted net income (loss) per share allocable to common stockholders(2)	<u>\$ 0.38</u>	<u>\$ (0.06)</u>	<u>\$ (0.94)</u>	<u>\$ (1.21)</u>	<u>\$ (1.82)</u>
Shares used in computing basic per share amounts(2)	12,094,638	11,234,652	10,413,663	8,711,668	8,597,676
Shares used in computing diluted per share amounts(2)	12,836,364	11,234,652	10,413,663	8,711,668	8,597,676

	As of December 31,				
	<u>2003</u>	<u>2002</u>	<u>2001</u>	<u>2000</u>	<u>1999</u>
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and short-term investments	\$ 32,670	\$ 10,112	\$ 6,171	\$ 5,448	\$ 14,367
Working capital	32,010	5,992	6,194	5,308	12,987
Total assets	43,305	17,634	14,698	10,431	18,563
Note payable, less current portion	—	—	—	47	116
Accumulated deficit	(69,854)	(74,681)	(73,954)	(64,130)	(53,611)
Total stockholders' equity	33,956	8,352	7,127	5,264	13,607

- (1) Refers to the Company's adoption of Staff Accounting Bulletin No. 101 during 2000 and the corresponding cumulative effect of the change in accounting principle.
- (2) See Note 2 of Notes to Consolidated Financial Statements for information concerning computation of net income (loss) per share.

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

Overview

CollaGenex Pharmaceuticals, Inc. and subsidiaries is a specialty pharmaceutical company currently focused on providing innovative medical therapies to the dental and dermatology markets. Our first product, Periostat®, is an orally administered, prescription pharmaceutical product that was approved by the United States Food and Drug Administration in September 1998 and is the first and only dental pharmaceutical to treat adult periodontitis by inhibiting the enzymes that destroy periodontal support tissues.

We are marketing Periostat and other pharmaceutical products to the dental and dermatology communities through our own professional pharmaceutical sales force of approximately 115 sales representatives and managers. Pursuant to an exclusive License and Marketing Agreement with Atrix Laboratories, Inc., we began, in October 2001, to actively market Atrix's proprietary dental products, Atridox® and Atrisorb FreeFlow®, and Atrisorb-D®, to the United States dental market. In May 2002, we executed a sublicense agreement with Altana Inc. to, among other things, market and distribute, in the United States and Puerto Rico, Pandel®, a mid-potency topical corticosteroid product developed by Altana Inc. We distribute Periostat and Pandel exclusively through drug wholesalers in the United States. Periostat is also sold through wholesalers and direct to dentists in the United Kingdom through our wholly-owned subsidiary, CollaGenex International Ltd., and by distributors and licensees in certain other overseas markets. The Atrix dental products are distributed through specialty distributors who sell these products directly to dental practitioners in the United States and Puerto Rico.

For the years ended December 31, 2003 and 2002, we achieved net income of approximately \$6.4 million and \$902,000, respectively. We have, however, incurred losses in each year from inception through 2002 and have an accumulated deficit of \$69.9 million at December 31, 2003.

During the years ended December 31, 2003, 2002 and 2001, Periostat accounted for approximately 82%, 82% and 87% of our total net revenues, respectively. Although we currently derive additional revenue from marketing and/or selling other products (Atridox, Atrisorb FreeFlow, Atrisorb-D and Pandel) and from licensing fees from foreign marketing partners, our revenue and profitability in the near future will depend on our ability to successfully market and sell Periostat.

Mutual has submitted an application to the FDA for approval of a generic version of Periostat. We have filed suits to enforce our patent rights and to compel the FDA to award patent and exclusivity protections that would prevent a generic drug application from being approved now. We cannot predict the outcome of these matters. In addition, we cannot be sure that one or more generic versions of Periostat will not be approved and marketed. If one or more generic versions of Periostat are approved and marketed, our revenues from Periostat would significantly decrease and, as a result, our business, financial condition, cash flows and results of operations would be materially adversely affected.

This Annual Report on Form 10-K and the documents incorporated herein contain forward-looking statements within the meaning of Section 21E of the Securities and Exchange Act of 1934, as amended. For this purpose, any statements contained herein or incorporated herein that are not statements of historical fact may be forward-looking statements. For example, the words "may," "will," "continue," "believes," "expects," "anticipates," "intends," "estimates," "should" and similar expressions are intended to identify forward-looking statements. There are a number of important factors that could cause our results to differ materially from those indicated by such forward-looking statements. These factors include those set forth in the section entitled "Additional Factors That May Affect Future Results" included in Item 1 of this Annual Report. In particular, our business of selling, marketing and developing pharmaceutical products is subject to a number of significant risks, including risks relating to the implementation of our sales and marketing plans for Periostat and other products that we market, risks inherent in research and development activities, risks associated with enforcement of our intellectual property rights, including risks relating to the outcome and consequences of our patent litigation against Mutual, risks that the FDA will approve products, such as Mutual's product, that will compete with and limit the market for Periostat, risks relating to our litigation with the FDA, risks associated with conducting

business in a highly regulated environment and uncertainty relating to clinical trials of products under development. Our success depends to a large degree upon the market acceptance of Periostat by periodontists, dental practitioners, other health care providers, patients and insurance companies. There can be no assurance that our product candidates (other than the FDA's approval of Periostat for marketing in the United States, the United Kingdom Medicines Control Agency's approval of Periostat for marketing in the United Kingdom and Periostat's marketing approval in Austria, Finland, Switzerland, Ireland, Israel, Italy, Luxembourg, the Netherlands, Portugal and Canada) will be approved by any regulatory authority for marketing in any jurisdiction or, if approved, that any such products will be successfully commercialized by us. In addition, there can be no assurance that we will successfully promote Pandel, Atridox, Atrisorb-FreeFlow or Atrisorb-D. As a result of such risks, those risks set forth in the section entitled "Additional Risks That May Affect Results" and others expressed from time to time in our filings with the Securities and Exchange Commission, our actual results may differ materially from the results discussed in or implied by the forward-looking statements contained herein. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Critical Accounting Policies and Estimates

Management's discussion and analysis of its financial position and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make judgments and estimates that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. Management believes the critical accounting policies and areas that require the most significant judgments and estimates to be used in the preparation of the consolidated financial statements pertain to revenue recognition, stock compensation and deferred taxes.

Revenue Recognition

We recognize product sales revenue upon shipment, net of estimated returns, provided that collection is determined to be probable and no significant obligations remain. Sales revenue from our customers is subject to agreements allowing limited rights of return, rebates and price protection. Accordingly, we reduce revenue recognized for estimated future returns, rebates and price protection at the time the related revenue is recorded. The estimates for returns are adjusted periodically based upon historical rates of returns, inventory levels in the distribution channel and other related factors. While management believes it can make reliable estimates for these matters, unsold products in these distribution channels may be exposed to expiration. Accordingly, it is possible that these estimates will change in the future or that the actual amounts could vary materially from our estimates and that the amounts of such changes could impact our results of operations, financial condition and our business. Our contract revenues are fee-based arrangements where revenue is earned as prescriptions are filled. Accordingly, since we never take title to the product being promoted, no significant obligations exist beyond the point that revenue is recognized.

Since our inception, a portion of our revenue has been generated from license and distribution agreements for our products. We recognize nonrefundable signing or license fees that are not dependent on future performance under these agreements as revenue when received and over the term of the arrangement if we have continuing performance obligations. Any amounts deferred are amortized to revenue over the expected performance period of each underlying agreement. The expected performance period is based on management's best estimate and is subject to change based on current market conditions. Deferred revenue represents the portion of up front license payments received that has not been earned. Milestone revenue from licensing arrangements is recognized upon completion of the milestone event or requirement if it represents the achievement of a significant step in the research, development or regulatory process.

Stock-Based Compensation

It is our policy to apply Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations to account for our stock option grants rather than Statement of Financial

Accounting Standards No. 123, "Accounting for Stock-Based Compensation". As such, compensation expense is recorded on fixed stock option grants only if the current market value of the underlying stock exceeds the exercise price of the option at the date of grant and is recognized on a straight-line basis over the vesting period. Had we applied SFAS No. 123, which requires recording stock option grants at their fair value, our net income (loss) for each of the years ended December 31, 2003, 2002 and 2001 would have varied from the reported net income (loss) as we would have recorded additional expenses in each period.

Deferred Taxes

In assessing the realizability of deferred tax assets, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. This assessment requires significant judgment and estimates. The ultimate realization of the deferred tax assets is dependent upon the generation of future taxable income during the period in which those temporary differences become deductible. We consider our history of losses, scheduled reversal of deferred tax assets and liabilities and projected future taxable income over the periods in which the deferred tax asset items are deductible. Should we continue to be profitable, we will assess and may reduce the valuation allowance. The Tax Reform Act of 1986 contains provisions that may limit the net operating loss (NOL) and research and experimentation credit carryforwards available to be used in any given year upon the occurrence of certain events, including significant changes in ownership interest. The rules providing for the definition of an ownership change are complex.

Recently Issued Accounting Standards

FASB Statement No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*, was issued in May 2003. This Statement establishes standards for the classification and measurement of certain financial instruments with characteristics of both liabilities and equity. The Statement also includes required disclosures for financial instruments within its scope. For us, the Statement was effective for instruments entered into or modified after May 31, 2003. For certain mandatorily redeemable financial instruments, the Statement will be effective at a later date. The effective date has been deferred indefinitely for certain other types of mandatorily redeemable financial instruments. We currently do not have any financial instruments that are within the scope of this Statement.

Results of Operations

We generated net income allocable to common stockholders of \$4.8 million, or \$0.38 per diluted share, for the year ended December 31, 2003 as compared to a net loss of \$727,000, or \$0.06 per diluted share for the year ended December 31, 2002. The increase in profitability from 2002 to 2003 was primarily a result of increases in net product sales, contract revenues, and licensing revenues. Product sales increased as a result of the increased volume in Periostat product sales as well as increases in Pandel product sales, which we began to sell direct in July 2002. The increase in contract revenues was primarily attributable to our co-promotion efforts related to the AVAR and Denavir product lines, partially offset by the termination of other co-promotion agreements. License revenues increased primarily as the result of milestones achieved by our foreign partners in 2003 and the accelerated recognition of previously deferred up-front payments that were recognized as the result of terminated license agreements. These increases were partially offset by increased research and development expenditures as well as increases in cost of products sold and selling, general and administrative expenses.

Our revenues are affected by a number of factors, including our ability to influence physician prescribing habits, managing the purchasing practices of the United States drug wholesalers, managing our sales professionals and delivering our marketing message effectively. We believe future revenues will be affected by our ability to maintain the current business and expand the use of Periostat for new indications.

In order to effectively manage the wholesale channel, we executed Inventory Management Agreements with our major wholesalers in 2003. These agreements help us manage the level of inventory of our products in the

wholesale channel, obtain weekly retail demand information for our products and to make sales that are consistent with end-user prescription demand for our products. In exchange for retail demand data, we allow our wholesalers to purchase a specific amount of inventory from us at the sales price in effect immediately prior to announced price increases.

Periostat sales have historically been subject to seasonality in the United States market based on holiday schedules and vacation patterns. Our sales may fluctuate on a quarterly basis based on such seasonal fluctuations.

Years Ended December 31, 2003 and December 31, 2002

Revenues

	<u>2003</u>	<u>Change</u>	<u>2002</u>
	(dollars in thousands)		
Net Product Sales	\$49,038	16.4%	\$42,111
Contract Revenues	3,122	33.9	2,332
License Revenues	699	297.2	176
<i>Total</i>	<u>\$52,859</u>	18.5%	<u>\$44,619</u>

Total revenues during the year ended December 31, 2003 were \$52.9 million, an 18.5% increase over total revenues of \$44.6 million during the year ended December 31, 2002. Such 2003 revenues included approximately \$49.0 million in net product sales of Periostat, Atridox, Atrisorb FreeFlow, Atrisorb-D and Pandel, \$3.1 million in contract revenues, which were derived from our co-promotion of Vioxx, Denavir and AVAR, and \$699,000 in international licensing revenues. Our agreement with Novartis Consumer Health Inc. to co-promote Devavir expired on September 30, 2003, and we and Novartis mutually decided not to renew our arrangement with respect to Denavir. Our agreement with Merck to co-promote Vioxx expired on December 31, 2003 and the parties mutually decided not to renew such arrangement. In addition, our co-promotion agreement with Sirius Laboratories, Inc. with respect to our joint marketing activities of the AVAR product line and Pandel was mutually terminated on December 31, 2003. Net product sales increased \$6.9 million, or 16.4%, during the year ended December 31, 2003 to \$49.0 million compared to \$42.1 million during the year ended December 31, 2002, mainly due to increased volume of prescriptions and price increases relating to Periostat and the addition of the Pandel product line which we began selling direct in July 2002. Total international sales increased to \$558,000 in 2003 from \$350,000 in 2002.

Contract revenues for the year ended December 31, 2003 increased 33.9% to \$3.1 million from \$2.3 million during the year ended December 31, 2002, primarily due to increased contract revenues relating to our co-promotion activities with respect to Denavir and the AVAR product line, which were partially offset by lower Pandel contract revenues earned during 2003 following our acquisition of a license to Pandel when we began selling Pandel directly and recording related product sales. We do not expect to earn contract revenues for Denavir and AVAR in 2004. During 2003, our co-promotional agreements with Merck, Novartis and Sirius generated approximately \$3.1 million in revenue. We will continue to earn nominal residual contract revenues through 2005 from our expired agreement with Merck for Vioxx.

We recorded \$52,000 and \$59,000 in licensing revenues for the years ended December 31, 2003 and December 31, 2002, respectively, that was attributable to our recognition of previously received up-front license fees recognized for various agreements that were deferred and are being recognized as licensing revenue over the expected performance period of the agreements. We also recorded licensing revenues of \$222,000 and \$47,000 during the years ended December 31, 2003 and 2002, respectively, from previously deferred foreign up-front licensing fees where the recognition of revenue was accelerated in connection with certain licensing agreements that were mutually terminated during the respective periods. Additionally, during the years ended December 31, 2003 and 2002, respectively, we recognized \$425,000 and \$70,000 in license milestone fees received from foreign licensing partners upon the achievement of certain milestones.

Cost of Product Sales

	<u>2003</u>	<u>Change</u>	<u>2002</u>
	<u>(dollars in thousands)</u>		
Cost of Product Sales	\$7,362	9.7%	\$6,713
Percent of Net Product Sales	15.0%		15.9%

Cost of product sales includes product packaging, third-party royalties, amortization of product licensing fees, and the costs associated with the manufacturing, storage and stability of Periostat, Pandel and the Atrix products.

Cost of product sales were \$7.4 million, or 15.0% of net product sales for the year ended December 31, 2003, compared to \$6.7 million, or 15.9% of net product sales during the year ended December 31, 2002. During the year ended December 31, 2003, cost of product sales increased in absolute dollars as a result of increased product sales. As a percentage of net product sales, cost of product sales decreased during the year ended December 31, 2003, compared to the year ended December 31, 2002, primarily due to product sales price increases for Periostat in 2003, offset in part by higher cost of product sales (as a percentage of net product sales) for the Pandel product line, launched in July 2002.

Research and Development

	<u>2003</u>	<u>Change</u>	<u>2002</u>
	<u>(dollars in thousands)</u>		
Research and Development	\$5,462	24.3%	\$4,394
Percentage of Total Revenue	10.3%		9.8%

Research and development expenses consist primarily of funds paid to third parties for the provision of services and materials for drug development, including milestone fees, manufacturing and formulation enhancements, clinical trials, statistical analysis and report writing and regulatory compliance costs.

Research and development expenses increased \$1.1 million, or 24.3%, to \$5.5 million during the year ended December 31, 2003 from \$4.4 million during the year ended December 31, 2002.

Development projects conducted during the year ended December 31, 2003 included our continuing formulation development work for a once-a-day formulation of Periostat and formulation and stability testing for several potential products utilizing our licensed Restoraderm™ technology, which totaled \$2.0 million and \$820,000, respectively. If all of the potential products are successful, additional formulation development expenses and milestone fees could be as much as \$11.1 million.

Clinical projects totaling \$832,000 were conducted during the year ended December 31, 2003 and included several Phase IV studies for Periostat in various dental indications and continued clinical development work relating to Periostat in dermatological indications and including a Phase III trial in 134 patients to evaluate Periostat for the treatment of rosacea. Until the outcome of these trials is determined, it is premature to estimate the future costs associated with the clinical development of Periostat for any indication.

Other research and development expenses incurred during the year ended December 31, 2003 included \$108,000 in regulatory consulting and legal and filing fees under the Mutual Recognition Procedure in Europe and \$484,000 for various regulatory costs, including annual FDA filing fees, patent fees and regulatory expenses in the United States, and \$335,000 in development costs for Metastat and the IMPACS compounds. Direct salaries and other personnel expenses incurred during the year ended December 31, 2003 were \$657,000. Additionally, during such period we incurred \$243,000 in consulting, travel and other office expenses. We expect to significantly increase our investment in research and development in 2004.

Development projects conducted during the year ended December 31, 2002 included our continuing formulation development work for a once-a-day formulation of Periostat and formulation and stability testing for several potential products utilizing our licensed Restoraderm technology, which totaled \$1.3 million and \$349,000, respectively.

Clinical projects totaling \$1.1 million were conducted during the year ended December 31, 2002 and included several Phase IV studies for Periostat in various dental indications, initiation of a 70-patient clinical study to evaluate the efficacy of Periostat to treat meibomianitis, clinical development work relating to Periostat in dermatological indications, limited clinical testing of Restoraderm formulations and initiation of a Phase III trial in 134 patients to evaluate Periostat for the treatment of rosacea. Additionally, during 2002 we granted \$253,000 for research to various academic institutions for conducting research related to our core technology.

Other research and development expenses incurred during the year ended December 31, 2002 included \$247,000 in regulatory consulting and filing fees under the Mutual Recognition Procedure in Europe and \$373,000 for various regulatory costs, including annual FDA filing fees, legal, and regulatory expenses in the United States. Direct salaries and other personnel expenses incurred during the year ended December 31, 2002 were \$480,000. Additionally, during such period we incurred \$266,000 in consulting, travel and other office expenses.

Selling, General and Administrative

	<u>2003</u>	<u>Change</u>	<u>2002</u>
	(dollars in thousands)		
Selling, General and Administrative	\$33,668	3.0%	\$32,699
Percentage of Total Revenues	63.7%		73.3%

Selling, general and administrative expenses consist primarily of personnel salaries and benefits, direct marketing costs, professional, legal and consulting fees, insurance and general office expenses.

Selling, general and administrative expenses increased 3.0% to \$33.7 million during the year ended December 31, 2003 from \$32.7 million during the year ended December 31, 2002. This increase of \$969,000 was primarily the result of approximately \$2.5 million in increased legal fees and settlement costs relating to our ongoing litigation, net of reimbursable legal expenses from SUNY, additional personnel costs of \$1.2 million, approximately \$1.9 million in additional promotional expenses for AVAR and Pandel, offset in part by a \$4.7 million reduction in selling and marketing expenditures for Periostat, Vioxx and the Atrix products.

Significant components of selling, general and administrative expenses incurred during the year ended December 31, 2003 included \$15.7 million in direct selling and sales training expenses, \$8.8 million in marketing expenses (including advertising and promotion expenditures for Periostat, the Atrix products and Pandel and co-promotion expenses relating to Vioxx and AVAR) and \$8.9 million in general and administrative expenses, which include business development, finance, legal and corporate activities. Significant components of selling, general and administrative expenses incurred during the year ended December 31, 2002 included \$15.7 million in direct selling and sales training expenses, \$11.3 million in marketing expenses (including direct to consumer advertising and promotion expenditures for Periostat, the Atrix products and co-promotion expenses relating to Vioxx and Pandel) and \$5.7 million in general and administrative expenses, which include business development, finance and corporate activities.

Selling, general and administrative expenses also included \$251,000 during the year ended December 31, 2003 which resulted from certain modifications made to stock option agreements held by Brian M. Gallagher, Ph.D., our former chairman, chief executive officer and president, in connection with a Transition Agreement we executed with Dr. Gallagher on March 18, 2003.

Other Income/Expense

	<u>2003</u>	<u>Change</u>	<u>2002</u>
	(dollars in thousands)		
Interest Income	\$148	92.2%	\$77
Interest Expense	\$ —	(100)%	\$ 5
Other Income (Expense)	\$ (3)	(117.6)%	\$17

Interest income increased to \$148,000 for the year ended December 31, 2003 compared to \$77,000 for the year ended December 31, 2002. This increase was due to higher average investment balances in 2003, partially offset by lower average yields. There was no interest expense for the year ended December 31, 2003, compared to \$5,000 for the year ended December 31, 2002. Other expense was \$3,000 for the year ended December 31, 2003 compared to other income of \$17,000 for the year ended December 31, 2002. Such other income (expense) was attributable to foreign currency transaction gains (losses).

Income Taxes

Income tax expense for the year ended December 31, 2003, consisted primarily of a provision for current Federal alternative minimum tax.

Preferred Stock Dividend

Preferred stock dividends included in net income (loss) allocable to common stockholders were \$1.6 million during each of the years ended December 31, 2003 and 2002. Such preferred stock dividends, paid in shares of our common stock through May 11, 2002, and thereafter in cash, are the result of our obligations in connection with the issuance of our Series D preferred stock in May 1999. As more fully set forth in the Amended Certificate of Designation, Preferences and Rights of the Series D Cumulative Convertible Preferred Stock, after May 11, 2002, we no longer pay dividends on the Series D preferred stock in shares of our common stock at a rate of 8.4%, and we became obligated to pay such dividends in cash, at a rate equal to 8% per annum.

Years Ended December 31, 2002 and December 31, 2001

We incurred net losses allocable to common stockholders of \$727,000, or \$0.06 per basic and diluted share, and \$9.8 million, or \$0.94 per basic and diluted share, for the years ended December 31, 2002 and December 31, 2001, respectively. The decrease in the net loss allocable to common stockholders from 2001 to 2002 was primarily a result of increased product sales, including the addition of Atrix dental product sales in 2002, and decreased selling, general and administrative expenditures. Selling, general and administrative expenditures decreased primarily as a result of a decline in expenditures related to a direct to consumer campaign for Periostat. These contributors to the decrease in the net loss allocable to common stockholders from 2001 to 2002 were partially offset by a decrease in contract revenues as well as moderate increases in the cost of products sold and research and development expenditures. Contract revenues decreased primarily due to the termination of the Novartis arrangement to co-promote Denavir and a decline in co-promotion revenues related to Vioxx.

Revenues

	<u>2002</u>	<u>Change</u>	<u>2001</u>
	(dollars in thousands)		
Net Product Sales	\$42,111	34.3%	\$31,358
Contract Revenues	2,332	(31.1)	3,386
License Revenues	176	(63.9)	488
<i>Total</i>	<u>\$44,619</u>	26.6%	<u>\$35,232</u>

Total revenues during the year ended December 31, 2002 were \$44.6 million, representing a 26.6% increase over total revenues of \$35.2 million during the year ended December 31, 2001. Such 2002 revenues included

approximately \$42.1 million in net product sales of Periostat, Atridox, Atrisorb FreeFlow, Atrisorb-D and Pandel (since July 1, 2002), \$2.3 million in contract revenues, which were derived from our co-promotion of Vioxx and Pandel (prior to June 30, 2002) and Denavir (effective October 1, 2002), and \$176,000 in deferred foreign license and milestone revenues for Periostat. Net product sales increased \$10.8 million, or 34.3%, during the year ended December 31, 2002 to \$42.1 million compared to \$31.4 million during the year ended December 31, 2001, mainly due to increased volume of prescriptions and price increases relating to Periostat, the addition of the Atrix dental products, which we began marketing in October 2001, and Pandel, which we began selling on July 1, 2002. Total international sales increased to \$350,000 in 2002 from \$35,000 in 2001.

Contract revenues for the year ended December 31, 2002 declined 31.1% to \$2.3 million from \$3.4 million during the year ended December 31, 2001 as a result of the termination in April 2001 of our prior agreement with Novartis to co-promote Denavir and a decline in contract revenues from Merck relating to our co-promotion of Vioxx. Contract revenues for the year ended December 31, 2001 included \$297,000 in co-promotion revenues for Denavir. Contract revenues for the year ended December 31, 2002 included \$100,000 in co-promotion revenues for Denavir, pursuant to our Product Detailing agreement with Novartis executed in October 2002. We were compensated at a higher rate for sales growth for the previous year's sales of Vioxx. In 2001, a significant portion of our Vioxx-related compensation was attributed to sales growth. Vioxx sales, however, were lower in 2002 compared to 2001, and therefore we were paid at lower rates, resulting in a decline in contract revenues.

License revenues for the year ended December 31, 2002 declined 63.9% to \$176,000 from \$488,000 for the year ended December 31, 2001. In accordance with SAB 101, which we adopted in 2000, \$59,000 and \$60,000 in licensing revenues, respectively, for the years ended December 31, 2002 and 2001 was attributable to our recognition of up-front license fees received for various agreements that were deferred in accordance with SAB 101 and is recognized as income over the expected performance period of these agreements. We also recorded milestone revenues from our foreign licensing partners of \$70,000 and \$425,000 during the years ended December 31, 2002 and 2001, respectively, related to obtaining regulatory approval in certain countries.

Cost of Product Sales

	<u>2002</u>	<u>Change</u>	<u>2001</u>
	(dollars in thousands)		
Cost of Product Sales	\$6,713	15.2%	\$5,825
Percent of Net Product Sales	15.9%		18.6%

Cost of product sales includes product packaging, third-party royalties, obsolete inventory provisions, amortization of product licensing fees, and the costs associated with the manufacturing, storage and stability of Periostat, Pandel and the Atrix products.

Cost of product sales were \$6.7 million, or 15.9% of net product sales during the year ended December 31, 2002, compared to \$5.8 million, or 18.6% of net product sales during the year ended December 31, 2001. Cost of product sales increased in absolute dollars but decreased as a percentage of net product sales during 2002 compared to 2001, primarily due to manufacturing cost savings for Periostat tablets, which we launched in July 2001, compared to Periostat capsules and product price increases. Cost of product sales in 2001 also included a \$602,000 provision for obsolete inventory; there was no such provision in 2002. This decrease in percent of Periostat net product sales in 2002 was slightly offset by a higher percent of product sales for the Atrix products and Pandel, launched in November 2001 and July 2002, respectively, which have lower margins than Periostat.

Research and Development

	<u>2002</u>	<u>Change</u>	<u>2001</u>
	(dollars in thousands)		
Research and Development	\$4,394	16.7%	\$3,764
Percentage of Total Revenue	9.8%		10.7%

Research and development expenses consist primarily of funds paid to third parties for the provision of services and materials for drug development, manufacturing and formulation enhancements, clinical trials, statistical analysis, report writing, regulatory compliance and internal payroll and related costs.

Research and development expenses increased \$630,000, or 16.7% to \$4.4 million during the year ended December 31, 2002 from \$3.8 million during the year ended December 31, 2001.

Development projects conducted during the year ended December 31, 2002 included our continuing formulation development work for a once-a-day formulation of Periostat and formulation and stability testing for several potential products utilizing our licensed Restoraderm technology, which totaled \$1.3 million and \$349,000, respectively.

Clinical projects totaling \$1.1 million were conducted during the year ended December 31, 2002 and included several Phase IV studies for Periostat in various dental indications, initiation of a 70-patient clinical study to evaluate the efficacy of Periostat to treat meibomianitis, clinical development work relating to Periostat in dermatological indications, limited clinical testing of Restoraderm formulations and initiation of a Phase III trial in 134 patients to evaluate Periostat for the treatment of rosacea. Additionally, during 2002 we granted \$253,000 for research to various academic institutions for conducting research related to our core technology.

Other research and development expenses incurred during the year ended December 31, 2002 included \$247,000 in regulatory consulting and filing fees under the Mutual Recognition Procedure in Europe and \$373,000 for various regulatory costs, including annual FDA filing fees, legal, and regulatory expenses in the United States. Direct salaries and other personnel expenses incurred during the year ended December 31, 2002 were \$480,000. Additionally, during such period we incurred \$266,000 in consulting, travel and other office expenses.

Research and development expenses incurred in 2001 included \$210,000 in research grants to various academic institutions for conducting research related to our core technology and \$765,000 in contracted clinical and development expenses related to a completed safety and pharmacokinetic study for Metastat and other IMPACs compounds. During 2001, our three-year evaluation testing agreement for such compounds with SUNY expired and was not renewed. The amount paid to SUNY in 2001 under this agreement was \$168,000. The total cumulative costs incurred through 2001 under this agreement were approximately \$1.4 million.

Development projects contracted in 2001 included an initial feasibility study and formulation development work for a once-a-day formulation of Periostat, which totaled \$455,000 in 2001.

Clinical projects conducted during 2001 included the completion of several Phase 3b studies for Periostat in various dental indications and the initiation of clinical trials for Periostat in dermatological indications. Clinical project costs incurred in 2001 were \$230,000.

Other expenses incurred in 2001 included \$400,000 in regulatory consulting and filing fees under the Mutual Recognition Procedure in Europe and \$535,000 for various regulatory costs, including annual FDA filing fees, legal, and regulatory expenses in the United States related to obtaining FDA approval for Periostat tablets. During 2001 we incurred \$535,000 in direct salaries and other personnel and \$164,000 in noncash compensation expense relating to the extension of the exercisability of certain stock options for one of our ex-board members. Additionally, we incurred \$110,000 in ongoing manufacturing support relating to our existing products and \$194,000 in travel and other office expenses.

Selling, General and Administrative

	<u>2002</u>	<u>Change</u>	<u>2001</u>
	(dollars in thousands)		
Selling, General and Administrative	\$32,699	(3.9%)	\$34,010
Percentage of Total Revenues	73.3%		96.5%

Selling, general and administrative expenses consist primarily of personnel salaries and benefits, direct marketing costs, professional, legal and consulting fees, insurance and general office expenses.

Selling, general and administrative expenses decreased 3.9% to \$32.7 million during the year ended December 31, 2002 from \$34.0 million during the year ended December 31, 2001. The decrease of \$1.3 million in selling, general and administrative expenses, or 3.9%, from the year ended December 31, 2001 to the year ended December 31, 2002, was the result of spending \$3.8 million less on our DTC campaign in 2002 compared to 2001. This was partially offset by incremental promotional expenses for the newly licensed Atrix dental products, other direct professional Periostat promotion expenses and the launch and promotional expenses for Pandel, effective July 1, 2002.

Significant components of selling, general and administrative expenses incurred during the year ended December 31, 2002 included \$15.7 million in direct selling and sales training expenses, \$11.3 million in marketing expenses (including Periostat DTC advertising and promotion expenditures for Periostat, the Atrix products and co-promotion expenses relating to Vioxx and Pandel) and \$5.7 million in general and administrative expenses, which include business development, finance and corporate activities. Significant components of selling, general and administrative expenses during the year ended December 31, 2001 included \$13.9 million in direct selling and training expenses, \$14.9 million in marketing expenses (including Periostat DTC advertising expenditures, launch expenses for the Atrix products and Dentaplex and co-promotion expenses related to Vioxx) and \$5.2 million in general and administrative expenses.

Other Income/Expense

	<u>2002</u>	<u>Change</u>	<u>2001</u>
	(dollars in thousands)		
Interest Income	\$77	(66.8%)	\$232
Interest Expense	\$ 5	(70.6%)	\$ 17
Other Income	\$17	(112.5%)	\$ 8

Interest income decreased to \$77,000 for the year ended December 31, 2002 compared to \$232,000 for the year ended December 31, 2001. This decrease was due to lower average balances in cash and short-term investments and lower investment yields during the year ended December 31, 2002. Interest expense for the year ended December 31, 2002 was \$5,000, compared to \$17,000 for the year ended December 31, 2001 due to lower average principle amounts outstanding on our notes payable. Other income for the year ended December 31, 2002 was \$17,000 compared to \$8,000 for the year ended December 31, 2001. These amounts represent foreign currency transaction gains and vary based on transaction volume.

Preferred Stock Dividend

Preferred stock dividends were \$1.6 million for the year ended December 31, 2002 and \$1.7 million for the year ended December 31, 2001. Such preferred stock dividends, paid in shares of our common stock through May 11, 2002, and thereafter in cash, were the result of our obligations in connection with the issuance of our Series D preferred stock in May 1999. As more fully set forth in the Amended Certificate of Designation, Preferences and Rights of the Series D Cumulative Convertible preferred stock, after May 11, 2002, we no longer pay dividends on the Series D preferred stock in shares of our common stock, and we became obligated to pay such dividends in cash, at a rate equal to 8% per annum. Cash dividends incurred for the period May 12, 2002 to December 31, 2002 were approximately \$1.0 million.

Liquidity and Capital Resources

On October 3, 2003, we announced that we had entered into agreements for the sale of 2,000,000 shares of our common stock registered under a registration statement on Form S-3 to certain institutional investors, at a per share purchase price of \$10.00 for aggregate gross proceeds of \$20.0 million, which generated net proceeds to us of approximately \$18.7 million, after the payment of placement agent fees and related expenses.

Our Series D preferred stock is convertible at any time into shares of our common stock at a current conversion price of \$9.89 per share, which conversion price reflects a decrease from the initial conversion price of \$11.00 per share as a result of certain subsequent equity issuances by us. Such conversion price is not subject to reset except in the event that we should fail to declare and pay dividends when due or we should issue new equity securities or convertible securities at a price per share or having a conversion price per share lower than the then applicable conversion price of the Series D preferred stock. During the first three years following issuance, holders of the Series D preferred stock received dividends payable in shares of fully registered common stock at a rate of 8.4% per annum. Thereafter, and beginning on May 12, 2002, we began paying such dividends in cash at a rate of 8.0% per annum.

All or a portion of the shares of Series D preferred stock shall, at our option (as determined by our board of directors), automatically be converted into fully paid, registered and non-assessable shares of common stock, if the following two conditions are met: (i) the last sale price, or, in case no such sale takes place on such day, the average of the closing bid and asked prices on the Nasdaq National Market is at least 200% of the conversion price then in effect (as of December 31, 2003, such conversion price was \$9.89 per share) for forty consecutive trading days; and (ii) a shelf registration statement is in effect for the shares of common stock to be issued upon conversion of the Series D preferred stock. Without written approval of a majority of the holders of record of the Series D preferred stock, we, among other things, shall not: (i) declare or pay any dividend or distribution on any shares of our capital stock other than dividends on the Series D preferred stock; (ii) make any loans, incur any indebtedness or guarantee any indebtedness, advance capital contributions to, or investments in any person, issue or sell any securities or warrants or other rights to acquire our debt securities, except that we may incur such indebtedness in any amount not to exceed \$10.0 million in the aggregate outstanding at any time for working capital requirements in the ordinary course of business; or (iii) make research and development expenditures in excess of \$7.0 million in any continuous twelve month period, unless we have reported positive net income for four consecutive quarters immediately prior to such twelve month period.

We have a revolving credit facility with Silicon Valley Bank which expires on March 15, 2004. We are currently negotiating to renew the credit facility for a two-year term upon expiration. We may borrow up to the lesser of \$4.0 million or 80% of eligible accounts receivable, as defined, under the credit facility. The amount available to us is also reduced by outstanding letters of credit which may be issued under the credit facility in amounts totaling up to \$1.5 million. On April 1, 2003, we secured our expected purchase order commitments for the next twelve months with a letter of credit for approximately \$1.1 million. As of December 31, 2003, the letter of credit had been reduced to \$124,000. As we continue to pay down amounts under the letter of credit, the amount available to us under the Facility will increase. We are not obligated to draw amounts and any such borrowings bear interest, payable monthly, currently at the prime rate plus 1.0% to 1.5% per annum and may be used only for working capital purposes. Without the consent of Silicon Valley Bank, we, among other things, shall not: (i) merge or consolidate with another entity; (ii) acquire assets outside the ordinary course of business; or (iii) pay or declare any cash dividends on our common stock. We must also maintain a certain tangible net worth of \$5.0 million, subject to certain upward adjustments, as a result of profitable operations or additional debt or equity financings and a minimum of \$2.0 million in cash at Silicon Valley Bank, net of borrowings under the credit facility. In addition, we have secured our obligations under the credit facility through the granting of a security interest in favor of the bank with respect to all of our assets, including our intellectual property. As of December 31, 2003, we had no borrowings outstanding against the credit facility

On August 24, 2001, we signed a License and Marketing Agreement with Atrix Laboratories, Inc. to market Atrix's proprietary dental products, Atridox, Atrisorb FreeFlow and Atrisorb-D, to the United States dental market. Pursuant to the terms of this agreement, among other things: (i) Atrix will manufacture the dental products for us at an agreed upon transfer price and will receive royalties on future net sales of the products each calendar year; (ii) we paid to Atrix a \$1.0 million licensing fee to market such products; (iii) we committed to no less than \$2.0 million in advertising and selling expenses related to the Atrix products during the fiscal year beginning January 1, 2002 (which requirement we met during 2002); (iv) we agreed to maintain, through August 2003, a force of no less than ninety full time dental consultants and divisional and regional managers to make

sales and product recommendation calls on dental professionals (which requirement we have fulfilled); and (v) we agreed that the Atrix products would be the subject of a specific number of detail calls in the United States during 2002, which we achieved. We are also required to make certain annual minimum expenditures for advertising and promotional activities over the term of the agreement beginning January 1, 2003, including: (i) the lesser of \$4.0 million or 30% of our contribution margin, as defined in the agreement, relating to a specific Atrix product that we market, and (ii) the lesser of \$2.0 million or 30% of our contribution margin, as defined in the agreement, relating to a separate Atrix product that we market. These annual requirements were met by us during 2003.

During 2003, our co-promotional agreements with Merck, Novartis and Sirius, generated approximately \$3.1 million in revenue and approximately \$1.6 million in positive cash-flows. As of December 31, 2003, all of these agreements either expired or were mutually terminated. We do not expect any future revenues or cash inflows from Merck, Novartis and Sirius other than nominal residual contract revenues through 2005 from our expired agreement with Merck for Vioxx.

On February 11, 2002, we executed a Co-operation, Development and Licensing Agreement pursuant to which we were granted an exclusive, sublicenseable, transferable license with respect to the Restoraderm topical drug delivery system which we intend to develop for dermatological applications. Pursuant to the terms of such agreement, upon the occurrence of certain events, we will be required to pay certain future consulting, royalty and milestone payments in the aggregate amount of up to approximately \$3.2 million, of which no more than \$2.2 million could be payable prior to January 1, 2004 and of which no more than an additional \$1.0 million shall be payable prior to January 1, 2005. We paid \$600,000 under this agreement in the year ended December 31, 2003. The term of such agreement is for the life of any patent that may be issued to us for the first product we develop utilizing such technology, or, if such a patent fails to issue, seven years.

At December 31, 2003, we had cash and cash equivalents of approximately \$32.7 million, an increase of \$22.6 million from the \$10.1 million balance at December 31, 2002. In accordance with investment guidelines approved by our Board of Directors, cash balances in excess of those required to fund operations have been invested in money market funds. Our working capital at December 31, 2003 was \$32.0 million, an increase of \$26.0 million from \$6.0 million at December 31, 2002. This increase was primarily attributable to the operating profitability experienced during 2003, the addition of \$1.8 million in cash proceeds from the exercise of stock options and warrants and the sale of 2,000,000 shares of our common stock, at a per share purchase price of \$10.00, which generated net proceeds to us of approximately \$18.7 million. During the year ended December 31, 2003, we generated \$4.8 million in cash from our operating activities principally from net income of \$6.4 million less changes in certain assets and liabilities. During the year ended December 31, 2003, we invested \$305,000 in capital expenditures, made \$900,000 in licensing payments to Altana Inc. and paid \$1.6 million in cash dividends to the holders of our Series D preferred stock.

We currently believe that our working capital at December 31, 2003 will allow us to fund our operations, capital expenditures and preferred stock dividend requirements for at least the foreseeable future and we do not anticipate requiring additional capital to fund our operations. Our line of credit is due to expire on March 15, 2004. While it is our intention to renew the credit facility for an additional two-year term, we believe our current cash balance along with our cash flows from operations is adequate to fund our operations in the event that the line of credit is not renewed. At this time, however, we cannot accurately predict the effect of certain developments on future product sales such as the degree of market acceptance of our products and technology, competition, the effectiveness of our sales and marketing efforts and the outcome of our research and development to demonstrate the utility of Periostat in indications beyond those already included in the FDA approved label. We expect to significantly increase our investment in research and development in 2004. Contract and license revenues include receipts from co-promotion agreements and performance milestones. The continuation of any of these agreements is subject to the achievement of certain milestones and to periodic review by the parties involved.

We believe that other key factors that could affect our internal and external sources of cash are:

- Revenues and profits from sales of Periostat and other products and contracted services;
- The success of our dermatology franchise;
- The success of our pre-clinical, clinical and development programs;
- The receptivity of the capital markets to future financings;
- Our ability to enter into additional strategic collaborations and to maintain existing and new collaborations and the success of such collaborations; and
- The outcome and consequences of our patent litigation and our litigation with the FDA.

Contractual Obligations

Our major outstanding contractual obligations relate to cash dividends on our outstanding Series D preferred stock, operating leases for our office space, operating leases for our sales force, computer equipment, and contractual commitments with our marketing partners for certain selling and promotional expenses associated with the products we are currently detailing. Additionally, we also expect to make certain inventory purchases from our contract manufacturer of Periostat.

Below is a table which presents our contractual obligations and commercial commitments as of December 31, 2003:

<u>Contractual Obligations</u>	<u>Payments Due by Period</u>				
	<u>Total</u>	<u>2004</u>	<u>2005 and 2006</u>	<u>2007 and 2008</u>	<u>2009 and after</u>
Operating Leases(1)	\$ 2,528,000	\$ 530,000	\$1,108,000	\$ 694,000	\$196,000
Unconditional Purchase					
Obligations	\$ 1,139,000(2)	\$1,139,000(2)	—	—	—
Co-Promotional Commitments . . .	(3)	(3)	(3)	(3)	(3)
Cash Dividends on Series D					
Preferred Stock	\$ 8,000,000(4)	\$1,600,000(4)	\$3,200,000(4)	\$3,200,000(4)	(4)
Consulting Payments	\$ 628,000(5)	\$ 324,000(5)	304,000(5)	—	—
Total Contractual Obligations	\$12,295,000	\$3,593,000	\$4,612,000	\$3,894,000	\$196,000

(1) Such amounts primarily include minimum rental payments for our office lease in Newtown, Pennsylvania, as well as payments for sales force computer equipment leases.

(2) Such amount represents purchase order commitments for inventory purchases and clinical supplies with various vendors.

(3) We will be required to make certain annual minimum expenditures for advertising and promotional activities amounting to: (i) the lesser of \$4.0 million or 30% of our contribution margin (as defined in the agreement) relating to a specific Atrix product that we market, and (ii) the lesser of \$2.0 million or 30% of our contribution margin (as defined in the agreement) relating to a separate Atrix product that we market. See further information regarding the Atrix License and Marketing Agreement under the heading "Liquidity and Capital Resources."

(4) Pursuant to the terms of our Series D Cumulative Convertible preferred stock and unless earlier converted pursuant to its terms, the holders of the Series D preferred stock are entitled to dividends payable in cash at a rate of 8.0% per annum, which are declared and paid every six months. See further information regarding our Series D preferred stock under the heading "Liquidity and Capital Resources."

(5) Such amount represents consulting payments to be made to Brian M. Gallagher, our former chief executive officer and president, upon his separation from the Company and pursuant to the terms of a consulting agreement executed March 18, 2003.

In May 1999, we entered into a lease agreement relating to our office space in Newtown, Pennsylvania. The lease has an initial term of ten years. Rent is expected to be approximately \$318,000 per year and is subject to market adjustments in 2004.

On February 11, 2002, we executed a Co-operation, Development and Licensing Agreement pursuant to which we were granted an exclusive, sublicenseable, transferable license with respect to the Restoraderm topical drug delivery system which we intend to develop for dermatological applications. Pursuant to the terms of such agreement, upon the occurrence of certain events, we will be required to pay certain future consulting, royalty

and milestone payments in the aggregate amount of up to \$3.2 million, of which no more than \$2.2 million could be payable prior to January 1, 2004 and of which no more than an additional \$1.0 million shall be payable prior to January 1, 2005. We paid \$600,000 under this agreement in the year ended December 31, 2003. The term of such agreement is for the life of any patent that may be issued to us for the first product we develop utilizing such technology, or, if such a patent fails to issue, seven years.

On June 10, 2002, we executed a Development and Licensing Agreement with Shire Laboratories, Inc. pursuant to which we were granted an exclusive worldwide license (including the right to sublicense) to develop, make, have made, use, supply, export, import, register and sell products for the treatment of various inflammatory disorders. In addition, under the agreement, certain product development functions shall be performed for us. Pursuant to the terms of such agreement, we will pay to Shire a percentage of certain net sales of products, if any, utilizing any part of Shire's technology. Also under the agreement, we have committed to payments in cash, or, at our option, a combination of cash and our common stock, upon the achievement of certain clinical and regulatory milestones in the event we pursue certain applications of the technology which could total up to \$7.9 million in the aggregate.

Item 7A. *Quantitative and Qualitative Disclosures about Market Risk.*

We had cash equivalents at December 31, 2003 which are exposed to the impact of interest rate changes and our interest income fluctuates as our interest rates change. Due to the short-term nature of our investments in money market funds, the carrying values of our cash equivalents approximate their fair value at December 31, 2003.

Item 8. *Financial Statements and Supplementary Data.*

The financial statements and supplementary data required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K. A list of the financial statements filed herewith is found at "Item 15. Exhibits, Financial Statement Schedules, and Reports on Form 8-K."

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

Not applicable.

Item 9A. *Controls and Procedures.*

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2003. In designing and evaluating our disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our chief executive officer and chief financial officer concluded that, as of December 31, 2003, our disclosure controls and procedures were (1) designed to ensure that material information relating to us, including our consolidated subsidiaries, is made known to our chief executive officer and chief financial officer by others within those entities, particularly during the period in which this report was being prepared and (2) effective, in that they provide reasonable assurance that information required to be disclosed by us in our reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended as of December 31, 2003 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART III

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

The information relating to our directors, nominees for election as directors and executive officers under the headings "Election of Directors", "Executive Officers" and "Section 16(a) Beneficial Ownership Reporting Compliance" in our definitive proxy statement for the 2004 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. We will make available our code of business conduct and ethics free of charge through our website which is located at www.collagenex.com. We intend to disclose any amendments to, or waivers from, our code of business conduct and ethics that are required to be publicly disclosed pursuant to rules of the Securities and Exchange Commission and the Nasdaq National Market by filing such amendment or waiver with the Securities and Exchange Commission and by posting it on our website.

Item 11. *Executive Compensation.*

The discussion under the heading "Executive Compensation" in our definitive proxy statement for the 2004 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

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

The discussion under the heading "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" in our definitive proxy statement for the 2004 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

Item 13. *Certain Relationships and Related Transactions.*

The discussion under the heading "Certain Relationships and Related Transactions" in our definitive proxy statement for the 2004 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

Item 14. *Principal Accountant Fees and Services.*

The discussion under the heading "Independent Auditors Fees and Other Matters" in our definitive proxy statement for the 2004 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

PART IV

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

(a) (1) Financial Statements.

Reference is made to the Index to Consolidated Financial Statements and Schedule on Page F-1.

(2) Financial Statement Schedule.

Reference is made to the Index to Consolidated Financial Statements and Schedule on Page F-1.

(3) Exhibits.

Reference is made to the Index to Exhibits on Page 62.

(b) Reports on Form 8-K.

On October 8, 2003, we filed a Current Report on Form 8-K under Item 5, announcing that we had entered into agreements for the sale of 2,000,000 shares of our common stock registered under a registration statement on Form S-3 to certain institutional investors.

On October 28, 2003, we furnished a Current Report on Form 8-K under Item 9, containing a copy of our earnings release for the period ended September 30, 2003 (including financial information) pursuant to Item 12 (Results of Operations and Financial Condition).

On November 10, 2003, we filed a Current Report on Form 8-K under Item 5, relating to our settlement of all pending litigation between West-ward Pharmaceutical Corporation and us.

On December 8, 2003, we filed a Current Report on Form 8-K under Item 5, relating to the appointment of Colin W. Stewart as our president and chief executive officer.

On December 8, 2003, we filed a Current Report on Form 8-K under Item 5, relating to our grant of inducement stock options to Colin W. Stewart in accordance with NASDAQ Marketplace Rule 4350.

On February 24, 2004, we furnished a Current Report on Form 8-K under Item 9, containing a copy of our earnings release for the quarter and year ended December 31, 2003 (including financial information) pursuant to Item 12 (Results of Operations and Financial Condition).

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities and Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized this 15th day of March, 2004.

COLLAGENEX PHARMACEUTICALS, INC.

By: /s/ COLIN W. STEWART
Colin W. Stewart,
 Chief Executive Officer and President

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/ COLIN W. STEWART Colin W. Stewart	President, Chief Executive Officer and Director (Principal Executive Officer)	March 15, 2004
..... /s/ NANCY C. BROADBENT Nancy C. Broadbent	Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)	March 15, 2004
..... /s/ BRIAN M. GALLAGHER Brian M. Gallagher, Ph.D.	Director	March 8, 2004
..... /s/ PETER R. BARNETT, D.M.D. Peter R. Barnett, D.M.D.	Director	March 15, 2004
..... /s/ ROBERT C. BLACK Robert C. Black	Director	March 15, 2004
..... /s/ JAMES E. DAVERMAN James E. Daverman	Chairman of the Board and Director	March 15, 2004
..... /s/ ROBERT J. EASTON Robert J. Easton	Director	March 15, 2004
..... /s/ STEPHEN A. KAPLAN Stephen A. Kaplan	Director	March 15, 2004
..... /s/ W. JAMES O'SHEA W. James O'Shea	Director	March 8, 2004

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
3.1(a)	Amended and Restated Certificate of Incorporation.
3.2(v)	Amended and Restated Bylaws.
3.3(m)	Amended Certificate of Designation, Preferences and Rights of the Series D Cumulative Convertible Preferred Stock of CollaGenex Pharmaceuticals, Inc. dated as of October 15, 2001.
3.4(t)	Amended Certificate of Designation of Series A Participating Preferred Stock, as filed with the Secretary of State of the State of Delaware on June 5, 2002.
4.1(a)	Registration Rights Agreement dated September 29, 1995 by and among the Company and certain investors, as supplemented.
4.2(a)	Fourth Investment Agreement as of September 29, 1995 by and among the Company and certain Investors.
4.3(t)	Amended and Restated Shareholder Protection Rights Agreement, dated as of May 29, 2002, by and between CollaGenex Pharmaceuticals, Inc. and American Stock Transfer & Trust Company.
†10.1(a)	Assignment of, Amendment to and Restatement of Agreement, with all exhibits, as amended, and schedules, dated January 13, 1992 by and among the Company, Johnson & Johnson Consumer Products, Inc. and Research Foundation of State University of New York.
†10.2(a)	Supply Agreement dated January 23, 1995 between the Company and Hovione International Limited.
10.3(a)	Form of Non-Disclosure Agreement executed by all Employees as employed from time to time.
10.4(a)(b)	Form of Non-Competition Agreement executed by each of Nancy C. Broadbent and Robert A. Ashley.
10.5(a)	Form of Mutual Non-Disclosure Agreement executed by certain consultants and research collaborators as retained from time to time.
10.6(a)(b)	Form of Indemnification Agreement executed by each of the Company's directors and officers.
10.7(a)	Forms of Consulting Agreement executed by each of Lorne M. Golub and Thomas F. McNamara.
10.8(a)	Form of Material Transfer Agreement between the Company and Researchers.
10.9(a)(b)	1992 Stock Option Plan of the Company, as amended to date.
10.10(a)(b)	1996 Stock Plan of the Company.
10.11(a)(b)	1996 Non-Employee Director Stock Option Plan of the Company.
†10.12(e)	Distribution Services Agreement dated August 15, 1998 between Cord Logistics, Inc. and the Company.
10.13(f)	Stock Purchase Agreement dated March 19, 1999, between the Company, OCM Principal Opportunities Fund, L.P. and other Purchasers set forth therein.
10.14(g)	Lease Agreement dated March 15, 1999 between the Company and Newton Venture IV Associates, effective May 15, 1999.
10.15(h)	Stockholders and Registration Rights Agreement, dated March 19, 1999, by and among CollaGenex Pharmaceuticals, Inc., OCM Principal Opportunities Fund, L.P. and the Purchasers set forth therein.
10.16(i)	Form of Common Stock Purchase Agreement, dated March 12, 2001, between the Company and the Investors set for therein, together with form of Registration Rights Agreement as an exhibit thereto and form of Warrant as an exhibit thereto.

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
10.17(j)	Loan and Security Agreement dated March 19, 2001, between the Company and Silicon Valley Bank.
†10.18(k)	Services and Supply Agreement dated as of September 26, 2000 as amended by letter agreement dated as of December 1, 2000, by and between the Company and Pharmaceutical Manufacturing Research Services, Inc.
10.19(l)	Letter Agreement dated as of June 26, 2001 by and between the Company and Pharmaceutical Manufacturing Research Services, Inc.
10.20(m)	Amendment No. 1 to Stockholders and Registration Rights Agreement, dated March 19, 1999, by and among CollaGenex Pharmaceuticals, Inc., OCM Principal Opportunities Fund, L.P, and the Purchasers set forth therein.
10.21(m)	Amendment No. 2 to Stockholders and Registration Rights Agreement, dated March 19, 1999, by and among CollaGenex Pharmaceuticals, Inc., OCM Principal Opportunities Fund, L.P, and the Purchasers set forth therein.
†10.22(n)	License Agreement dated August 24, 2001 by and between CollaGenex Pharmaceuticals, Inc. and Atrix Laboratories, Inc.
†10.23(n)	Stock Purchase Agreement dated August 24, 2001 by and between CollaGenex Pharmaceuticals, Inc. and Atrix Laboratories, Inc.
†10.24(o)	First Addendum December 10, 2001 to the Supply Agreement dated January 23, 1995 by and between CollaGenex, Inc. and Hovione International Limited.
10.25(p)	Common Stock Purchase Agreement dated February 14, 2002 by and between CollaGenex Pharmaceuticals, Inc. and Kingsbridge Capital Limited.
10.26(p)	Warrant dated February 14, 2002 issued to Kingsbridge Capital Limited.
†10.27(r)	Wholesale Service Agreement effective as of November 1, 2001, by and between CollaGenex Pharmaceuticals, Inc. and National Specialty Services, Inc.
†10.28(r)	First Amendment to Wholesale Service Agreement effective as of November 12, 2001, by and between CollaGenex Pharmaceuticals, Inc. and National Specialty Services, Inc.
†10.29(r)	Exclusive Distribution Agreement dated as of March 1, 2002, by and between CollaGenex Pharmaceuticals, Inc. and CORD Logistics, Inc.
10.30(r)	First Loan Modification Agreement dated as of March 22, 2002 by and between CollaGenex Pharmaceuticals, Inc. and Silicon Valley Bank.
10.31(r)	Second Loan Modification Agreement dated as of March 27, 2002 by and between CollaGenex Pharmaceuticals, Inc. and Silicon Valley Bank.
†10.32(u)	Agreement by and between Altana Inc. and CollaGenex Pharmaceuticals, Inc., dated May 24, 2002.
10.33(v)	Form of Change of Control Agreement executed with each of Nancy C. Broadbent, Robert Ashley, David Pfeiffer and Douglas Gehrig.
†10.34	Letter Agreement dated as of September 12, 2002 by and between the Company and Pharmaceutical Manufacturing Research Services, Inc.
10.35(w)	Transition Agreement and Release dated March 18, 2003 by and between Brian Gallagher and CollaGenex Pharmaceuticals, Inc.
10.36(w)	Consulting Agreement dated March 18, 2003 by and between Brian Gallagher and CollaGenex Pharmaceuticals, Inc.
10.37(x)	Form of Incentive Bonus Agreement executed with each of David F. Pfeiffer and Robert A. Ashley.

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
10.38(y)	Severance Agreement by and between CollaGenex Pharmaceuticals, Inc. and Paul Lubetkin.
21*	List of subsidiaries of the Registrant.
23.1*	Consent of KPMG LLP.
31.1*	Certification Pursuant to Rule 13a-14(a) and 15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Chief Executive Officer).
31.2*	Certification Pursuant to Rule 13a-14(a) and 15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer).
32.1*	Certification Pursuant to 18 U.S.C. Section 1350.

* Filed herewith

† Confidential treatment has been requested and granted for a portion of this Exhibit.

- (a) Incorporated by reference to the Company's Registration Statement on Form S-1 (File Number 333-3582) which became effective on June 20, 1996.
- (b) A management contract or compensatory plan or arrangement required to be filed as an exhibit pursuant to Item 14(c) of Form 10-K.
- (c) Incorporated by reference to the Company's Current Report on Form 8-K, dated September 16, 1997, which was filed with the Securities and Exchange Commission on September 17, 1997.
- (d) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 1998, which was filed with the Securities and Exchange Commission on November 16, 1998.
- (e) Incorporated by reference to the Company's Current Report on Form 8-K, dated March 19, 1999 which was filed with the Securities and Exchange Commission on March 25, 1999.
- (f) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 1999, which was filed with the Securities and Exchange Commission on May 7, 1999.
- (g) Incorporated by reference to the Company's Current Report on Form 8-K, dated May 12, 1999, which was filed with the Securities and Exchange Commission on May 26, 1999.
- (h) Incorporated by reference to the Company's Current Report on Form 8-K, dated March 16, 2001, which was filed with the Securities and Exchange Commission on March 16, 2001.
- (i) Incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 2000, which was filed with the Securities and Exchange Commission on March 26, 2001. The Company amended such Form 10-K by filing a Form 10-K/A on January 2, 2002.
- (j) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2001, which was filed with the Securities and Exchange Commission on May 15, 2001.
- (k) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2001, which was filed with the Securities and Exchange Commission on August 14, 2001.
- (m) Incorporated by reference to the Company's Current Report on Form 8-K, dated October 15, 2001, which was filed with the Securities and Exchange Commission on October 18, 2001.
- (n) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2001, which was filed with the Securities and Exchange Commission on November 14, 2001. The Company amended such Form 10-Q by filing a Form 10-Q/A on February 14, 2002.
- (o) Incorporated by reference to the Company's Current Report on Form 8-K, dated December 10, 2001, which was filed with the Securities and Exchange Commission on December 10, 2001.
- (p) Incorporated by reference to the Company's Current Report on Form 8-K, dated February 14, 2002, which was filed with the Securities and Exchange Commission on February 15, 2002.

- (q) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2001, which was filed with the Securities and Exchange Commission on November 14, 2001. The Company amended such Form 10-Q by filing a Form 10-Q/A on February 14, 2002.
- (r) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2002, which was filed with the Securities and Exchange Commission on May 15, 2002.
- (s) Incorporated by reference to the Company's Current Report on Form 8-K, dated May 15, 2002, which was filed with the Securities and Exchange Commission on May 20, 2002.
- (t) Incorporated by reference to the Company's Current Report on Form 8-K, dated May 29, 2002, which was filed with the Securities and Exchange Commission on June 5, 2002.
- (u) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, which was filed with the Securities and Exchange Commission on August 14, 2002.
- (v) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002, which was filed with the Securities and Exchange Commission on November 14, 2002.
- (w) Incorporated by reference to the Company's Current Report on Form 8-K, dated March 18, 2003, which was filed with the Securities and Exchange Commission on March 19, 2003.
- (x) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003, which was filed with the Securities and Exchange Commission on November 14, 2003.
- (y) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003, which was filed with the Securities and Exchange Commission on November 14, 2003.

COLLAGENEX PHARMACEUTICALS, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS
AND FINANCIAL STATEMENT SCHEDULE

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INDEPENDENT AUDITORS' REPORT

The Board of Directors and Stockholders
CollaGenex Pharmaceuticals, Inc.:

We have audited the consolidated financial statements of CollaGenex Pharmaceuticals, Inc. and subsidiaries as listed in the accompanying index. In connection with our audits, we also have audited the financial statement schedule as listed in the accompanying index. These consolidated financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of CollaGenex Pharmaceuticals, Inc. and subsidiaries as of December 31, 2003 and 2002, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion the related financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly in all material respects, the information set forth therein.

/s/ KPMG LLP

Princeton, New Jersey
February 20, 2004

COLLAGENEX PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

December 31, 2003 and 2002

(Dollars in thousands, except per share data)

	<u>2003</u>	<u>2002</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 32,670	\$ 10,112
Accounts receivable, net of allowances of \$1,308 and \$1,412 in 2003 and 2002, respectively	4,959	2,142
Inventories	1,672	1,415
Prepaid expenses and other current assets	1,732	1,044
Total current assets	<u>41,033</u>	<u>14,713</u>
Equipment and leasehold improvements, net	496	559
Acquired product rights, net	1,749	2,335
Other assets	27	27
Total assets	<u>\$ 43,305</u>	<u>\$ 17,634</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	3,273	3,616
Accrued expenses	4,950	4,305
Preferred dividends payable	800	800
Total current liabilities	<u>9,023</u>	<u>8,721</u>
Deferred revenue	326	561
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, \$0.01 par value, 5,000,000 shares authorized, 200,000 shares of Series D cumulative convertible preferred stock issued and outstanding in 2003 and 2002, (liquidation value \$20,800); 150,000 shares of Series A participating preferred stock, \$0.01 par value, designated and no shares issued and outstanding in 2003 and 2002	2	2
Common stock, \$0.01 par value; 25,000,000 shares authorized, 13,842,200 and 11,377,631 shares issued and outstanding in 2003 and 2002, respectively	138	114
Additional paid in capital	103,670	82,917
Accumulated deficit	<u>(69,854)</u>	<u>(74,681)</u>
Stockholders' equity	<u>33,956</u>	<u>8,352</u>
Total liabilities and stockholders' equity	<u>43,305</u>	<u>17,634</u>

See accompanying notes to consolidated financial statements.

COLLAGENEX PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

Years ended December 31, 2003, 2002 and 2001

(Dollars in thousands, except per share data)

	<u>2003</u>	<u>2002</u>	<u>2001</u>
Revenues:			
Net product sales	\$ 49,038	\$ 42,111	\$ 31,358
Contract revenues	3,122	2,332	3,386
License revenues	699	176	488
Total revenues	<u>52,859</u>	<u>44,619</u>	<u>35,232</u>
Operating expenses:			
Cost of product sales	7,362	6,713	5,825
Research and development	5,462	4,394	3,764
Selling, general and administrative	33,668	32,699	34,010
Total operating expenses	<u>46,492</u>	<u>43,806</u>	<u>43,599</u>
Operating income (loss)	6,367	813	(8,367)
Other income (expense):			
Interest income	148	77	232
Interest expense	—	(5)	(17)
Other	(3)	17	8
Income (loss) before income taxes	6,512	902	(8,144)
Income taxes	85	—	—
Net income (loss)	6,427	902	(8,144)
Preferred stock dividends	1,600	1,629	1,680
Net income (loss) allocable to common stockholders	<u>\$ 4,827</u>	<u>\$ (727)</u>	<u>\$ (9,824)</u>
Basic net income (loss) per share allocable to common stockholders	<u>\$ 0.40</u>	<u>\$ (0.06)</u>	<u>\$ (0.94)</u>
Diluted net income (loss) per share allocable to common stockholders	<u>\$ 0.38</u>	<u>\$ (0.06)</u>	<u>\$ (0.94)</u>
Weighted average shares used in computing per share amounts:			
Basic	<u>12,094,638</u>	<u>11,234,652</u>	<u>10,413,663</u>
Diluted	<u>12,836,364</u>	<u>11,234,652</u>	<u>10,413,663</u>

See accompanying notes to consolidated financial statements.

COLLAGENEX PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

Years ended December 31, 2003, 2002 and 2001
(Dollars in thousands)

	Series D cumulative convertible preferred stock		Common stock		Common stock to be issued	Additional paid-in capital	Deferred compensation	Accumulated deficit	Total stockholders' equity
	Number of shares	Par value	Number of shares	Par value					
Balance, December 31, 2000	200,000	\$ 2	8,775,176	\$ 88	\$ 872	\$ 68,461	\$(64,130)	\$ 5,264	
Issuance of common stock for common stock options previously exercised	—	—	16,000	—	(32)	32	—	—	
Issuance of common stock, net of issuance costs	—	—	1,830,556	18	—	9,796	—	9,814	
Common stock dividends issued on Series D cumulative convertible preferred stock	—	—	377,841	4	(840)	1,676	(840)	—	
Common stock dividends declared on Series D cumulative convertible preferred stock	—	—	—	—	840	—	(840)	—	
Compensation expense resulting from modifications of options	—	—	—	—	—	164	—	164	
Amortization of deferred compensation	—	—	—	—	—	—	29	29	
Net loss	—	—	—	—	—	—	(8,144)	(8,144)	
Balance, December 31, 2001	200,000	2	10,999,573	110	840	80,129	(73,954)	7,127	
Exercise of common stock options and warrants	—	—	35,704	—	—	165	—	165	
Issuance of common stock, net of issuance cost	—	—	151,522	2	—	1,174	—	1,176	
Common stock dividends declared on Series D cumulative convertible preferred stock	—	—	—	—	611	—	(611)	—	
Common stock dividends issued on Series D cumulative convertible preferred stock	—	—	190,832	2	(1,451)	1,449	—	—	
Cash dividends paid on Series D cumulative convertible preferred stock	—	—	—	—	—	—	(218)	(218)	
Cash dividends declared on Series D cumulative convertible preferred stock	—	—	—	—	—	—	(800)	(800)	
Net income	—	—	—	—	—	—	902	902	
Balance, December 31, 2002	200,000	2	11,377,631	114	—	82,917	(74,681)	8,352	
Exercise of common stock options and warrants	—	—	464,569	4	—	1,819	—	1,823	
Issuance of common stock, net of issuance cost	—	—	2,000,000	20	—	18,683	—	18,703	
Cash dividends declared on Series D cumulative convertible preferred stock	—	—	—	—	—	—	(1,600)	(1,600)	
Compensation expense resulting from the modification of options	—	—	—	—	—	251	—	251	
Net income	—	—	—	—	—	—	6,427	6,427	
Balance, December 31, 2003	200,000	\$ 2	13,842,200	\$138	\$ —	\$103,670	\$(69,854)	\$33,956	

See accompanying notes to consolidated financial statements.

COLLAGENEX PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

Years ended December 31, 2003, 2002 and 2001

(Dollars in thousands)

	<u>2003</u>	<u>2002</u>	<u>2001</u>
Cash flows from operating activities:			
Net income (loss)	\$ 6,427	\$ 902	\$(8,144)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Noncash compensation expense	251	—	193
Depreciation and amortization expense	954	524	263
Accounts receivable provisions	(104)	462	569
Change in assets and liabilities:			
Accounts receivable	(2,713)	1,874	(2,009)
Inventories	(257)	(13)	(1,125)
Prepaid expenses and other assets	(688)	156	(111)
Accounts payable	(343)	(153)	1,904
Accrued expenses	1,545	252	639
Deferred revenue	(235)	(53)	(62)
Net cash provided by (used in) operating activities	<u>4,837</u>	<u>3,951</u>	<u>(7,883)</u>
Cash flows from investing activities:			
Capital expenditures	(305)	(298)	(131)
Acquisition of product rights	(900)	(800)	(1,000)
Proceeds from the sale of short-term investments	—	—	2,035
Purchase of short-term investments	—	—	(296)
Net cash provided by (used in) investing activities	<u>(1,205)</u>	<u>(1,098)</u>	<u>608</u>
Cash flows from financing activities:			
Net proceeds from issuance of common stock	20,526	1,341	9,814
Payment of preferred dividends	(1,600)	(218)	—
Repayment of long-term debt	—	(35)	(77)
Net cash provided by financing activities	<u>18,926</u>	<u>1,088</u>	<u>9,737</u>
Net increase in cash and cash equivalents	22,558	3,941	2,462
Cash and cash equivalents at beginning of year	10,112	6,171	3,709
Cash and cash equivalents at end of year	<u>32,670</u>	<u>\$10,112</u>	<u>\$ 6,171</u>
Supplemental schedule of noncash investing and financing activities:			
Common stock dividends issued or issuable on preferred stock	<u>\$ —</u>	<u>\$ 1,451</u>	<u>\$ 1,680</u>
Accrued liability for Altana license	<u>\$ —</u>	<u>\$ 900</u>	<u>\$ —</u>
Cash dividends declared on preferred stock	<u>\$ 800</u>	<u>\$ 800</u>	<u>\$ —</u>
Issuance of warrants to purchase common stock in connection with equity line	<u>\$ —</u>	<u>\$ 248</u>	<u>\$ —</u>
Supplemental disclosure of cash flow information:			
Cash paid during the year for interest	<u>\$ —</u>	<u>\$ 5</u>	<u>\$ 17</u>
Cash paid during the year for income taxes	<u>\$ 197</u>	<u>\$ —</u>	<u>\$ —</u>

See accompanying notes to consolidated financial statements.

COLLAGENEX PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2003, 2002 and 2001

(Dollars in thousands, except per share data)

(1) Business

CollaGenex Pharmaceuticals, Inc. and subsidiaries ("CollaGenex Pharmaceutical" or the "Company") was incorporated in Delaware on January 10, 1992. The Company is a specialty pharmaceutical company focused on providing innovative medical therapies to the dental and dermatology markets. The Company, through its own sales and marketing group, is currently marketing Periostat®, the Company's lead drug for the treatment of adult periodontal disease, Atridox, Atrisorb FreeFlow and Atrisorb-D (the "Atrix Products") under an exclusive licensing and marketing agreement with Atrix Laboratories, Inc. ("Atrix") and Pandel under a sublicensing agreement with Altana, Inc. ("Altana"). During 2001, 2002 and 2003, the Company also co-promoted VIOXX® with Merck and Co. ("Merck") and Denavir® with Novartis Consumer Health, Inc. ("Novartis") to dental professionals on a contract basis. Beginning in April of 2003, the Company was engaged in a co-promotion agreement with Sirius Laboratories, Inc. ("Sirius") in which the parties jointly marketed Sirius' AVAR™ product line to dermatologists in the United States, while Sirius co-promoted the Pandel product line. Co-promotion agreements with Merck, Novartis and Sirius expired or were mutually terminated as of December 31, 2003. The Company has other internally developed proprietary compounds for cancer metastasis and a broad range of inflammatory diseases that are currently in the research and development stage.

The accompanying consolidated financial statements include the results of operations of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

(2) Summary of Significant Accounting Policies

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. All cash equivalents are invested in money market funds.

Inventories

Inventories are stated at the lower of cost or market. Cost is determined using the first-in, first-out method.

Acquired Product Rights

Product rights are stated at cost and are amortized over the estimated useful life of the products using the straight-line method and have a weighted average useful life of 6 years. Amortization of product rights is charged to cost of product sales.

Equipment and Leasehold Improvements

Equipment and leasehold improvements, consisting of computer and office equipment, exhibit equipment and leasehold improvements are recorded at cost. Depreciation and amortization is provided using the straight-line method over the estimated useful lives of the assets or the related lease term, whichever is shorter, generally three to ten years. Expenditures for repairs and maintenance are expensed as incurred.

Segment Information

The Company is managed and operated as one business. The entire business is managed by a single management team that reports to the chief executive officer. The Company does not operate separate lines of

COLLAGENEX PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—CONTINUED

December 31, 2003, 2002 and 2001

(Dollars in thousands, except per share data)

business or separate business entities with respect to any of its products or product candidates. Accordingly, the Company does not prepare discrete financial information with respect to separate product areas or by location and does not have separately reportable segments.

Financial Instruments

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable, accrued expenses and preferred dividends payable approximate fair value because of the short term nature of these instruments.

Net Product Sales

In September 1998 the Company received approval from the Food and Drug Administration (“FDA”) to market Periostat. In 2001, the Company entered into an exclusive licensing and marketing agreement with Atrix for the Atrix Products. In 2002, the Company entered into a sublicense agreement with Altana to market and distribute Pandel. The Company recognizes sales revenue for Periostat, Pandel and the Atrix Products upon shipment. Sales are reported net of allowances for discounts, rebates, wholesaler and distributor chargebacks and product returns which are provided for at the time of the sale.

Contract Revenues

Contract revenues for Vioxx and Denavir are fee-based arrangements where revenue is earned as prescriptions are filled and recognized according to the provisions of each collaborative agreement. Contract revenues for AVAR are calculated as a percentage of the sales gross margin recognized by Sirius, in accordance with the provisions of the agreement with Sirius and are recognized when product is shipped by Sirius. The Company does not take title to the products being promoted under these arrangements.

License Revenue

Milestone revenue from license arrangements is recognized upon completion of the milestone event or requirement if it represents the achievement of a significant step in the research, development or regulatory process. Payments, if any, received in advance of performance under a contract are deferred and recognized when earned. Upfront license fees where the Company has continuing involvement are deferred and recognized over the estimated performance period of each individual licensing agreement in accordance with the SEC’s Staff Accounting Bulletin No. 104 (SAB 104). In 2003, SAB 104 replaced Staff Accounting Bulletin No. 101 (SAB 101) which the Company adopted in 2000. The provisions related to up-front license fees were unchanged in SAB 104 versus SAB 101. During 2003, 2002, and 2001, respectively, the Company recorded \$52, \$59 and \$60 in license revenues which were deferred upon the implementation of SAB 101 and which were previously recognized as license revenues under the historical revenue recognition policy prior to the adoption of SAB 101.

Advertising Costs

The Company incurs advertising costs from print advertisements in various periodicals and television advertisements. The Company records advertising expense when incurred. Such amounts charged to the consolidated statements of operations for 2003, 2002 and 2001 were \$139, \$3,091 and \$6,190, respectively.

COLLAGENEX PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—CONTINUED

December 31, 2003, 2002 and 2001

(Dollars in thousands, except per share data)

Research and Development

Research and development expenses consist primarily of funds paid to third parties for the provision of services and materials for drug development, manufacturing and formulation enhancements, clinical trials, statistical analysis and report writing and regulatory compliance costs. Research and product development costs are expensed as incurred.

Accounting for Income Taxes

Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when such differences are expected to reverse. The measurement of deferred tax assets is reduced, if necessary, by a valuation allowance for any tax benefits which are not expected to be realized. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted.

Management Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates.

Stock-Based Compensation

Statement of Financial Accounting Standards (SFAS) No. 123 (SFAS 123), "Accounting for Stock-Based Compensation," encourages but does not require companies to record compensation cost for stock-based employee and director compensation plans at fair value. Accordingly, compensation cost for stock options issued to employees and directors is measured as the excess, if any, of the market price of the Company's stock at the date both the number of shares and price per share are known (measurement date) over the exercise price. Such amounts are amortized on a straight-line basis over the respective vesting periods of the option grants. Transactions with nonemployees, in which goods or services are the consideration received for the issuance of equity instruments, are accounted for on a fair value basis in accordance with SFAS 123 and related interpretations.

COLLAGENEX PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—CONTINUED

December 31, 2003, 2002 and 2001
(Dollars in thousands, except per share data)

The Company has elected to account for stock-based compensation under APB Opinion No. 25, "Accounting for Stock Issued to Employees" and related interpretations. As set forth below, the pro forma disclosures of net income (loss) allocable to common stockholders and income (loss) per share allocable to common stockholders are as if the Company had adopted the fair value based method of accounting in accordance with SFAS No. 123, as amended by SFAS No. 148, which assumes the fair value based method of accounting had been adopted using the assumptions described in note 8:

	<u>2003</u>	<u>2002</u>	<u>2001</u>
Net income (loss) allocable to common stockholders:			
As reported	\$ 4,827	\$ (727)	\$ (9,824)
Add: Stock-based employee compensation expenses included in net income (loss) allocable to common stockholders reported	251	—	29
Less: Stock-based employee compensation under fair value based method	<u>(5,015)</u>	<u>(3,735)</u>	<u>(3,898)</u>
Pro forma	<u>\$ 63</u>	<u>\$(4,462)</u>	<u>\$(13,693)</u>
Basic net income (loss) per share allocable to common stockholders:			
As reported	<u>\$ 0.40</u>	<u>\$ (0.06)</u>	<u>\$ (0.94)</u>
Pro forma	<u>\$ 0.01</u>	<u>\$ (0.40)</u>	<u>\$ (1.31)</u>
Diluted net income (loss) per share allocable to common stockholders:			
As reported	<u>\$ 0.38</u>	<u>\$ (0.06)</u>	<u>\$ (0.94)</u>
Pro forma	<u>\$ 0.01</u>	<u>\$ (0.40)</u>	<u>\$ (1.31)</u>

Concentration of Credit and Other Risks

The Company invests its excess cash in money market funds with major U.S. financial institutions. The Company has established guidelines relative to diversification and maturities that maintain safety and liquidity.

The Company currently contracts with a single source for the domestic manufacturing of Periostat tablets which are sold throughout the United States exclusively to wholesale and retail distributors. In addition, the Company has a supply agreement with a single company to supply the active ingredient in Periostat®. A single company also provides all warehousing and distribution services to the Company. During 2003, three customers accounted for 43%, 31% and 20% of net product sales, respectively. During 2002, three customers accounted for 32%, 24% and 19% of net product sales, respectively. During 2001, four customers accounted for 28%, 15%, 13% and 10%, of net product sales, respectively.

During the years ended December 31, 2003, 2002 and 2001, Periostat® accounted for approximately 82%, 82% and 87% of our total net revenues, respectively.

The Company's business of selling, marketing and developing pharmaceutical products is subject to a number of significant risks, including risks relating to the implementation of the Company's sales and marketing plans, risks inherent in research and development activities, risks associated with conducting business in a highly regulated environment and uncertainties related to clinical trials of products under development.

COLLAGENEX PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—CONTINUED

December 31, 2003, 2002 and 2001

(Dollars in thousands, except per share data)

Impairment of Long-Lived Assets

Pursuant to SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," we evaluate long-lived assets and intangible assets for impairment when factors indicate that the carrying amount of an asset may not be recoverable. When factors indicate that such assets should be evaluated for possible impairment, we review the realizability of our long-lived assets by analyzing the projected undiscounted cash flows in measuring whether the asset is recoverable. Impairment, if any, is recognized as the difference between the asset carrying value and its fair value. No such adjustments were recorded in 2003, 2002 or 2001.

Net Income (Loss) Per Share

Basic income per share (EPS) is calculated by dividing income (loss) allocable to common stockholders by the weighted average shares of common stock outstanding. Net income (loss) allocable to common stockholders includes dividends on the preferred stock. Diluted EPS reflects the potential dilution that could occur if outstanding options and warrants were exercised. As of December 31, 2002 and December 31, 2001, the Company had outstanding stock options and stock warrants which were not included in the calculation of diluted net loss per share allocable to common stockholders because to do so would be anti-dilutive. Diluted EPS would also include the effect of dilution to income of convertible securities. As of December 31, 2003, 2002 and 2001, the Company had certain convertible preferred stock which had not been included in the calculation of diluted net income (loss) per share allocable to common stockholders because to do so would be anti-dilutive. As such, the numerator and denominator used in computing both basic and diluted net loss per share allocable to common stockholders were equal in 2002 and 2001. For the year ended December 31, 2003, the denominator used to calculate diluted income per share was 741,726 higher than the denominator used to calculate basic income per share. This difference in share amounts related to in the money employee stock options and warrants.

Recently Issued Accounting Standards

SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*, was issued in May 2003. This Statement establishes standards for the classification and measurement of certain financial instruments with characteristics of both liabilities and equity. The Statement also includes required disclosures for financial instruments within its scope. For the Company, the Statement was effective for instruments entered into or modified after May 31, 2003. For certain mandatorily redeemable financial instruments, the Statement will be effective for the Company on a later date. The Company currently does not have any financial instruments that are within the scope of this Statement.

Reclassification

Certain amounts in the 2002 consolidated financial statements have been reclassified to the 2003 presentation.

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(3) Composition of Certain Financial Statement Captions

Inventories

Inventories at December 31, 2003 and 2002 consist of the following:

	<u>2003</u>	<u>2002</u>
Raw materials	\$ 396	\$ 233
Work-in-process	52	56
Finished goods	1,224	1,126
	<u>\$1,672</u>	<u>\$1,415</u>

Equipment and Leasehold Improvements

Equipment and leasehold improvements at December 31, 2003 and 2002 consist of the following:

	<u>2003</u>	<u>2002</u>	<u>Useful Life</u>
Computer and office equipment	\$ 1,133	\$ 1,203	3-5 years
Exhibit equipment	451	327	5 years
Leasehold improvements	45	45	Shorter of 10 years or lease term
	1,629	1,575	
Less: accumulated depreciation and amortization	<u>(1,133)</u>	<u>(1,016)</u>	
	<u>\$ 496</u>	<u>\$ 559</u>	

Acquired Product Rights

Acquired product rights at December 31, 2003 and 2002 consist of the following:

	<u>2003</u>	<u>2002</u>
Acquired product rights	\$2,700	\$2,700
Less: accumulated amortization	<u>(951)</u>	<u>(365)</u>
	<u>\$1,749</u>	<u>\$2,335</u>

Amortization expense which is included in cost of product sales was \$586, \$366 and \$17 in 2003, 2002 and 2001, respectively. Expected amortization of acquired product rights is as follows:

2004	\$ 586
2005	586
2006	100
2007	100
2008	100
Thereafter	277
	<u>\$1,749</u>

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Accrued Expenses

Accrued expenses at December 31, 2003 and 2002 consist of the following:

	<u>2003</u>	<u>2002</u>
Product licensing fees	\$ —	\$ 900
Contracted development and manufacturing costs	835	456
Sales and marketing costs	202	255
Payroll and related costs	1,925	1,479
Professional and consulting fees	922	339
Royalties	645	553
Deferred revenue	52	59
Income taxes	85	—
Miscellaneous taxes	139	103
Other	145	161
	<u>\$4,950</u>	<u>\$4,305</u>

(4) Note Payable

In April 1999, the Company received \$219 in proceeds from the issuance of a note payable. The proceeds of such note were used to fund the purchase of equipment, fixtures and furniture for the Company's leased corporate office in Newtown, Pennsylvania. The term of the note was three years with interest at 9.54% per annum, with monthly minimum payments of principal and interest. The Company repaid the note in 2002.

(5) Stockholders' Equity

The Company's Board of Directors may, without further action by the Company's stockholders, from time to time, direct the issuance of shares of preferred stock in series and may, at the time of issuance, determine the rights, preferences and limitations of each series. The holders of preferred stock would normally be entitled to receive a preference payment in the event of any liquidation, dissolution or winding-up of the Company before any payment is made to the holders of the common stock.

On May 12, 1999, the Company consummated a \$20,000 financing (the Financing) through the issuance of 200,000 shares of its Series D Cumulative Convertible preferred stock (the preferred stock), which generated net proceeds to the Company of approximately \$18,500. OCM Principal Opportunities Fund, L.P. (OCM) led the investor group, which also included certain current stockholders of the Company.

During the first three years following issuance, the preferred stock paid dividends in common stock at a rate of 8.4% per annum. Beginning May 12, 2002, the preferred stock pays dividends in cash at a rate of 8.0% per annum. The preferred stock was convertible into common shares of the Company at an initial conversion price of \$11.00 per share, subject to adjustment (see below and note 6), at any time by the holder and under certain conditions by the Company. The conversion price is subject to adjustment in the event the Company fails to declare or pay dividends when due or should the Company issue new equity securities or convertible securities at a price per share or having a conversion price per share lower than the applicable conversion price of the preferred stock (see below and note 6). Dividends totaling \$1,600, \$1,629 and \$1,680 were declared in 2003, 2002 and 2001, respectively.

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The holders of the preferred stock are entitled to vote with the holders of the Company's common stock on all matters to be voted on by the Company's stockholders on an as converted to common stock basis, subject to adjustment. The holders of the preferred stock are entitled to liquidation preferences equal to the original purchase price plus dividends accrued and unpaid plus other dividends in certain circumstances. In connection with the issuance of the preferred stock, the rights of the holders of the Company's common stock may be limited in certain instances with respect to dividend rights, rights on liquidation, winding up and dissolution of the Company, and the right to vote in connection with certain matters submitted to the Company's stockholders.

Without written approval of a majority of the holders of record of the preferred stock, the Company, among other things, shall not: (i) declare or pay any dividend or distribution on any shares of capital stock of the Company other than dividends on the preferred stock; (ii) make any loans, incur any indebtedness or guarantee any indebtedness, advance capital contributions to, or investments in any person, issue or sell any securities or warrants or other rights to acquire debt securities of the Company, except that the Company may incur such indebtedness in any amount not to exceed \$10,000 in the aggregate outstanding at any time for working capital requirements in the ordinary course of business; or (iii) make research and development expenditures in excess of \$7,000 in any continuous twelve month period, unless the Company has reported positive net income for four consecutive quarters immediately prior to such twelve month period.

On March 12, 2001, the Company consummated a private equity offering of 1,500,000 shares of common stock for an aggregate purchase price of \$7,500, which generated net proceeds to the Company of approximately \$6,800. In addition, the investors in this financing were also issued an aggregate of 400,000 warrants which are exercisable for up to three years into 400,000 shares of the Company's common stock at an exercise price per share of \$6.00. The consideration received for such warrants is included in the aggregate proceeds received in the financing. No warrants have been exercised and all 400,000 warrants remain outstanding at December 31, 2003. The Company also issued to its financial advisor in this financing, warrants to purchase an aggregate of 150,000 shares of the Company's common stock, exercisable for up to three years, at an exercise price of \$5.70 per share. During 2002, 7,140 warrants were exercised into 4,654 shares of the Company's common stock. During 2003, the remaining 142,860 warrants were exercised into 92,195 shares of the Company's common stock. The majority of these warrant exercises were in cashless transactions. Accordingly, none of the 150,000 warrants remain outstanding at December 31, 2003. As a result of this financing, the conversion price of the preferred stock was reduced to \$9.94 per share. Such conversion price was further reduced to \$9.91 per share in connection with the sale of shares of the Company's common stock to Atrix (see note 6).

On February 14, 2002, the Company entered into an equity line arrangement under the terms of a Common Stock Purchase Agreement with Kingsbridge Capital Limited. Pursuant to this agreement, the Company was able, at its sole discretion and from time to time through February 13, 2003, to sell shares of its common stock to Kingsbridge at a discount to market price, as determined prior to each such sale. The equity line provided for the sale of up to \$8,500 in registered shares of the Company's common stock to Kingsbridge. The equity line terminated pursuant to its terms on February 13, 2003 and, prior to such termination, the Company issued an aggregate of 151,522 shares of common stock for gross proceeds of \$1,266.

In connection with the consummation of such equity line and pursuant to the terms of a warrant agreement executed by the Company, the Company issued Kingsbridge a warrant to purchase 40,000 shares of its common stock at an exercise price of \$9.38 per share. The conversion price of the Company's preferred stock was reduced to \$9.89 as a result of the issuance of shares under the equity line and the issuance of such warrant. Such warrant is exercisable as of August 14, 2002, and will expire on August 13, 2007. The fair value of the warrants issued in

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connection with the Equity Line of approximately \$248 has no net impact as the increase to additional paid in capital representing the value of the warrants issued is offset by the decrease in additional paid in capital representing a cost of the offering. No warrants have been exercised and all 40,000 warrants are outstanding at December 31, 2003.

On May 29, 2002, the Company's Board of Directors approved an Amended and Restated Shareholder Protection Rights Agreement (the "Rights Agreement"). The Rights Agreement amended and restated, in its entirety, the Company's then existing Shareholder Protection Rights Agreement (the "Prior Rights Agreement") dated September 15, 1997, as amended, by and between the Company and American Stock Transfer & Trust Company, as rights agent thereunder. American Stock Transfer & Trust Company remains as rights agent under the Rights Agreement. Each right previously authorized and distributed under the Prior Rights Agreement was deemed to constitute a Right under the Rights Agreement effective May 29, 2002. The Board of Directors further authorized the issuance of one Right for each share of the Company's common stock issued between the date of the Rights Agreement and the earlier of the Distribution Date or the Expiration Date, as defined in the Rights Agreement.

Each Right, once exercisable, entitles the holder to purchase from the Company one one-hundredth of a share of the Company's Series A Participating preferred stock at an exercise price of \$65. All Rights expire on September 26, 2007 unless earlier redeemed. At December 31, 2003, the Rights were neither exercisable nor traded separately from the Company's common stock, and become exercisable only if a person or a group of affiliated or associated persons has acquired, or obtained the right to acquire, beneficial ownership of 20% or more of the voting power of all outstanding shares of the Company's common stock and in certain other limited circumstances. Upon separation from the common stock, each Right will entitle the holder, other than the acquiring person that has triggered such separation, to effectively purchase certain shares of the Company's common stock equal in market value to two times the then applicable exercise price of the Right. If the Company is acquired in a merger or other business combination transaction, or 50% or more of the Company's assets or earning power are sold in one or more related transactions, the Rights will entitle holders, upon exercise of the Rights, to receive shares of common stock of the acquiring or surviving company with a market value equal to twice the exercise price of each Right.

In February 2003, the Company filed a registration statement on Form S-3 with the Securities and Exchange Commission related to the public offering of up to an aggregate of 2,000,000 shares of common stock. In October 2003, the Company sold 2,000,000 shares of its common stock previously registered on its Registration Statement on Form S-3 for an aggregate purchase price of \$20,000, which generated net proceeds to the Company of approximately \$18,703, after the payment of placement agent fees and related expenses.

(6) Licensing and Marketing Agreements

On August 24, 2001, the Company signed an exclusive License Agreement (the "Atrix License Agreement") with Atrix to market Atrix's proprietary dental products, Atridox[®], Atrisorb[®] FreeFlow and Atrisorb[®]-D, to the United States dental markets. Pursuant to the terms of the Atrix License Agreement, among other things, Atrix will manufacture the dental products for the Company at an agreed upon transfer price and will receive royalties on future net sales of the products each calendar year. The Company paid a \$1,000 licensing fee to Atrix in 2001 to market such products in the United States. The Company has also committed to no less than \$2,000 in advertising and selling expenses related to the licensed products during 2002, which was met for 2002, and on an annual basis commencing with fiscal year 2003, the lesser of \$4,000 or 30% of the Company's contribution

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margin, as defined in the agreement, relating to a specific Atrix product that the Company markets and the lesser of \$2,000 or 30% of the Company's contribution margin, as defined in the agreement, relating to a separate Atrix product that the Company markets. These annual requirements were met by the Company in 2003. Additionally, the Company must maintain a minimum amount of full time sales professionals and make a specific amount of sales presentations over the first twenty-four months of the agreement, which were met. The \$1,000 license fee payment has been capitalized and is being amortized to cost of product sales over the ten year estimated term of the license on a straight-line basis.

In addition, pursuant to the terms of a Stock Purchase Agreement dated August 24, 2001 by and between the Company and Atrix, Atrix purchased 330,556 of unregistered shares of the Company's common stock for an aggregate purchase price of approximately \$3,000. As a result of the sale of such shares to Atrix, the conversion price of the Company's preferred stock was reduced to \$9.91 per share.

On May 24, 2002, the Company executed a Sublicense Agreement with Altana Inc. ("Altana"), the United States subsidiary of Altana Pharma AG, pursuant to which the Company was granted the exclusive right to create improvements to, market, advertise, promote, distribute, offer for sale and sell, in the United States and Puerto Rico, Pandel[®] Cream, a mid-potency topical corticosteroid that is indicated for the relief of mild-to-moderate inflammatory disorders of the skin, such as atopic dermatitis and psoriasis. Altana currently licenses such rights from Taisho Pharmaceutical Co., Ltd., a company organized and existing under the laws of Japan. The Company will purchase from Altana all Pandel products to be sold. Pursuant to the terms of such agreement, the Company agreed to pay Altana an aggregate sublicense fee of \$1,700, of which \$800 was paid in September 2002 and \$900 of which was paid in May 2003. The sublicense fee has been capitalized and is being amortized to cost of product sales over the estimated term of agreement. In addition, the Company is required to pay a royalty fee equal to a percentage of the net sales of the product, if any. The agreement may be terminated by the Company: (i) at any time, without cause, upon twelve months prior written notice; (ii) if Altana shall commit any uncured, willful or material breach of the provisions of the agreement; or (iii) if Altana shall cease to manufacture or supply the product to the Company. Altana may terminate the agreement: (i) at any time, without cause, upon twelve months written notice; (ii) if the Company shall commit any uncured, willful or material breach of the provisions of the agreement; (iii) if the Company shall cease to offer the product for distribution to its customers; or (iv) if the Company fails to make certain payments or fulfill certain invoicing obligations.

On March 14, 2003, the Company terminated its license agreement with Roche S.P.A. As a result of the termination of the agreement, during 2003, the Company accelerated the recognition of the remaining \$222 of unamortized deferred revenue related to the \$400 up-front payment received in 1996. In June 2003, the Company recognized \$425 related to the collection of outstanding milestone payments from Roche.

Pursuant to a Co-Promotion Agreement the Company executed with Merck in September 1999, the Company received the exclusive right to co-promote Vioxx, a prescription strength non-steroidal anti-inflammatory drug that was approved by the FDA on May 20, 1999 to relieve osteoarthritis and manage acute pain in adults, including dental pain. The agreement provided for certain payments by Merck to the Company upon sales of Vioxx to the dental community. On September 23, 2002, the Company executed an amendment, extension and restatement of the Co-Promotion Agreement with Merck with respect to Vioxx. In accordance with that amendment, extension and restatement, the Company's agreement with Merck automatically expired on December 31, 2003.

In March 2003, the Company executed co-promotion agreements with Sirius pursuant to which we jointly marketed both the Sirius' AVAR product line and Pandel to dermatologists in the United States. These agreements were mutually terminated in December 2003.

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On October 1, 2002, the Company entered into a Product Detailing Agreement with Novartis pursuant to which the Company co-promoted Denavir to target dentists in the United States and received detailing fees and performance incentives from Novartis. The agreement with Novartis to co-promote Denavir expired on September 30, 2003, and the Company and Novartis decided not to renew the arrangement with respect to Denavir.

(7) Line of Credit

On March 19, 2001, the Company consummated a revolving credit facility with Silicon Valley Bank, which was subsequently amended in March 2002. The credit facility, as amended, extends through March 15, 2004. The Company may borrow up to the lesser of \$4,000 or 80% of eligible accounts receivable, as defined, under the credit facility. The amount available to the Company is also reduced by outstanding letters of credit which may be issued under the credit facility in amounts totaling up to \$1,500. As of December 31, 2003, the Company had an outstanding letter of credit approximating \$124 that served as collateral for certain inventory purchase commitments of the Company (see note 11). As the Company pays down amounts under the letter of credit, the amount available to it under the Facility will increase. The Company is not obligated to draw amounts and any such borrowings bear interest, payable monthly, currently at the prime rate plus 1.0% to 1.5% per annum and may be used only for working capital purposes. Without the consent of the Silicon Valley Bank, the Company, among other things, shall not (i) merge or consolidate with another entity; (ii) acquire assets outside the ordinary course of business; or (iii) pay or declare any cash dividends on the Company's common stock. The Company must also maintain a certain tangible net worth of \$5,000, subject to certain upward adjustments as defined in the amendment, as a result of profitable operations or additional debt or equity financings and a minimum of \$2,000 in cash at Silicon Valley Bank, net of borrowings under the credit facility, which expires March 15, 2004. The Company is currently negotiating to renew the credit facility for a two-year term upon termination. In addition, the Company has secured its obligations under the credit facility through the granting of a security interest in favor of the bank with respect to all of its assets, including intellectual property. As of December 31, 2003 and 2002, the Company had no borrowings outstanding against the credit facility.

(8) Stock Option Plans

The Company has three stock-based compensation plans (the Plans) and has adopted the disclosure-only provisions of SFAS 123 and SFAS 148, "Accounting For Stock Based Compensation-Transition and Disclosures and Amendment of SFAS 123". The Company continues to apply APB Opinion No. 25 in accounting for its stock option plans and, accordingly, no compensation expense has been recognized at the date of grant in the consolidated financial statements for stock options issued to employees and directors as exercise prices equal the market value on the grant date.

The 1992 Stock Option Plan, as amended, (the 1992 Plan) provided for the granting of incentive and nonqualified options to directors, employees and consultants to purchase up to 291,000 shares of the Company's common stock at a price, for the incentive options, not less than the fair market value on the measurement date. Such options are exercisable for a period of ten years from the grant date and generally vest over a four year period. All such 291,000 options available under the 1992 Plan were granted by 1996.

The 1996 Stock Option Plan, as amended, (the 1996 Plan) provides for the granting of incentive and nonqualified options to employees and consultants to purchase up to 3,000,000 shares of the Company's common stock at a price, for the incentive options, not less than the fair market value on the measurement date. Incentive

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and nonqualified options granted to individuals owning more than 10% of the voting power of all classes of stock at the time of grant must have an exercise price no less than 110% of the fair market value on the date of grant. Such options are exercisable for a period of ten years from the grant date and generally vest over a two to five year period, and may be accelerated for certain grants in certain circumstances.

The Nonemployee Director Stock Option Plan (the Nonemployee Director Plan) provides for the issuance of stock options to new nonemployee directors to purchase up to 300,000 shares of common stock at an exercise price equal to the fair market value on the date of grant. Such options vest 20% per annum commencing one year from the grant date.

During 2003 and 2002, certain existing members of the Board of Directors were granted 74,500 and 62,136 options, respectively, at a fair market value of \$10.80 and \$6.60 per share, respectively. These grants were issued under the 1996 Stock Option Plan. Such options vest 25% per annum, commencing one year from the grant date.

During 2001 and 2000, 360,000 and 237,750 options were granted to employees at fair market value with weighted average exercise prices of \$5.19 and \$5.00 per share, respectively. These grants were not issued under the terms of any of the above Plans. Such options are exercisable for a period of ten years from the date of grant and generally vest over a two to five year period.

At December 31, 2003, there were 575,672 shares available for grant under the 1996 Plan and 100,000 under the Nonemployee Director Plan.

Deferred compensation had been recorded in years prior to 1998 for options granted where the fair value of the Company's stock on the measurement date exceeded the exercise price of such options. Deferred compensation has been amortized to compensation expense in the accompanying consolidated statements of operations over the respective vesting periods of such grants \$0, \$0 and \$29 in 2003, 2002 and 2001, respectively.

In 2001, the Company extended through the remaining contractual life the exercisability of certain vested options for an ex-board member of the Company. Accordingly, \$164 was recognized as compensation expense in 2001, based on the fair value of the options on the date the extension was granted as determined using a Black-Scholes option pricing model.

As a result of a transition agreement with Brian M. Gallagher, Ph.D., the Company's former chairman, chief executive officer and president, the Company recognized a non-cash compensation charge of \$251 for the year ended December 31, 2003 relating to certain modifications to Dr. Gallagher's stock option agreements (see note 11).

On December 8, 2003, the Company granted stock options to Colin W. Stewart, its newly appointed president and chief executive officer, effective the date of commencement of his employment. These options were granted without stockholder approval under the following terms: 300,000 non-qualified stock options, exercise price equal to the fair market value on the grant date, ten-year term and vesting at the rate of 20% for each year of service with the Company. In certain circumstances, if the closing price of the Company's common stock exceeds a pre-determined per share price for a certain number of consecutive days, a portion of such options will vest immediately.

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The following table summarizes stock option activity for 2001 through 2003 :

	Options	Weighted average exercise price per share
Balance, December 31, 2000	2,023,009	\$10.20
Granted	570,100	5.85
Cancelled	(140,500)	10.87
Balance, December 31, 2001	2,452,609	\$ 9.15
Granted	616,086	7.91
Exercised	(31,050)	4.70
Cancelled	(82,475)	9.90
Balance, December 31, 2002	2,955,170	\$ 8.91
Granted	899,350	10.23
Exercised	(374,374)	4.52
Cancelled	(47,142)	10.38
Balance, December 31, 2003	<u>3,433,004</u>	<u>\$ 9.72</u>

As of December 31, 2003, the following options were outstanding and exercisable by price range as follows:

Range of exercise prices	Outstanding		Exercisable	
	Number of options	Weighted average remaining contractual life (in years)	Number of options	Weighted average exercise price per share
\$ 0.33-\$ 2.00	69,000	1.6	69,000	\$ 1.02
\$ 4.62-\$ 6.75	643,871	6.1	436,143	5.56
\$ 7.01-\$ 8.88	603,640	7.9	241,726	8.04
\$ 9.00-\$11.88	1,534,413	6.8	620,313	9.88
\$12.00-\$22.63	582,080	5.7	487,579	15.92
	<u>3,433,004</u>	<u>6.6</u>	<u>1,854,761</u>	<u>\$ 9.88</u>

The weighted average fair values of stock options granted to employees during 2003, 2002 and 2001 were \$6.39, \$6.07 and \$4.57 per share, respectively, on the date of grant. Such fair values were determined using the Black-Scholes option pricing model and are based on the following assumptions:

	2003	2002	2001
Expected life in years - Employees and directors	7	7	7
Risk-free interest rate	3.52%	4.30%	4.88%
Volatility	81%	83%	85%
Expected dividend yield	—%	—%	—%

On September 18, 2002, the Company executed agreements with each of five officers of the Company that provided, among other things, for the accelerated vesting of unvested options upon a change of control of the Company. As of December 31, 2003, there were 300,000 options whose vesting would have accelerated as a result of these agreements if a change of control had occurred, and in this circumstance the Company would have

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recorded compensation expense of \$116, as measured by the difference in the exercise price of the options with potentially accelerated vesting and the fair value of the Company's common stock on the date the agreements were executed. A non-cash charge will be recorded in the future upon a change in control for only those options which would have otherwise expired unvested except for the resulting acceleration of vesting as a result of these agreements.

(9) Income Taxes

The Company utilizes the asset and liability method of accounting for income taxes in accordance with SFAS No. 109, "Accounting for Income Taxes". Under the asset and liability method, deferred taxes are determined based on the differences between the financial statement and tax bases of assets and liabilities using currently enacted tax rates.

For 2003, income tax expense consists of current Federal alternative minimum tax of \$80 and state income tax of \$5. The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liability at December 31, 2003 and 2002 are presented below:

	<u>2003</u>	<u>2002</u>
Deferred tax assets:		
Depreciation	\$ 14	\$ 16
Amortization	230	—
Net operating loss carryforwards	23,198	23,952
Tax credit carryforwards	973	874
Accrued expenses	1,190	1,053
Deferred revenue	<u>134</u>	<u>242</u>
Total gross deferred assets	25,739	26,137
Less valuation allowance	<u>(25,739)</u>	<u>(26,137)</u>
Net deferred taxes	<u>\$ —</u>	<u>\$ —</u>

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which temporary differences are deductible and carryforwards are available. Due to the uncertainty of the Company's ability to realize the benefit of the deferred tax assets, the net deferred tax assets are fully offset by a valuation allowance at December 31, 2003 and 2002. As of December 31, 2003 and 2002, \$1,463 and \$45, respectively, of the Company's gross deferred tax assets are attributable to stock option compensation. To the extent such asset is realized in the future, the benefit would be credited directly to stockholders' equity.

The net change in the valuation allowance for the years ended December 31, 2003 and 2002 was a decrease of approximately \$1,816 and \$544, respectively, related primarily to utilization of net operating losses in 2003 and 2002.

At December 31, 2003, the Company had approximately \$57,000 of Federal and \$32,000 of state net operating loss carryforwards available to offset future taxable income. The Federal and state net operating loss

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carryforwards will begin expiring in 2010 and 2006, respectively, if not utilized. The Company also has research and development tax credit carryforwards of approximately \$893 available to reduce Federal income taxes which begin expiring in 2007. In addition, the Company had approximately \$3,400 of foreign net operating loss carryforwards with an indefinite expiration date.

Section 382 of the Internal Revenue Code of 1986 subjects the future utilization of net operating losses and certain other tax attributes, such as research and development credits, to an annual limitation in the event of an ownership change, as defined. Due to the Company's equity transactions, a portion of the net operating losses and tax credits of the Company are subject to an annual limitation of approximately \$3,800. To the extent that any single-year limitation is not utilized to the full amount of the limitation, such unused amounts are carried over to subsequent years until the earlier of its utilization or the expiration of the relevant carryforward period. As of December 31, 2003, approximately \$35,000 is immediately available to offset future taxable income. In addition to the section 382 limitation, the state net operating loss carryforwards are subject to a \$2,000 annual limitation.

Reconciliations of the income tax expense (benefit) from the Federal statutory rates for 2003, 2002 and 2001 are as follows:

	Year Ended December 31,					
	2003		2002		2001	
Statutory Federal income tax	\$ 2,214	34.0%	\$ 307	34.0%	\$(2,769)	(34.0)%
Adjustments resulting from:						
State taxes, net of Federal benefit	3	—	16	1.8	(588)	7.2
Permanent items and others	(316)	(4.8)	221	24.5	1,506	18.5
Increase (decrease) in valuation allowance	(1,816)	(27.9)	(544)	(60.3)	1,851	22.7
Total income tax expense (benefit)	\$ 85	1.3%	\$ —	—%	\$ —	—%

(10) Technology License

At the time of its formation in 1992, the Company entered into an agreement with the Research Foundation of the State University of New York at Stony Brook ("SUNY") whereby the Company received an option to acquire a certain technology license. The Company's option to acquire the license was exercised in 1995 and remains in effect for a period not to exceed twenty years from the date of the first sale of product incorporating the technology under license or the last to expire of the licensed patents in each country. The Company is liable to SUNY for annual royalty fees based on net Periostat sales, if any, as defined in the agreement. Legal costs incurred by the Company in defending the patent underlying the technology license, if any, are deducted from royalties paid to SUNY (See Note 12). A minimum annual royalty of \$50 per year is required for the duration of the technology license. The Company incurred royalty expense for this technology of \$1,832, \$1,563 and \$1,348 in 2003, 2002 and 2001, respectively.

In addition, the Company is required to reimburse SUNY for certain patent related costs, as well as to support certain additional research efforts.

COLLAGENEX PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—CONTINUED

December 31, 2003, 2002 and 2001

(Dollars in thousands, except per share data)

(11) Commitments and Contingencies

The Company maintains various operating leases, primarily for office space and equipment. As of December 31, 2003, future minimum rent payments under noncancellable operating leases are as follows:

2004	\$ 530
2005	554
2006	554
2007	360
2008	334
Thereafter	<u>196</u>
Total	<u>\$2,528</u>

Rent expense for the years ended December 31, 2003, 2002 and 2001 totaled \$327, \$356 and \$337, respectively.

During 2003, the Company entered into a three-year operating lease agreement for certain sales automation equipment. Under this agreement the Company is required to make monthly payments based on the monthly number of users.

Pursuant to the terms of the Atrix License Agreement (see note 6), the Company will be required to make certain annual minimum expenditures for the lesser of \$4,000 or 30% of the Company's contribution margin, as defined in the agreement, relating to a specific Atrix product that the Company markets and the lesser of \$2,000 or 30% of the Company's contribution margin, as defined in the agreement, relating to a separate Atrix product that the Company markets commencing with fiscal year 2003. The Company met the required spending requirements in 2002 and 2003 related to this Agreement.

On February 11, 2002, the Company executed a Co-operation, Development and Licensing Agreement pursuant to which the Company was granted an exclusive, sublicenseable, transferable license with respect to the Restoraderm™ topical drug delivery system which the Company intends to develop for dermatological applications. Pursuant to the terms of such agreement, upon the occurrence of certain events, the Company will be required to pay certain future consulting, royalty and milestone payments in the aggregate amount of up to \$3,188, and no more than \$2,150 and \$1,038 of which shall be payable prior to January 1, 2004 and January 1, 2005, respectively. The Company paid \$600 and \$330, respectively, under this Agreement in 2003 and 2002. The term of such agreement is for the life of any patent that may be issued to the Company for the first product the Company develops utilizing such technology, or, if the Company does not acquire any patentable products, seven years.

On June 10, 2002, the Company executed a Development and Licensing Agreement with Shire Laboratories, Inc. pursuant to which the Company was granted an exclusive worldwide license (including the right to sublicense) to develop, make, have made, use, supply, export, import, register and sell products for the treatment of various inflammatory disorders. In addition, under the agreement, certain product development functions shall be performed for the Company. Also under the agreement, the Company has committed to payments, in cash or at the Company's option, a combination of cash and the Company's common stock, upon the achievement of certain clinical and regulatory milestones in the event the Company pursues certain

COLLAGENEX PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—CONTINUED

December 31, 2003, 2002 and 2001

(Dollars in thousands, except per share data)

applications of the technology which could total up to \$7,900 in the aggregate. Pursuant to the terms of such agreement, the Company shall also pay a percentage of certain net sales of products, if any, utilizing any part of the technology. The Company may terminate the agreement upon sixty days notice.

As of December 31, 2003, the Company has obligations to purchase \$1,139 of inventory from various suppliers over the next twelve months.

In December 2003, Brian M. Gallagher, Ph.D., the Company's former chairman, chief executive officer and president, left the Company to pursue other interests. Dr. Gallagher will continue to serve as a member of the Company's Board of Directors. In March 2003, the Company executed an agreement with Dr. Gallagher, pursuant to which Dr. Gallagher will also remain a consultant to the Company through December 2005. Expected future payments to Dr. Gallagher, are \$324 and \$304 for 2004 and 2005, respectively. The Company paid \$20 in consulting fees to Dr. Gallagher for the year ended December 31, 2003. In 2003, the Company also recognized a stock compensation charge of approximately \$251 relating to certain modifications of Dr. Gallagher's stock option agreements.

(12) Litigation

In November 2002, the Company commenced an action in the United States District Court for the Eastern District of New York seeking to prevent West-ward Pharmaceutical Corporation ("West-ward") from selling 20 mg. Capsules of doxycycline hyclate to treat periodontal disease, which the Company believes would infringe patents covering the Company's Periostat® product. As discussed below, the Company has settled all pending litigation with West-ward.

In July 2003, the Company commenced an action against United Research Laboratories/Mutual Pharmaceutical Company ("Mutual") in the United States District Court for the Eastern District of New York seeking to prevent Mutual from introducing 20 mg. tablets of doxycycline hyclate into the market in the United States. The Company's suit alleges infringement on patents to which it is the exclusive licensee.

In July 2003, Mutual commenced an action against the Company in the United States District Court for the Eastern District of Pennsylvania. Mutual alleges that the Company has engaged in an overall scheme to monopolize the market for low-dose doxycycline products. In addition, the suit alleges that the Company has engaged in exclusionary, unfair, and anticompetitive practices. Mutual seeks an award of treble damages, injunctive relief, compensatory, punitive and exemplary damages and reasonable attorneys' fees. In January 2004, the Court stayed all procedures in the case.

In June 2003, we commenced an action and filed a motion for a preliminary injunction in the United States District Court for the District of Columbia challenging FDA's decision to treat Periostat as an antibiotic drug, thus denying Periostat certain protections afforded non-antibiotic drugs under the Food, Drug, and Cosmetic Act against FDA approval of generic copies of Periostat. West-ward and Mutual intervened in this action. On July 22, 2003, the Court granted a preliminary injunction temporarily restraining the FDA from approving any ANDA submitted for a generic version of Periostat (doxycycline hyclate) 20 mg.

Until the United States District Court for the District of Columbia has made a final ruling on the regulatory status of Periostat, the FDA cannot approve the ANDAs for West-ward's 20 mg. doxycycline hyclate capsule, Mutual's 20 mg. doxycycline hyclate tablet, or any other ANDA for a generic version of Periostat. Cross motions for summary judgment are pending.

COLLAGENEX PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—CONTINUED

December 31, 2003, 2002 and 2001

(Dollars in thousands, except per share data)

As a result of the ruling in the United States District Court for the District of Columbia, the Company withdrew its then pending motion for a temporary restraining order and preliminary injunction in its patent infringement suit against Mutual, which was filed in the United States District Court for the Eastern District of New York, although its complaint remains outstanding. In November, 2003 the proceedings in the patent infringement case were stayed pending a determination by the United States Patent and Trademark Office of its re-examination of the patents-in-suit, subject to the parties' right to conduct limited discovery related to the potential re-instatement of the Company's motion for a temporary restraining order and preliminary injunction. The Company cannot predict the outcome of these matters.

On November 7, 2003, the Company settled all pending litigation between the Company and West-ward. In the settlement, West-ward agreed and confessed to judgment that the Company's Periostat patents are valid and infringed by the filing of West-ward's ANDA. West-ward also agreed and confessed to judgment that the Company's Periostat patents would be infringed by the manufacture and sale of a generic version of Periostat. West-ward consented to a judgment enjoining West-ward and any party acting in concert with West-ward from making and selling a generic version of Periostat until the Company's patents expire or are declared invalid or unenforceable by a court of competent jurisdiction. Finally, West-ward agreed to withdraw from the FDA case in the District of Columbia. In connection with this settlement, the Company agreed to pay a portion of West-ward's actual legal expenses in the amount of \$700.

The Company anticipates that its future legal costs in these matters relating to patent infringement and defense will be reimbursed by SUNY pursuant to a Technology License Agreement with SUNY to the extent that these legal expenses do not exceed royalties earned by SUNY during that period. During the years ended December 31 2003 and 2002, the Company incurred \$3,757 and \$129, respectively, in legal, defense, litigation and settlement costs for the aforementioned law suits with West-ward and Mutual, \$1,750 and \$129 of which was deducted from royalties payable to SUNY during these periods. In the event such cumulative legal costs exceed the amount of the royalties payable to SUNY, the Company will not be able to recover such legal costs from SUNY. As of December 31, 2003, the Company has \$1,749 in previously recorded legal expenses available to offset future royalties which may become payable to SUNY, if any.

(13) 401(k) Salary Reduction Plan

In January 1995, the Company adopted a 401(k) Salary Reduction Plan (the 401(k) Plan) available to all employees meeting certain eligibility requirements. The 401(k) Plan permits participants to contribute up to 15% of their annual salary, as defined, not to exceed the limits established by the Internal Revenue Code. All contributions made by participants vest immediately in the participant's account. During each of the years ended December 31, 2003 and 2002, the Company made a discretionary contribution of \$100 to the Plan. The Company did not make any contributions in 2001.

(14) Related Party Transactions

During 2003, the Company engaged an outside firm to perform certain consulting services for approximately \$55. One of the primary stakeholders in the outside firm is a current member of the Company's Board of Directors.

COLLAGENEX PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—CONTINUED

December 31, 2003, 2002 and 2001
(Dollars in thousands, except per share data)

(15) Quarterly Financial Data (Unaudited)

The tables below summarize the Company's unaudited quarterly operating results for 2003 and 2002.

	Three months ended			
	March 31, 2003	June 30, 2003	September 30, 2003	December 31, 2003
Total revenues	\$12,157	\$12,686	\$13,916	\$14,099
Gross margin on product sales	9,456	10,012	10,890	11,319
Net income	1,228	1,597	1,230	2,371
Net income allocable to common stockholders	828	1,197	830	1,971
Basic net income per share allocable to common stockholders	0.07	0.10	0.07	0.14
Diluted net income per share allocable to common stockholders	\$ 0.07	\$ 0.10	\$ 0.06	\$ 0.14

	Three months ended			
	March 31, 2002	June 30, 2002	September 30, 2002	December 31, 2002
Total revenues	\$10,760	\$10,967	\$11,229	\$11,662
Gross margin on product sales	8,301	8,779	9,054	9,263
Net income (loss)	(557)	(385)	756	1,088
Net income (loss) allocable to common stockholders	(977)	(794)	356	688
Basic and diluted net income (loss) per share allocable to common stockholders	\$ (0.09)	\$ (0.07)	\$ 0.03	\$ 0.06

COLLAGENEX PHARMACEUTICALS, INC. AND SUBSIDIARIES
FINANCIAL STATEMENT SCHEDULE

VALUATION AND QUALIFYING ACCOUNTS

Years Ended December 31, 2003, 2002 and 2001

(in thousands)

<u>Col A</u>	<u>Col B</u>	<u>Col C</u>		<u>Col D</u>	<u>Col E</u>
<u>Description</u>	<u>Balance at the Beginning of Period</u>	<u>Additions</u>		<u>Deductions</u>	<u>Balance at the End of Period</u>
		<u>Charged to Statement of Operations</u>	<u>Other</u>		
Accounts Receivable Allowance:					
2003	\$1,412	\$3,009	\$—	\$3,113	\$1,308
2002	\$ 950	\$3,462	\$—	\$3,000	\$1,412
2001	\$ 381	\$1,906	\$—	\$1,337	\$ 950

Corporate Information

Board of Directors

Peter R. Barnett, D.M.D.

Former President and
Chief Executive Officer
Group Dental Service, Inc.

Robert C. Black

Retired President
U.S. Pharmaceuticals Division
of AstraZeneca, Inc.

James E. Daverman

Chairman of the Board, CollaGenex
Pharmaceuticals, Inc.
Managing General Partner
Redfish Partners LP

Robert J. Easton

Chairman
Easton Associates, LLC

Brian M. Gallagher, Ph.D.

Former Chairman, President
and Chief Executive Officer
CollaGenex Pharmaceuticals, Inc.

Stephen Kaplan

Principal
Oaktree Capital Management, LLC

W. James O'Shea

President and Chief Operating Officer
Sepracor, Inc.

Colin W. Stewart

President and Chief Executive Officer
CollaGenex Pharmaceuticals, Inc.

Corporate Officers

Colin W. Stewart

President and Chief Executive Officer

Nancy C. Broadbent

Chief Financial Officer,
Treasurer and Secretary

Klaus A. Theobald, M.D., Ph.D.

Senior Vice President
and Chief Medical Officer

David F. Pfeiffer

Senior Vice President,
Sales and Marketing

Corporate Information

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Phone: 215-579-7388
Fax: 215-579-8577
Email: cgpi@collagenex.com
Internet: <http://www.collagenex.com>

Independent Auditors

KPMG LLP
Princeton, NJ

Legal Counsel

Hale and Dorr LLP
650 College Road East, 4th Floor
Princeton, NJ 08540

Transfer Agent

American Stock Transfer & Trust
Company
59 Maiden Lane
New York, NY 10007
Phone: 212-936-5100

Annual Meeting

The Annual Meeting of Shareholders will be held on Tuesday, May 25, 2004 at 8:30 a.m. at the Philadelphia Marriott Downtown Hotel, 1201 Market Street, Philadelphia, PA 19107. The record date for the meeting is April 14, 2004.

Stockholder Inquiries

Questions regarding stock transfer requirements, lost certificates and changes of address should be directed to the transfer agent as listed.

Other stockholder or investor inquiries, including requests for our filings with the U.S. Securities Exchange Commission, should be directed to Investor Relations at the Company's address or phone number as listed.

The Company's press releases, annual report and SEC filings are available on the Company's web site at www.collagenex.com

Securities and Related Information

The Company's Common Stock is traded on the NASDAQ National Market under the symbol CGPI. As of March 23, 2004, there were approximately 113 holders of record of the Company's common stock, which does not include shareholders whose common stock is held in street name. The Company has never declared or paid a cash dividend on its common stock.

The following table sets forth the high and low per share closing market price for our common stock for each of the quarters in the period beginning January 1, 2002 through December 31, 2003 as reported on the NASDAQ National Market.

Quarter Ended:	High	Low	Quarter Ended:	High	Low
2003			2002		
March 31	\$11.03	\$6.66	March 31	\$7.72	\$12.00
June 30	\$13.27	\$8.62	June 30	\$11.65	\$5.75
September 30	\$15.84	\$10.50	September 30	\$7.34	\$4.70
December 31	\$11.82	\$8.90	December 31	\$9.93	\$4.05

Safe Harbor

This annual report contains forward-looking statements within the meaning of Section 21E of the Securities and Exchange Act of 1934, as amended. Investors are cautioned that forward-looking statements involve risks and uncertainties, which may affect the Company's business and prospects. The Company's business of selling, marketing, and developing pharmaceutical products is subject to a number of significant risks, including risks relating to the implementation of the Company's sales and marketing plans for Periostat® and other products that the Company markets; risks inherent in research and development activities; risks associated with enforcement of the Company's intellectual property rights; including issues relating to the outcome and consequences of the Company's patent litigation against United Research Laboratories/ Mutual Pharmaceutical Company; risks associated with conducting business in a highly regulated environment; and uncertainty relating to clinical trials of products under development, all as discussed in the Company's periodic filings with the U.S. Securities and Exchange Commission.



Corporate Headquarters

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