



Opportunity. Focus. Commitment.

2004 Annual Report



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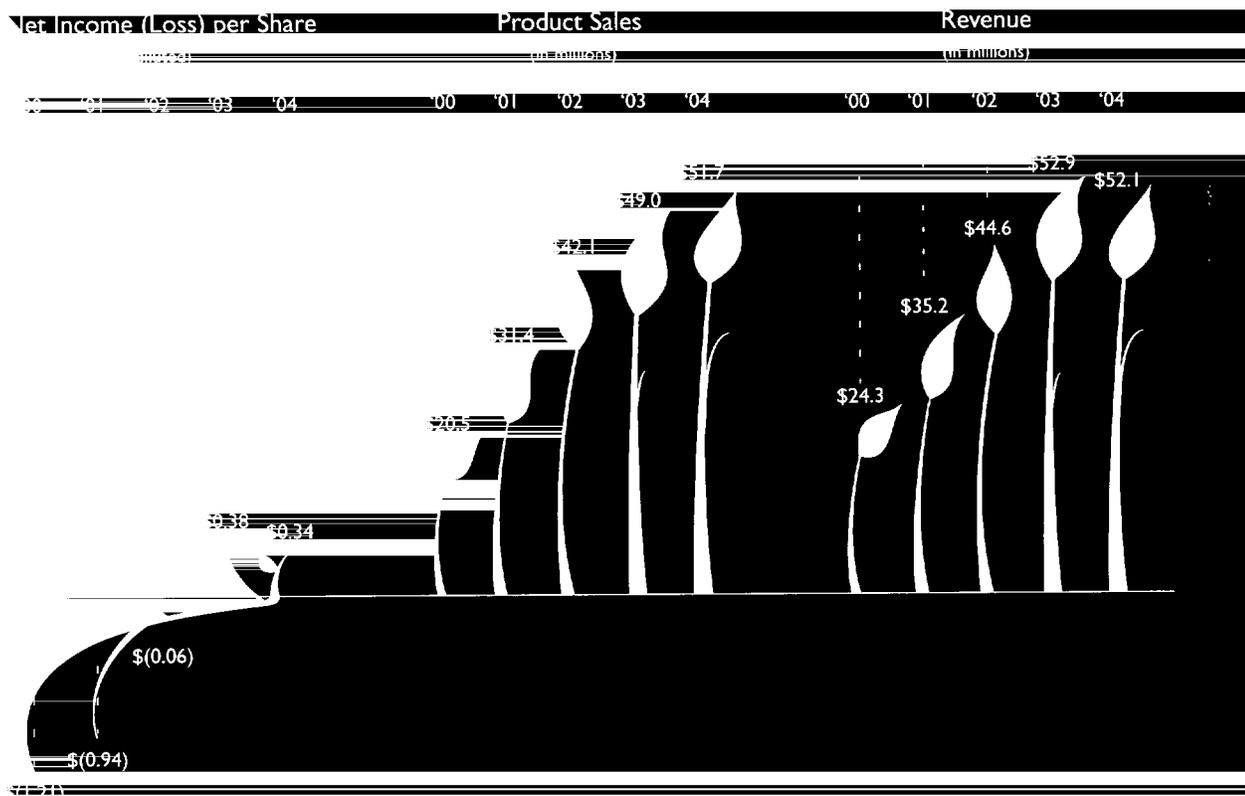


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COLLAGENEX
PHARMACEUTICALS

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Financial Highlights



Consolidated Statement of Operations Data

(in thousands, except share amounts)	2000	2001	2002	2003	2004
Total revenue	\$ 24,271	\$ 35,232	\$ 44,619	\$ 52,859	\$ 52,146
Operating expenses	32,944	43,599	43,806	46,492	45,074
Net income (loss) allocable to common stockholders	\$ (10,519)	\$ (9,824)	\$ (727)	\$ 4,827	\$ 4,928
Basic net income (loss) per common share	\$ (1.21)	\$ (0.94)	\$ (0.06)	\$ 0.40	\$ 0.35
Diluted net income (loss) per common share	\$ (1.21)	\$ (0.94)	\$ (0.06)	\$ 0.38	\$ 0.34

Consolidated Balance Sheet Data

(in thousands)	2000	2001	2002	2003	2004
Cash, cash equivalents and short-term investments	\$ 5,448	\$ 6,171	\$ 10,112	\$ 32,670	\$ 38,645
Working capital	5,308	6,294	5,992	32,010	39,714
Total assets	10,431	14,698	17,634	44,132	52,121
Total stockholders' equity	\$ 5,264	\$ 7,127	\$ 8,352	\$ 33,956	\$ 41,215

Opportunity. Focus. Commitment.

As CollaGenex evolves into a broader-based specialty pharmaceutical company, we are building on three core values - opportunity, focus and commitment. Our product development efforts are driven by our ability to identify and serve market segments where we can provide unique and proprietary therapeutic products. As we move into new markets, we remain highly focused on developing a strong and differentiated product portfolio, as well as a dedicated and responsive sales force to serve our target customers. We have demonstrated our capabilities in the dental market. As we move forward into dermatology with the development of Oracea, we are redoubling our commitment to understand our customers' needs and ensure that we build a competitive, successful, and durable presence in this high-opportunity market.

Who We Are

CollaGenex Pharmaceuticals is a research-based specialty pharmaceutical company that develops and markets innovative new therapeutics for the dental and dermatology markets. The company currently markets five products - including Periostat®, the most successful branded drug in the dental pharmaceutical market - and plans to file this year for regulatory approval of Oracea™, a proprietary new treatment for rosacea.

CollaGenex is traded on the NASDAQ Stock Market under the symbol CGPI.



COLLAGENEX
PHARMACEUTICALS





Colin Stewart

President and Chief Executive Officer





Dear Stockholders,

We made excellent progress in 2004, generating solid financial results, advancing our product development pipeline and strengthening our market presence. Our goal for the past 18 months has been to transition CollaGenex into a more diversified specialty pharmaceutical company and position the company for accelerated growth in revenues and earnings.

Our accomplishments in 2004 brought us closer to achieving these objectives. We advanced Periostat MR™ and Oracea through the clinic by initiating and completing the enrollment of more than 760 patients in three Phase III clinical trials. We made progress in the development of our Restoraderm™ topical drug delivery technology. We also continued to protect the market position of Periostat against threats by potential generic competitors and generated \$52.1 million in total revenues and \$4.9 million, or \$0.34 diluted share, in net income allocable to common stockholders while significantly increasing our investment in research and development.

Since we introduced Periostat® in 1999, it has been the only systemic pharmaceutical treatment approved for adult periodontitis. We established a strong brand and a reputation for innovative solutions in the dental market, and we intend to build on these accomplishments and skills in the dermatology market.

Early in 2005, a federal court ruling allowed the U.S. Food and Drug Administration (FDA) to approve generic versions of Periostat. However, as of this writing, no generic forms of Periostat have been approved by the FDA. The magistrate judge in a separate district court hearing in March recommended a denial of our request for a preliminary injunction to prevent two generic pharmaceutical companies from launching their generic forms of Periostat after FDA approval. If upheld, we anticipate that Periostat will be subject to generic competition sometime during 2005, which will cause our sales of Periostat and Mutual's branded version of Periostat to decline significantly. When this occurs, we will execute plans to reduce our cost base. None of these actions will affect our commitment to develop Oracea and our dermatology franchise.

Building a Strong, Focused Specialty Pharmaceutical Company

The primary driver of the company's future growth will be the expansion of our product offering beyond the dental market. To that end, we are developing two promising technology platforms that we believe will form the basis for a number of pharmaceutical products in the years ahead.

Our IMPACs™ (Inhibitors of Multiple Proteases and CytokineS) platform evolved from the expertise we gained in the development and marketing of Periostat, where our research and clinicians' experience revealed a broad range of therapeutic activity, including reducing inflammation and connective tissue destruction. This was observed in the treatment of adult periodontitis, which is the FDA-approved indication for Periostat, as well as in certain inflammatory dermatologic conditions including acne, rosacea and peri-oral dermatitis. Col-3, a second-generation IMPACs compound created by chemically modifying the tetracycline molecule, shows potential in treating certain inflammatory conditions with much greater potency than Periostat. Col-3 has been in Phase I and II clinical trials in patients



with Kaposi's sarcoma under the sponsorship of the National Cancer Institute and appears to have an acceptable side-effect profile. During 2005, we will begin to explore the potential utility of Col-3 in Phase II clinical trials in other patient groups, most notably acne patients.

Our second product development platform is a unique, foam-based topical drug delivery technology called Restoraderm. With a proprietary, water-based composition that mimics the naturally occurring lipids in the skin, Restoraderm is cosmetically elegant and designed to enhance the dermal delivery of a variety of therapeutic agents.

These technology platforms provide a strong foundation for our planned expansion into the dermatology market. Our core strategy is to focus our resources on developing and launching new products in the dermatology market and to out-license potential applications of our technology in other therapeutic markets.

Positioned for Growth in Dermatology Market

By the end of 2004, we had completed enrollment of more than 550 patients in two Phase III, double-blinded, placebo-controlled clinical trials to evaluate the efficacy of Oracea to treat rosacea. We anticipate completing the trials and announcing the results in the second quarter of 2005. Assuming the results are favorable, we will file a New Drug Application with the FDA in the third quarter of 2005 and plan for a 12-month FDA review with an anticipated launch in the third quarter of 2006. When approved, Oracea will be the first FDA-approved systemic treatment for rosacea. We believe that its efficacy, safety and the convenience of taking a pill once-a-day will expand the current \$500 million market for prescription pharmaceuticals to treat rosacea.

As Oracea progresses through the clinic, we have been laying the groundwork for a successful launch in the dermatology market. In 2002, we licensed Pandel[®] cream, a prescription topical corticosteroid to treat mild-to-moderate skin conditions such as dermatitis and psoriasis. Pandel has enabled us to build working relationships with dermatologists and establish CollaGenex's credibility in this market ahead of the Oracea launch.

In 2004, we took several steps to improve our focus on our North American dental and dermatology markets. In April 2004, we restructured our 115-person sales force calling on both dentists and dermatologists and created two separate sales forces. We now have 56 sales representatives and managers focused on our top-prescribing dentists and 33 sales representatives and managers focused on the highest potential dermatologists. We expect to increase our dermatology sales force significantly in early 2006 for the Oracea launch. We also sold our U.K. and European dental assets in order to focus on the company's domestic sales effort. We received \$3.3 million in gross proceeds for these assets, which were primarily the use of trademarks, marketing authorizations and other intangible assets. This price was nearly six times 2003 sales in the U.K. and Europe.

We have established a strong brand and a reputation for innovative solutions.

A Growing Pipeline Targeting High-Opportunity Markets

The dermatology market represents a significant revenue opportunity, especially for a pharmaceutical company that offers innovative therapeutic approaches to treating conditions that are typically treated with reformulations of existing products. The annual U.S. market for dermatology prescription drugs is almost \$6 billion. Rosacea affects approximately 13.6 million people in the U.S., and about 1.1 million of these people use \$500 million of prescription products each year to treat their rosacea. Acne is currently a \$1.2 billion market, and we believe that Col-3 may represent an effective and safe future alternative for patients with this potentially disfiguring disease.

Col-3 will enter Phase II clinical trials this year for acne. We also have two Restoraderm-based products in development, which contain FDA-approved active ingredients in our proprietary topical delivery matrix. We hope to complete the required stability testing for a Restoraderm product for acne this year and launch it in the fourth quarter, and to develop a Restoraderm product for the treatment of psoriasis for a planned launch in 2008. Our development team is also actively assessing other active ingredients for use with our Restoraderm delivery system.

A Bright Future Ahead for CollaGenex

Clearly, we believe CollaGenex is entering an exciting new phase of its development. 2005 is an important transitional year for the company. We will continue to make the necessary investments in R&D and sales and marketing to pursue our long-term strategy of expanding our product portfolio and strengthening our market presence.

We have a strong financial foundation, a very promising pipeline of products, and unique technology platforms to drive our growth. We also have an excellent team of employees committed to achieving the company's goals in 2005 and beyond. I look forward to reporting on our progress toward those goals in the months and years ahead.

Sincerely,



Colin W. Stewart
President and Chief Executive Officer

A Robust and Growing Product Portfolio

Since its inception, CollaGenex has pursued a strategy of developing new, more effective treatments to address underserved medical needs. Our first product, Periostat, remains the only systemic treatment approved to treat periodontitis, a chronic disease caused by the progressive degradation of connective tissue below the gum line. Periostat's active ingredient is a unique, sub-antimicrobial dose of doxycycline that works by suppressing the enzymes that degrade periodontal support tissues and by enhancing bone protein synthesis. These properties were novel discoveries and the subjects of two issued patents, the latest of which will expire in May 2007.

The next product to emerge from CollaGenex's development pipeline is Oracea for the treatment of rosacea, a chronic skin condition that affects 13.6 million adults in the U.S. Oracea contains the same active agent as Periostat and entered development after a number of Periostat patients reported that their rosacea conditions improved significantly while they were being treated with Periostat for adult periodontitis. In 2003 and early 2004, we tested this concept by conducting a large Phase III clinical trial using Periostat to treat patients with rosacea. The clinically and statistically significant results from this trial encouraged us to conduct two much larger Phase III clinical trials to evaluate Oracea as a treatment for rosacea. We expect these trials to be complete in the second quarter of 2005 and, assuming they are favorable, we will file an NDA for Oracea shortly thereafter.

Several additional product candidates in our development pipeline have the potential to strengthen our position in the \$6 billion dermatology market. These include COL-3 for the treatment of acne and topical treatments based on our proprietary Restoraderm foam delivery technology to treat acne and psoriasis. Longer-term, we are evaluating other IMPACs compounds in cardio-pulmonary disease, arthritis and other high potential market segments where we are seeking to leverage our expertise in novel anti-inflammatory compounds.

Dental

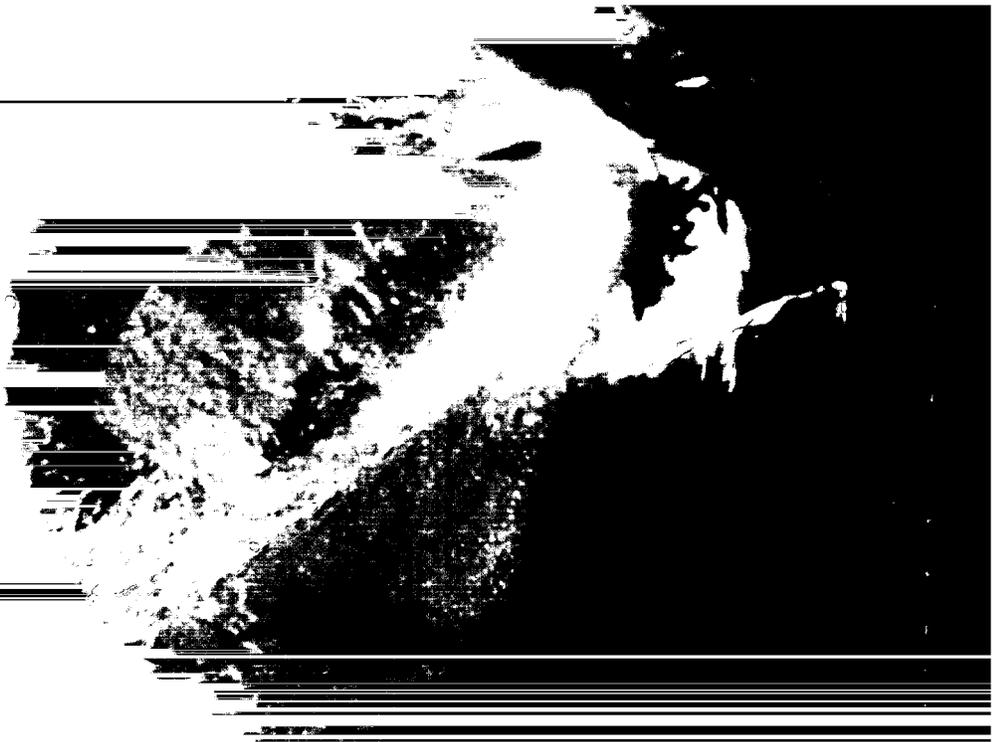
		Pre-Clinical	Phase I	Phase II	Phase III	Approved and Marketed	Phase IV
Periostat	Periodontitis	●	◐	◑	○	◑	●
Atridox	Periodontitis	●	◐	◑	○	◑	●
Atrisorb Freeflow	GTR Barrier	●	◐	◑	○	◑	
Atrisorb-D Freeflow	GTR Barrier	●	◐	◑	○	◑	
Periostat MR	Periodontitis	●	◐	◑	○	2006	

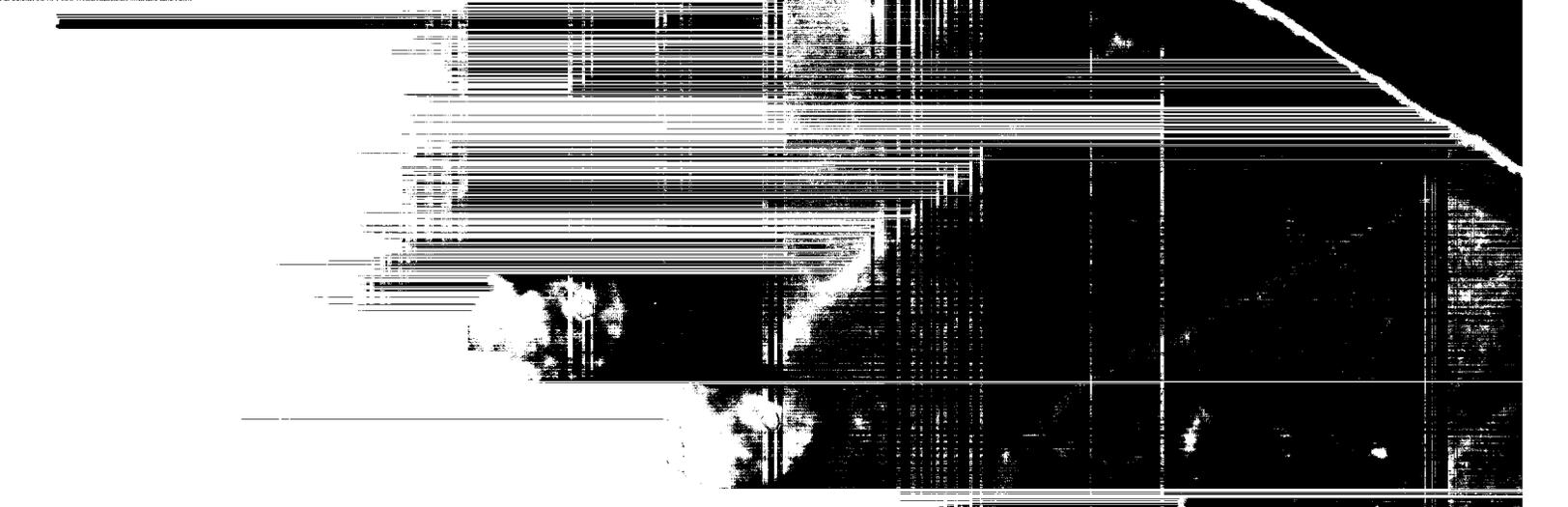
Dermatology

Pandel	Dermatoses	●	◐	◑	○	◑	●
Oracea	Rosacea	●	◐	◑	○	2006	
Restoraderm	Psoriasis	●				2008	
COL-3	Acne	●					
Restoraderm	Acne					2005	

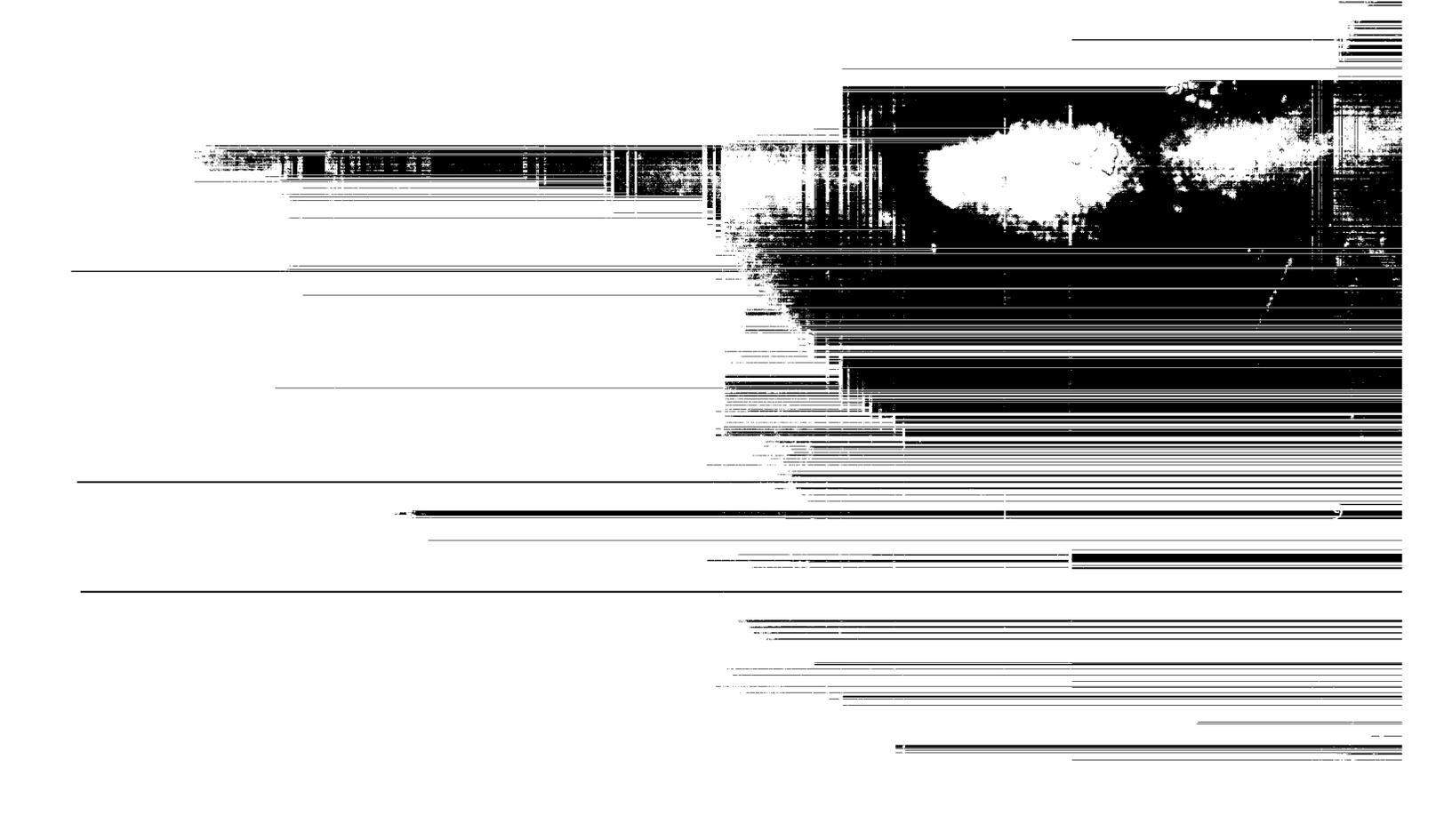
Other

COL-308	To Be Determined	●					
COL-1002	To Be Determined	●					





Our IMPACs and Restoraderm technologies form the basis for a range of potential proprietary products to address unmet medical needs in our target markets.



Two Platforms.

CollaGenex can be distinguished from other dermatology companies by our focus on developing - rather than in-licensing - our own products. While we have opportunistically in-licensed several products to establish our presence in certain markets and leverage our sales force, our product portfolio is being built primarily with internally developed products.

Two mainstays of this portfolio are two technology platforms unique to CollaGenex: MIPACs (inhibitors of Multiple Proteases and Cytokines) and Restoraderm. Our MIPACs compounds evolved from our experience with Periostat as well as our research into the biochemistry and anti-inflammatory properties of various tetracyclines and their ability to inhibit inflammation and tissue destruction. Restoraderm is a unique topical foam drug delivery technology that mimics natural skin lipids and is designed to transport both water- and fat-soluble drugs into the skin and restore the disrupted skin barrier that often characterizes dermatological diseases.

These technology platforms have generated promising product candidates with potentially significant therapeutic advantages over existing treatments.

Multiple Advantages.

IMPACs

Our proprietary IMPACs technology gives CollaGenex the opportunity to build a portfolio of compounds addressing a range of conditions and diseases that involve inflammation and tissue destruction. Periostat's active ingredient is doxycycline, a compound that has been used for over thirty years as an antibiotic. We have learned that doxycycline also has the ability to suppress inflammation and certain related enzymes that degrade connective tissues. Periostat contains a dose of doxycycline that is too low to exert an antibiotic effect, including the associated side effects of high-dose antibiotics, but is still capable of significantly reducing inflammation and connective tissue destruction. Unlike high-dose antibiotics, it can be administered over long periods of time, which is very important in treating chronic diseases such as adult periodontitis and rosacea. Both Periostat MR and Oracea contain sub-antibiotic dosages of doxycycline in a patent-pending, modified-release formulation.

Our second-generation IMPACs compounds are chemically modified tetracyclines. Col-3, our lead second-generation compound, is a tetracycline that has been chemically modified to eliminate the antibiotic properties of the molecule and increase the breadth and potency of its other properties, mainly, the ability to suppress inflammation and tissue destruction. Col-3 has been in Phase I and II clinical trials under the sponsorship of the National Cancer Institute in patients with Kaposi's sarcoma, an HIV-related skin condition. Based on the improvements seen in a number of these patients, we believe Col-3 could be a potent agent to treat acne, and we plan to initiate Phase II clinical trials in acne patients during 2005.

We also have a number of other chemically modified compounds derived from our IMPACs technology that we are screening for other potential therapeutic applications.

Restoraderm

Our Restoraderm foam-based drug delivery technology has a unique water-based composition containing ceramides that mimic the lipids found in human skin. Unlike many other topical drug delivery technologies that are alcohol-based, Restoraderm does not dry or irritate the skin, and we believe that the lipid precursors aid in restoring the disrupted skin barrier. Restoraderm's chemical structure should support an array of fat- and water-soluble drugs, delivering them through the external stratum corneum layer to the epidermis. We believe that Restoraderm has a number of potential applications in treating acne, rosacea, psoriasis and dermatitis, among others.

Our dedicated sales teams enable us to drive growth by delivering our messages to high-prescribing doctors in the dental and dermatological markets



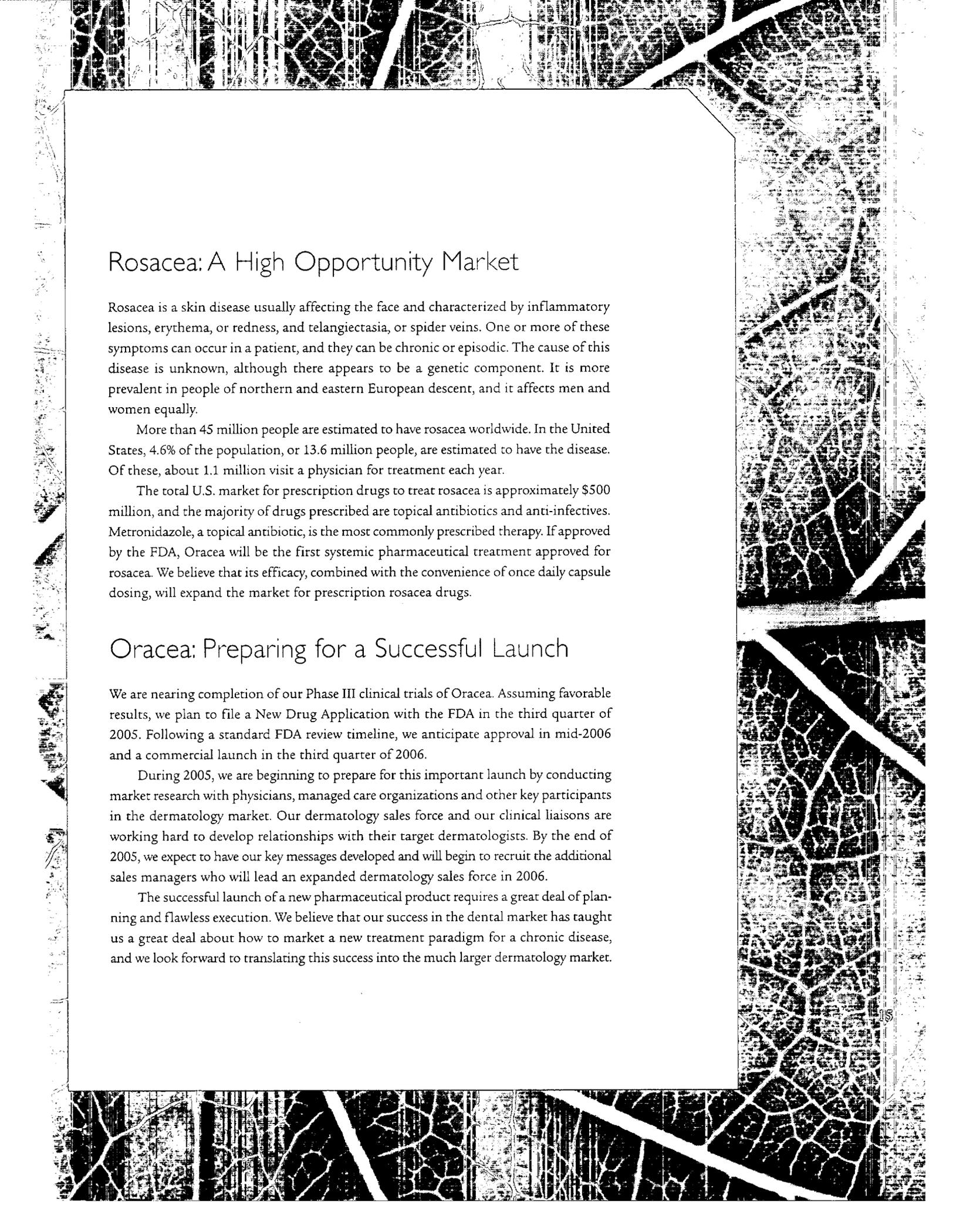


A Focused Sales and Marketing Strategy

A highly-trained, dedicated professional pharmaceutical sales force has always been a key part of CollaGenex's strategy. Our target markets in dentistry and dermatology generate a relatively high number of prescriptions from small numbers of prescribing physicians. Fewer than 4,000 dermatologists write 80% of the 1.9 million prescriptions for osteoporosis products written by dermatologists. Using sophisticated sales force automation and targeting tools, we are able to cover our target markets effectively with two relatively small sales forces.

Our sales messages are based on evidence-based medicine. Strong clinical results and the ability to explain them clearly are key advantages for us. Educating our physicians and consumers is a critical part of the selling process.

It works. A panel of the American Academy of Periodontology analyzing the data we provide to support the efficacy of Periostat gave the product a "strong" rating, the highest it could achieve. We believe we can gain similar third-party acknowledgment of all our novel products by continuing to present clinical evidence in a clear and compelling manner.



Rosacea: A High Opportunity Market

Rosacea is a skin disease usually affecting the face and characterized by inflammatory lesions, erythema, or redness, and telangiectasia, or spider veins. One or more of these symptoms can occur in a patient, and they can be chronic or episodic. The cause of this disease is unknown, although there appears to be a genetic component. It is more prevalent in people of northern and eastern European descent, and it affects men and women equally.

More than 45 million people are estimated to have rosacea worldwide. In the United States, 4.6% of the population, or 13.6 million people, are estimated to have the disease. Of these, about 1.1 million visit a physician for treatment each year.

The total U.S. market for prescription drugs to treat rosacea is approximately \$500 million, and the majority of drugs prescribed are topical antibiotics and anti-infectives. Metronidazole, a topical antibiotic, is the most commonly prescribed therapy. If approved by the FDA, Oracea will be the first systemic pharmaceutical treatment approved for rosacea. We believe that its efficacy, combined with the convenience of once daily capsule dosing, will expand the market for prescription rosacea drugs.

Oracea: Preparing for a Successful Launch

We are nearing completion of our Phase III clinical trials of Oracea. Assuming favorable results, we plan to file a New Drug Application with the FDA in the third quarter of 2005. Following a standard FDA review timeline, we anticipate approval in mid-2006 and a commercial launch in the third quarter of 2006.

During 2005, we are beginning to prepare for this important launch by conducting market research with physicians, managed care organizations and other key participants in the dermatology market. Our dermatology sales force and our clinical liaisons are working hard to develop relationships with their target dermatologists. By the end of 2005, we expect to have our key messages developed and will begin to recruit the additional sales managers who will lead an expanded dermatology sales force in 2006.

The successful launch of a new pharmaceutical product requires a great deal of planning and flawless execution. We believe that our success in the dental market has taught us a great deal about how to market a new treatment paradigm for a chronic disease, and we look forward to translating this success into the much larger dermatology market.



Opportunity. Focus. Commitment.

Since our founding in 1992, CollaGenex has emphasized these three critical attributes. We have been able to recognize opportunities, focus on executing strategies to take advantage of them, and sustain the necessary commitment to maximize their value for customers, shareholders, and the patients who use our products.

As we move through 2005 toward the launch of Oracea, the 135 people of CollaGenex will need to demonstrate these same three virtues if we are to succeed. We fully intend to do so. These values have driven our progress to date, and they will continue to inspire all of us as we build CollaGenex into a leading specialty pharmaceutical company.

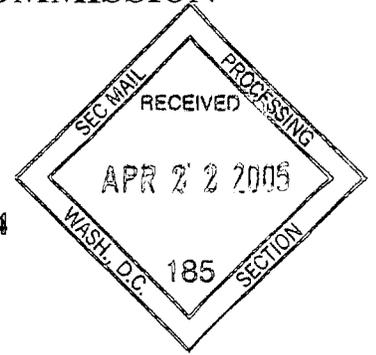


UNITED STATES SECURITIES AND EXCHANGE COMMISSION

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)

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2004

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 are code
(215) 579-7388

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

Table with 2 columns: Title of Each Class, Name of Each Exchange on Which Registered. Row: 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: [X] No: []

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2).

Yes: [X] No: []

The aggregate market value of the registrant's voting shares of common stock held by non-affiliates of the registrant on June 30, 2004, based on \$9.40 per share, the last reported sale price on the NASDAQ National Market on that date, was \$114.5 million.

The number of shares outstanding of each of the registrant's classes of common stock, as of March 1, 2005:

Table with 2 columns: Class, Number of Shares. Row: Common Stock, \$0.01 par value, 14,410,677

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 2005 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 developing and marketing innovative proprietary medical therapies to the dental and dermatology markets. We currently market four pharmaceutical products to the dental market through our professional dental sales force, and we market one prescription product to the dermatology market through our professional dermatology sales force.

Our first product, Periostat[®], is an orally administered, prescription pharmaceutical product that was approved by the United States Food and Drug Administration (the "FDA") in September 1998 and is the first and only dental pharmaceutical to treat adult periodontitis. Periostat works by inhibiting the enzymes that destroy periodontal support tissues and by enhancing bone protein synthesis. Periostat is indicated as an adjunct to scaling and root planing, or SRP, the most prevalent therapy for adult periodontitis, to reduce pocket depth and to promote attachment level gain 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, can cause tooth loss if untreated.

Pursuant to an exclusive License and Marketing Agreement with Atrix Laboratories, Inc. ("Atrix," the predecessor to QLT USA, Inc., who purchased the assets of Atrix in November 2004), we began, in October 2001, to actively market Atrix's proprietary dental products, Atridox[®] and Atrisorb FreeFlow[®], and, in February 2002, 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 primarily through drug wholesalers in the United States. 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.

We also sell a separately branded form of Periostat to United Research Laboratories/Mutual Pharmaceutical Company, Inc. ("Mutual") pursuant to a License and Supply Agreement we executed with Mutual in April 2004. This Agreement formed part of a settlement of outstanding litigation with Mutual relating to our patents for Periostat. In the settlement Mutual agreed and confessed to judgment that our Periostat patents are valid and infringed by Mutual's Abbreviated New Drug Application ("ANDA") for a generic form of Periostat. The License and Supply Agreement provides for us to sell a separately branded version of Periostat to Mutual at prices below our average sales price for Periostat.

Prior to the sale of our U.K. and European dental assets in November 2004 to Alliance Pharma plc ("Alliance"), a U.K. specialty pharmaceuticals company, Periostat was also sold through wholesalers and directly to dentists in the United Kingdom through our wholly-owned subsidiary, CollaGenex International, Ltd., and by distributors and licensees in certain other overseas markets.

On April 22, 2004, we announced the restructuring of our pharmaceutical sales organization into dedicated dental and dermatology sales forces. The restructuring was intended to increase our sales focus on high-prescribing dentists and dermatologists while reducing our cost base. Prior to the reorganization, virtually all of our 115-person pharmaceutical sales force called on both dentists and dermatologists to market our portfolio of dental and dermatology products. After the restructuring, we have a 56-person dental sales force calling on 10,000 high prescribing dentists and a 33-person dermatology sales force calling on the 5,600 dermatologists who comprise our target market.

In addition to our marketed products, we have a pipeline of products in clinical and pre-clinical development. These products are based on our two proprietary platform technologies, IMPACs[™] and Restoraderm[™]. The IMPACs (Inhibitors of Multiple Proteases and Cytokines) platform includes a series of novel, proprietary tetracycline-based compounds discovered during the development of Periostat. Research

has shown that certain unique properties of these tetracyclines may be applicable to other diseases involving inflammation and/or destruction of the body's connective tissues, including acne, rosacea (a dermatological condition sometimes referred to as acne rosacea), ocular rosacea, acute lung injury and cancer metastasis, among others. We are further evaluating various compounds to assess whether they are safe and effective in these applications.

Periostat is our first FDA-approved IMPACs product. Periostat-MR™ is a once-a-day, modified-release formulation of Periostat currently in a Phase III clinical trial for the treatment of adult periodontitis. Oracea™, which has the same active ingredient and modified-release formulation as Periostat-MR, is in two Phase III clinical trials for the treatment of rosacea. Col-3, a second generation IMPACs compound, has completed Phase II trials for the treatment of HIV-related Kaposi's sarcoma and is currently in Phase II clinical trials for the treatment of rosacea.

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 this technology on a project basis.

Our Restoraderm technology is a proprietary, foam-based, topical drug delivery technology that originated from a Swedish collaborator. We have acquired all right, title and interest to the Restoraderm technology and are committed to initiate the development of five products based on this technology before the end of 2005. We are currently developing Restoraderm products for the treatment of acne and psoriasis.

During 2004, we continued to implement our plans to expand into the dermatology market. We completed and announced the preliminary results of a double-blinded, placebo-controlled 134-patient Phase III clinical trial to evaluate the safety and efficacy of Periostat to treat rosacea. We also completed enrollment of two double-blinded, placebo-controlled Phase III clinical studies to evaluate the use of Oracea to treat rosacea. As noted above, we purchased the Restoraderm topical drug delivery technology and in addition, we continue to actively seek product licensing opportunities to enhance our near-term offerings to the dermatology market.

During 2004, we also filled key spots on our management team with the addition of Dr. Klaus Theobald as Senior Vice President and Chief Medical Officer, Greg Ford as Vice President of Business Development and Strategic Planning and Andrew Powell as Vice President and General Counsel.

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.

We are subject to the informational requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and, accordingly, file reports, proxy statements and other information with the Securities and Exchange Commission. Such reports, proxy statements and other information can be read and copied at the public reference facilities maintained by the Securities and Exchange Commission at the Public Reference Room, 450 Fifth Street, NW, Washington, D.C. 20549. Information regarding the operation the Public Reference Room may be obtained by calling the Securities and Exchange Commission at 1-800-SEC-0330. The Securities and Exchange Commission maintains a web site (<http://www.sec.gov>) that contains material regarding issuers that file electronically with the Securities and Exchange Commission.

Our Internet address is www.collagenex.com. We are not including the information contained on our web site as a part of, or incorporating it by reference into, this Annual Report on Form 10-K. We make available free of charge on our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission.

CollaGenex Pharmaceuticals, Inc. — United States trademarks:

Periostat®, Metastat®, Dermostat®, Nephrostat®, Osteostat®, Arthrostat®, Rheumastat®, Corneostat®, Gingi-
stat®, IMPACS™, PS20®, The Whole Mouth Treatment®, Restoraderm™, Dentaplex®, Lytra™, Periostat-
MR™ and Oracea™.

CollaGenex Pharmaceuticals, Inc. — European Community trademarks:

Periostat®, Nephrostat®, Optistat®, Xerostat® and IMPACS®.

CollaGenex International, Ltd. (our wholly-owned subsidiary) — United Kingdom trademarks:

Periostat®, Nephrostat®, Optistat®, Xerostat®, IMPACS®, Dentaplex®, Restoraderm®, Periocycline®, Perios-
tatus®, Periostat-MR® and Periostat-SR®.

CollaGenex International, Ltd. — European Community and United Kingdom trademarks:

CollaGenex®, PS20®, Dermastat®, Periostan®, “C” Logo® and “The Whole Mouth Treatment” Logo®.

CollaGenex International, Ltd. — European Community Trademarks:

Periocycline™, Restoraderm®, Periostat-SR® and Periostat-MR™.

Marks listed herein may additionally be registered in jurisdictions not specified in the above list. 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	Canada	Pharmascience, Inc.
Atridox	United States and Puerto Rico	Atrix Laboratories, Inc./QLT USA, Inc.
Atrisorb FreeFlow	United States and Puerto Rico	Atrix Laboratories, Inc./QLT USA, Inc.
Atrisorb-D	United States and Puerto Rico	Atrix Laboratories, Inc./QLT USA, 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, as well as breakdown of the alveolar bone itself, ultimately resulting in tooth loss. According to industry data, an estimated one-third of all adults in the United States, 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 out 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. At such higher doses, it is indicated 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 primary mechanisms of action are believed to be through the down-regulation of the activity of collagenases, which belong to a broad class of enzymes known as matrix metalloproteinases. Collagenase is excessively produced as a result of the inflammation caused by bacterial infection in the gums. In addition to, and independent of regulating collagenases activity, doxycycline has also been shown to enhance bone protein synthesis, thereby helping to restore the damage caused by periodontitis.

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, nearly 4.0 million prescriptions for Periostat and Mutual's branded version of Periostat have been filled and over 40,000 dentists have written a prescription for either Periostat or Mutual's branded version of Periostat. Periostat tablets are manufactured for us by Pharmaceutical Manufacturing Research Services, Inc., a contract manufacturing company.

We currently actively sell Periostat in the United States and Puerto Rico and our partner, Pharmascience Inc., has launched sales of Periostat in Canada.

In April 2004, as part of a settlement of all outstanding litigation with Mutual relating to our patents for Periostat, we entered into a License and Supply Agreement with Mutual. The License and Supply Agreement provides for us to sell a separately branded version of Periostat to Mutual at prices below our average wholesale acquisition cost for Periostat. The Agreement runs through May 15, 2007, unless terminated earlier.

Prior to September 2004, we sold Periostat to wholesalers and directly to dentists in the United Kingdom, and our European partners marketed and distributed Periostat in Israel, Portugal, Austria and Switzerland. In November 2004, we sold all of our U.K. and European dental assets to Alliance, a U.K. specialty pharmaceuticals company, for gross proceeds of \$3.3 million. These assets consisted primarily of certain trademark rights, marketing authorizations, customer lists and other intangible assets. Pursuant to a Supply Agreement we executed on November 3, 2004 with Alliance, we supply Periostat in bulk tablet form to Alliance at a negotiated fair value transfer price for sales in the U.K., Europe and Israel.

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 (now known as QLT USA, Inc.), 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, in sufficient concentrations, 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 are 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 2004. 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 arrangement terminated on December 31, 2004.

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

In May 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 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 in adults, such as atopic dermatitis and psoriasis. Prior to May 2002, we had detailed Pandel on a co-promotional basis with Altana since October 2001. Altana currently licenses the rights to Pandel from Taisho Pharmaceutical Co., Ltd., a company organized and existing under the laws of Japan. Pursuant to the terms of our sublicense, we agreed to pay Altana an aggregate sublicense fee of \$1.7 million. We purchase from Altana all Pandel products to be sold and promotional samples, and are required to pay Altana a royalty fee equal to a percentage of the net sales of Pandel.

Our Previously Marketed Products

Vioxx

Pursuant to a Co-Promotion Agreement we executed with Merck & Co., Inc. in September 1999, we received the exclusive right to co-promote Vioxx[®], a prescription strength non-steroidal anti-inflammatory drug, to the dental community. The agreement provided for certain payments by Merck to us upon sales of Vioxx. In September 2002, we executed an amendment, extension and restatement of the Co-Promotion Agreement which provided that the agreement would expire on December 31, 2003. We will continue to earn nominal residual contract revenues through December 2005 from this agreement. The Co-Promotion Agreement provides for indemnification of us by Merck against any claims arising from manufacturing or design defects in the Vioxx product or for which we, as the promoter of the product, may be strictly liable as if we were a seller of an inherently dangerous product. During the year ended December 31, 2004, we recorded \$237,000 in residual contract revenues under this agreement.

AVAR

In March 2003, we executed co-promotion agreements with Sirius Laboratories, Inc. pursuant to which we jointly marketed Sirius Laboratories' AVAR[™] product line and Pandel to dermatologists in the United

States. These agreements were mutually terminated on December 31, 2003. We did not receive any revenue during the year ended December 31, 2004 and do not expect to receive any future contract revenues from Sirius Laboratories' AVAR.

Denavir

In October 2002, we entered into a Product Detailing Agreement with Novartis Consumer Health, Inc. pursuant to which we co-promoted Denavir® to target dentists in the United States and received detailing fees and performance incentives from Novartis Consumer Health, Inc. The agreement with Novartis to co-promote Denavir expired on September 30, 2003, and we and Novartis decided not to renew the arrangement with respect to Denavir. We did not receive any revenue during the year ended December 31, 2004 and do not expect to receive any future contract revenues from Novartis with respect to Denavir.

Sales and Marketing

United States

In an effort to increase our sales focus on high-prescribing dentists and dermatologists while reducing our cost base, in 2004 we restructured our pharmaceutical sales organization into dedicated dental and dermatology sales forces. Prior to the reorganization, each representative was responsible for covering a territory that included approximately 100 dentists and periodontists believed to be potential high volume prescribers of Periostat and was also expected to call on approximately 50 dermatology offices with a high potential for prescribing Pandel. After the restructuring, we have a 56-person dental sales force calling on a highly targeted group of 10,000 high prescribing dentists and a 33-person dermatology sales force calling on the 5,600 dermatologists who comprise our target market.

We believe that our sales effort is distinguished from typical dental and dermatology promotion by our focus on education. We produce educational marketing materials, detail aids and product samples that are used extensively by our representatives in their presentations to dentists and in promoting Pandel to dermatologists. Reprints of peer reviewed research and journal articles that relate to our technologies are also provided, as well as video presentations. We believe that peer-to-peer communications are vital to increasing the acceptance of Periostat by dentists and increasing our own understanding of the dermatology market. Therefore, we arrange speaking engagements and teleconferences where clinical experts and practitioners share their experiences with other 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 a complex regulatory environment, we also train sales personnel on compliance with the relevant rules and guidelines of the FDA and other government agencies.

International

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. In 2002 and 2003, we received approval for the marketing of Periostat in Austria, Finland, Switzerland, Ireland, Israel, Italy, Luxembourg, the Netherlands, Portugal and Canada. On November 3, 2004, CollaGenex International Limited ("CIL"), our wholly-owned U.K. subsidiary, sold its U.K. and European dental assets to Alliance, a U.K. specialty pharmaceuticals company, for net proceeds of \$3.0 million pursuant to a Sale of Assets Agreement. This agreement provided for the sale by CIL to Alliance of trademark rights, U.K. and European governmental marketing authorizations, and distribution agreements and other intangible assets relating to the sale or potential sale of Periostat in the U.K., Europe, Israel, South Africa, New Zealand and Australia. The agreement also granted Alliance an option to acquire a license to register and market Periostat-MR in the same territories. We have retained all rights to Periostat-MR for all other clinical indications. We also entered into a Supply Agreement with Alliance pursuant to which we will supply Periostat in bulk tablet form to Alliance at a negotiated fair value transfer price.

We continue to pursue foreign sales of Periostat in Canada under a licensing agreement entered into with Pharmascience Inc. in June 1999. 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 milestones fees will be due from Pharmascience upon individual provincial formulary approval.

Our partner in Japan, Showa Yakuhin Kako Co., Ltd. has provided us notice that it will terminate its License and Supply Agreement with us in March 2005 without having obtained regulatory approval for the sale of Periostat in that country.

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.

In September 2000, we entered into a Service and Supply Agreement with a contract manufacturer, Pharmaceutical Manufacturing Research Services, Inc. ("PMRS"), for the tablet formulation of Periostat. PMRS manufactures the Periostat brand and Mutual's branded version of 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. We intend to contract with additional manufacturers for the commercial manufacture of Periostat tablets. PMRS 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 in Laverne, 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 and contract administration. 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.

Customers/Backlog

During 2004, sales to Cardinal Health, Inc., McKesson Corporation, Amerisource-Bergen Corporation and Mutual represented approximately 33%, 29%, 19% and 14%, respectively, of our aggregate net product sales.

Historically in the pharmaceutical industry, wholesalers have been speculative in their purchasing practices in anticipation of product price increases. To manage this process, we executed Inventory Management Agreements with our major wholesaler customers in 2003, which will expire in 2005. Under these agreements, the wholesalers provide us with weekly retail demand information and current stocking levels for our products; additionally they agree to manage the variability of their purchases within specified limits. In return we give the wholesalers the right to purchase a specific amount of inventory from us at the sales price in effect immediately prior to announced price increases. In recent months, our wholesaler customers, as well as others in the industry, have begun to modify their business models from arrangements where they derive profits from the management of various discounts and rebates, to arrangements where they charge a fee for their services. We have not yet reached agreement with our wholesaler customers concerning the terms of our future relationship.

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.

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 demonstrates that tetracyclines also have the ability to stimulate new bone protein synthesis. These properties, which are independent from the anti-collagenolytic properties of the compounds, are particularly important during the development of certain types of bone deficiency diseases, including periodontitis. 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 by SUNY researchers has been conducted to identify, synthesize and characterize a new generation of IMPACs compounds, and we have filed patent applications on structure and use of these compounds.

Major research programs conducted by us include: (i) the clinical development of the sub-antimicrobial dose of doxycycline for the treatment of rosacea; (ii) the development of a "once-a-day" formulation of Periostat (Periostat-MR); and (iii) the development of our Restoraderm platform.

Rosacea

In February 2004, we announced the positive outcome of a Phase III 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 was presented at the Skin Disease Education Foundation's Dermatology Open Seminar on March 21, 2004.

The study results 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 evaluating Periostat for the treatment of Rosacea were \$2.4 million.

Based on these clinical results, we initiated two Phase III clinical trials enrolling more than 550 patients to confirm the safety and efficacy of Oracea, our once-a-day formulation of doxycycline for the treatment of rosacea. Both studies are identical in design and conducted concurrently. In December 2004, we announced that we had completed enrollment for these two trials, which include a 16 week treatment period, and we expect the trials to be completed in the second quarter of 2005.

The total expenses incurred to date relating to Oracea were \$2.9 million. We expect to incur an additional \$3.4 million in 2005 to complete this trial.

Modified Release Formulation

The development of a modified release formulation for Periostat-MR and Oracea is being conducted through an agreement with Shire Laboratories. During 2003, we announced that a suitable formulation had been developed, and Phase III clinical trials using the new formulation were initiated during 2004 for both Periostat-MR and Oracea. A patent covering the new formulation was filed with the United States Patent and Trademark Office (the "USPTO") in 2003. We have incurred approximately \$2.4 million in expenses developing a modified release formulation through December 31, 2004.

The total anticipated expenses, through commercialization of both Periostat-MR and Oracea, including various milestone payments to Shire, is estimated to be between \$15.0 million and \$20.0 million.

Restoraderm

In February 2002, we announced that we had licensed a topical drug delivery technology named Restoraderm. In August 2004, we purchased all right, title and interest in this technology, pursuant to the terms of an Asset Purchase and Product Development Agreement (the "Purchase Agreement"). The Purchase Agreement superseded our Co-operation, Development and License Agreement executed in February 2002. Under the terms of the Purchase Agreement, the purchase price of the assets shall be up to \$1.0 million, subject to the achievement of certain milestones. We are also required to pay certain product development milestone payments in the aggregate amount of up to approximately \$2.0 million as well as royalty and sublicense fees upon product commercialization. As of December 31, 2004, approximately \$283,000 of these fees had been paid by us. We paid an additional \$150,000 in January 2005. We anticipate spending approximately \$4.8 million in development expenses through commercialization of our first two prescription products to treat acne and psoriasis based on the Restoraderm technology.

Restoraderm is designed to enhance the dermal delivery of a variety of active ingredients and we intend to use it as the platform on which to develop a portfolio of topical dermatological pharmaceuticals. The Restoraderm technology incorporates certain lipid compositions to enhance the natural skin barrier and facilitate the delivery of therapeutic active ingredients into the skin. The Restoraderm technology is currently still under development, and we anticipate that the first products to be developed using the technology will be available towards the end of 2005.

IMPACs

Our IMPACs technology comprises a family of compounds which have shown the ability to inhibit inflammation as well as the activity of various enzymes in the inflammatory cascade that lead to tissue destruction. Periostat is our first FDA-approved IMPACs compound, and Periostat-MR and Oracea are currently in Phase III clinical trials to demonstrate their safety and efficacy in treating adult periodontitis and rosacea, respectively. A next generation compound, Col-3, has been in human clinical trials under the sponsorship of the National Cancer Institute, or NCI, for the treatment of various cancers, including HIV-related Kaposi's sarcoma, and we intend during 2005 to evaluate Col-3 as a treatment for acne.

Cancer Metastasis

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.

In 2001, at its cost, the NCI initiated an open-label, two-dose study to determine clinical efficacy of Metastat®, our lead compound for the treatment of metastatic cancer, in patients with HIV-related Kaposi's sarcoma. This multi-center, Phase 2 study enrolled 75 patients with HIV-related Kaposi's sarcoma by March 2003. Patients received one of two different doses of Metastat, in some cases for more than two years. The NCI conducted an interim analysis that was published in April 2004. The data suggests that some patients obtained significant relief (both partial responses and complete responses) of their tumor burden, which was maintained on average for more than 12 months. The study is still ongoing and awaiting final analysis.

We have not developed forecasts for the sale of products arising from the commercialization of Metastat in Kaposi's sarcoma, nor do we anticipate spending significant resources on the development of Metastat until it is clear from the currently conducted studies that the drug has a tolerable safety profile and a high likelihood of clinical and commercial success.

Preclinical and Other Research and Development Activities

In October 2002, we 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.

Our research and development expenditures were approximately \$8.8 million, \$5.5 million and \$4.4 million in 2004, 2003 and 2002, respectively. We expect to increase our investment in research and development in 2005.

Patents, Trade Secrets and Licenses

Our Patents

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 IMPACs 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. In consideration of the license granted to us, we: (i) issued to SUNY 78,948 shares of our 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. 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.

Thirty one United States patents and United States patent applications held by SUNY are licensed to us under the SUNY License. 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. Eighty-seven patents have been issued in foreign countries. All of SUNY's United States and foreign patents expire between 2004 and 2019.

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.

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 use Shire technology and patents to develop prescription products for the treatment of various inflammatory disorders. Under the agreement, certain product development functions will be performed for us by Shire. We have committed to pay Shire milestone payments in cash or, at our option, in a combination of cash and our common stock, upon the achievement of certain clinical and regulatory milestones. These payments could total up to \$5.2 million in the aggregate. Under the agreement we must also pay Shire a percentage of net sales of any products utilizing any part of the licensed technology. We may terminate the agreement upon sixty days notice.

Enforcing our Patents

We are currently involved in litigation where we have filed a complaint for patent infringement against IVAX Pharmaceuticals Inc. ("IVAX") and CorePharma LLC ("CorePharma") in the United States District Court for the Eastern District of New York.

Previously, we successfully settled various patent related litigation with West-ward Pharmaceutical Corporation ("West-ward") in 2003. West-ward, a generic pharmaceutical company, 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 infringed our patents for Periostat for the treatment of adult periodontitis by submitting an ANDA with the FDA, seeking FDA approval to market a generic capsule version of Periostat. In the settlement, West-ward agreed and confessed to judgment that our Periostat patents are valid and were infringed by the filing of West-ward's ANDA. We agreed to pay a portion of West-ward's actual legal expenses in the amount of \$700,000.

In a similar case, we settled all pending litigation with Mutual on April 8, 2004. Mutual, another generic pharmaceutical company, had filed an ANDA for a generic version of Periostat. We sued Mutual in the United States District Court for the Eastern District of New York, claiming that Mutual infringed the claims of our Periostat patents. In the settlement, Mutual agreed and confessed to judgment that our Periostat patents are valid and were infringed by the filing of Mutual's ANDA. We agreed to pay Mutual a portion of our anticipated savings in legal expenses in the amount of \$2.0 million. In connection with the settlement, we entered into a License and Supply Agreement pursuant to which Mutual received a license to sell a branded version of Periostat. We are the sole supplier of this product to Mutual, subject to certain conditions. The product will be sold to Mutual at prices below our average manufacturer's price for Periostat through May 15, 2007 or the earlier termination of such supply arrangements. Early termination may occur under certain circumstances, including the successful entry of a third party generic competitor to Periostat. If at any time a generic version of Periostat becomes available on the market at a price lower than the selling price of Mutual's branded version of Periostat, the value of the branded product then in Mutual's or its customers' inventory will decrease. Under our License and Supply Agreement with Mutual, if the generic product remains on the market for a specific period of time, we will have to provide retroactive credit to Mutual to offset such devaluations in Mutual's or its customers' inventory.

We vigorously enforce our patent rights against any and all third-party infringers. This strategy remains unchanged, although the decision in January 2005 of the United States District Court for the District of Columbia affects the legal framework and the process we must follow. That decision upheld the FDA's classification of Periostat as an antibiotic drug which is not entitled to the protection otherwise available to non-antibiotic drugs under the Hatch Waxman amendments to the Food, Drug, and Cosmetic Act. According to the reasoning in that decision, our future sub-antimicrobial doxycycline compounds, such as Oracea, would also be considered antibiotic drugs. As a consequence, unless we prevail in the appeal of that decision, we will not receive automatic notice of drug approval applications made by competitors for generic versions of Periostat or of our future doxycycline compounds such as Oracea, and we will not be entitled to an automatic

30 month stay of FDA approval of these applications while patent litigation is pending. We are appealing the decision of the United States District Court for the District of Columbia. Unless we are successful, our ability to exclude generic competitors will depend on our ability to enforce our patents.

As another part of our strategy to maintain enforceability and strengthen our Periostat patents, in 2003, we filed requests for reexamination of the Periostat patents in the office of the USPTO. The reexaminations were filed in view of additional prior art raised by West-ward and Mutual while defending against our patent infringement charges. In connection with the reexamination process, the patent examiner initially rejected the claims of the Periostat patents. However, following further interviews with the USPTO, we have been notified that the USPTO intends to issue a Reexamination Certificate confirming the patentability of certain amended claims of the RE 34,656 patent that we believe cover the use of Periostat. Although the reexamination procedure has upheld the validity of the RE 34,656 patent, we can give no assurances that the validity of our patents will be upheld in the litigation against IVAX and CorePharma or that the court will agree that generic 20 mg tablets of doxycycline hyclate sold by IVAX and CorePharma would infringe the RE 34,656 patent.

Protecting our Trade Secrets

Our success also depends on our know-how, trade secrets, and the skills, knowledge and experience of our scientific and technical personnel. We try to protect these assets by requiring all employees to enter into confidentiality agreements that prohibit the disclosure of confidential information to anyone outside Col-laGenex. We also seek 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.

Government Regulation

Government authorities regulate 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 classified as 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.

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. Atrisorb and Pandel have also received FDA approval. 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 requested a post-market animal study related to long-term dosing and carcinogenicity, which was completed in 2000.

In some circumstances, approved drugs are provided protection from generic versions of the approved drug for specified time periods. For example, the law provides for patent protection or market exclusivity in certain circumstances. The FDA has not provided such protection to Periostat, and the recent decision of the United States District Court for the District of Columbia upheld the FDA's actions.

Like drugs, medical devices also require FDA authorization before they can be marketed in the United States. Atrisorb FreeFlow and Atrisorb-D have received clearance for marketing. Modifications to those products, however, could require additional approval or clearance. Approved and cleared drugs and medical devices remain subject to comprehensive regulation by the FDA while they are being marketed. For example, marketers and manufacturers 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. The FDA does not permit marketing or promotion of 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 cGMP (for drugs) or Quality Systems Regulation (for medical devices) after approval. Accordingly, we, our manufacturers, and our suppliers 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, Mutual's branded version of 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.

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 and enhanced bone protein synthesis	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.

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 face competition from generic competitors. For example, IVAX and CorePharma have stated that the FDA is ready to approve their respective competitive generic versions of Periostat and we cannot be sure that we will be able to enforce our intellectual property rights to exclude them or other generic competitors. If one or more generic versions of Periostat are approved and marketed, our revenues and margins from Periostat and Mutual's branded version of Periostat would decrease significantly. As a consequence, we may be forced to reduce our reliance on Periostat and our resources devoted to Periostat. In addition, we would have to reduce our headcount and our research and development activities would be delayed, interrupted or discontinued. We may also experience difficulty in managing our cash and in raising additional capital which may not be available to us on acceptable terms, or at all.

We sell 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. Pandel is considered to be a Class 4 strength steroid, with Class 1 steroids being the most potent and Class 7 being the mildest. We expect that competition in the topical steroid area will be based on a variety of factors, including product efficacy, safety, cost-effectiveness, dosing regimen, ease of use, patient discomfort, availability, price, patent position and effective product promotion.

There are a number of patented and generic topical steroids with which Pandel competes. We believe that the following chart summarizes some of the Class 4 and 5 steroids available in the United States and indicated for conditions similar to that of Pandel:

<u>Product Name</u>	<u>Product Manufacturer/Marketer</u>	<u>Generic name</u>	<u>Generic Equivalent</u>	<u>Dosing Schedule</u>	<u>Indication</u>
Pandel cream 0.01%	CollaGenex Pharmaceuticals, Inc.	Hydrocortisone probutate	No	Once or twice per day	For relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients 18 years or older.
Cloderm cream 0.1%	Healthpoint	Clocortolone pivalate	No	Three times per day	For the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.
Cutivate cream 0.05%	GlaxoSmithKline	Fluticasone propionate	Yes	Once or twice per day	For the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. May be used with caution in pediatric patients three months of age or older.
Dermatop emollient cream 0.1%	Dermik (Sanofi Aventis)	Prednicarbate	No	Twice per day	For the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. May be used with caution in pediatric patients one year or older.
Elocon cream 0.1%	Schering	Mometasone furoate	Yes	Once per day	For the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. May be used with caution in pediatric patients two years or older.

<u>Product Name</u>	<u>Product Manufacturer/Marketer</u>	<u>Generic name</u>	<u>Generic Equivalent</u>	<u>Dosing Schedule</u>	<u>Indication</u>
Locoid Lipocream cream 0.1%	Ferndale Laboratories	Hydrocortisone butyrate	No	Two or three times per day	For the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.
Luxiq foam 0.12%	Connetics	Betamethasone valerate	No	Two times per day	For the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses of the scalp.

Many of the companies participating in the mid-potency topical steroid 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 face competition from generic manufacturers. While these generics are not directly substitutable for Pandel, many dermatologists and other practitioners who use mid-potency topical steroids consider them to be similar in efficacy and safety. The availability of quality generic steroids and the favorable co-pays given to generics by HMOs and PBMs may adversely affect our ability to grow Pandel prescriptions, and consequently our revenues and profits from the sale of Pandel.

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, 2004, we employed 131 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

Statements contained or incorporated by reference in this Annual Report on Form 10-K that are not based on historical fact are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Exchange Act. These forward-looking statements regarding future events and our future results are based on current expectations, estimates, forecasts, and projections and the beliefs and assumptions of our management including, without limitation, our expectations regarding results of operations, selling, general and administrative expenses, research and development expenses and the sufficiency of our cash for future operations. Forward-looking statements may be identified by the use of forward-looking terminology such as "may," "could," "will," "expect," "estimate," "anticipate," "continue," or similar terms, variations of such terms or the negative of those terms.

We cannot assure investors that our assumptions and expectations will prove to have been correct. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements. Such factors that could cause or contribute to such differences include those factors discussed below. We undertake no intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer.

We Rely on One Product, Periostat, and Mutual's Branded Version of Periostat, for Most of Our Revenue. The Commercial Launch of Generic Versions of Periostat Would Materially Reduce Our Revenues and Profitability and Force Changes in Our Organization and Activities.

We rely on sales of Periostat and Mutual's branded version of Periostat for most of our revenue. During the years ended December 31, 2004, 2003 and 2002, Periostat and Mutual's branded version of Periostat (with respect to the year ended December 31, 2004), accounted for approximately 88%, 82% and 82% of our total net revenues, respectively. During 2004, we have generated gross margins on our sales of Periostat and Mutual's branded version of Periostat of approximately 90%.

Our revenue and profitability in the near future will depend on our ability to market and sell Periostat and Mutual's branded version of Periostat, and to leverage our legal rights to exclude generic competitors. Even though we may successfully appeal the decision of the District Court for the District of Columbia classifying Periostat as an antibiotic drug, we do not currently enjoy the patent and exclusivity protection otherwise granted to innovator drugs under the Hatch Waxman amendments to the Food, Drug, and Cosmetic Act. Consequently, our ability to exclude generic competitors depends on our ability to enforce our patents. We continue to prosecute patent litigation with CorePharma and IVAX and currently are awaiting the Court's decision on our motion for a Temporary Restraining Order and for Preliminary Injunctive relief in that case.

We cannot be sure that our patent litigation will succeed, or that one or more generic competitors may not launch their products "at risk" before the conclusion of the litigation. It is possible that one or more generic versions of Periostat will be marketed during 2005 or thereafter. If one or more generic versions of Periostat are approved and marketed in 2005, our revenues and margins from Periostat and Mutual's branded version of Periostat would decrease significantly. As a consequence, we may be forced to reduce our reliance on Periostat and our resources devoted to Periostat. In addition, we would have to reduce headcount and our research and development activities would be delayed, interrupted or discontinued. We may also experience difficulty in managing our cash and in raising additional capital which may not be available to us on acceptable terms, or at all. As result, our business, financial condition, cash flows and results of operations would be materially adversely affected.

If a Generic Version of Periostat Becomes Available on the Market, We will Likely Have to Pay Substantial Rebates or Provide Credits to Mutual, and Mutual will be Permitted to Manufacture its Own Generic Version of Periostat.

If at any time a generic version of Periostat becomes available on the market at a price lower than the selling price of Mutual's branded version of Periostat, the value of the branded product then in Mutual's or its customers' inventory will decrease. Under our License and Supply Agreement with Mutual, if the generic product remains on the market for a specific period of time, we will have to provide credit to Mutual to offset such devaluations in Mutual's or its customers' inventory.

Specifically, we have agreed to pay rebates or provide credits to Mutual to offset rebates and similar retroactive price adjustments requested by, and actually provided by Mutual to its customers, up to a maximum amount based in part on certain inventory levels. We would also be required to pay rebates or provide credits to Mutual to reduce the cost of a certain number of bottles of the branded version of Periostat in Mutual's inventory through a predetermined formula, reflecting the lower price which Mutual's customers would be willing to pay. If a generic product had been introduced at December 31, 2004 at an initial price equivalent to 60% of the wholesale acquisition price of Periostat, we would have been obligated to issue credits to Mutual for approximately \$2.0 million to \$2.3 million, based on the estimated number of bottles in Mutual's inventory and the inventory of Mutual's customers at December 31, 2004.

Furthermore, upon a material default by us or a breach of our obligations under our agreement with Mutual or if a generic version of Periostat is shipped by a third-party generic competitor and remains available for sale for a certain period of time, Mutual would be entitled to manufacture and sell its own generic version of Periostat under Mutual's ANDA, if such were approved by the FDA. If Mutual manufactures and sells its own generic version of Periostat under its ANDA, Mutual will be entitled to sell its generic product to the market, including to our Periostat customers, and we will not receive any fees, royalties or other revenues from

these sales. If Mutual manufactures and sells its own generic version of Periostat, our revenues could decline significantly and our business will be materially harmed.

We Cannot Assure You that Our Clinical Trials will be Timely Completed or will Meet Agreed Upon End-Points.

As part of our plans to expand into the dermatology market, we will need to conduct extensive testing of our products, pursuant to protocols that measure end points agreed with the FDA. 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.

Our ongoing clinical trials for Periostat-MR and Oracea are currently fully enrolled. We also may commence additional clinical trials in the future. Although we have not to date experienced any significant delays in enrolling clinical trial patients for our ongoing clinical trials, delays in patient enrollment for future trials may result in increased costs and delays, which could have a harmful effect on our ability to develop products.

It may take several years to complete the testing of a product, and failure can occur at any stage of testing. For example:

- interim results of preclinical or clinical studies do not necessarily predict their final results, and results in early studies might not be seen in later studies;
- potential products that appear promising at early stages of development may ultimately fail for a number of reasons, including the possibility that the products may be ineffective, less effective than products of our competitors or cause harmful side effects;
- any preclinical or clinical test may fail to produce results satisfactory to the FDA or foreign regulatory authorities;
- preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval;
- negative or inconclusive results from a preclinical study or clinical trial or adverse medical events during a clinical trial could cause a preclinical study or clinical trial to be repeated or a program to be terminated, even if other studies or trials relating to the program are successful;
- the FDA can place a hold on a clinical trial if, among other reasons, it finds that patients enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury;
- we may encounter delays or rejections based on changes in regulatory agency policies during the period in which we develop a drug or the period required for review of any application for regulatory agency approval; and
- our clinical trials may not demonstrate the safety and efficacy needed for our products to receive regulatory approval.

If we are required to conduct additional clinical trials or other studies beyond those that we currently contemplate, if we are unable to successfully complete our clinical trials or other studies or if the results of these trials or studies are not positive or are only modestly positive, we may be delayed in obtaining marketing approval, we may not be able to obtain marketing approval or we may obtain approval for indications that are not as broad as intended. Our product development costs will also increase if we experience delays in testing or approvals. Significant clinical trial delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our products or potential products. If any of this occurs, our business will be materially harmed.

Our Products, and Our Products Under Development, 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 and Mutual's branded version of 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 unless the FDA approves the product for that indication. We have significant new products under development in the dermatology area. If the FDA does not approve these products under development or delays or withholds approval for additional indications for marketed products, our ability to execute on our strategies according to plan would be severely hampered, and our financial condition could be materially adversely affected.

In addition, drug and medical device products remain subject to comprehensive regulation by the FDA both before and after approval or clearance. 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.

Our failure, or the failure of our manufacturers or suppliers, to comply with FDA requirements could disrupt production and subject us to adverse consequences, including recalls, civil penalties, refusal to grant approvals, withdrawal of products from the market, seizures, 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 introduction and sales of our products. 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. Our failure to comply with or understand these processes would materially adversely affect our ability to execute on our strategies and our financial condition.

We Depend Upon Third Party Researchers and Providers of Clinical Services to Perform as Contractually Required if We are to be Successful in Bringing New Products to Market.

We do not have the ability to independently conduct the clinical trials required to obtain regulatory approval for our products. We rely on independent clinical investigators, contract research organizations and other third party service providers for successful execution of our clinical trials, but do not control many aspects of their activities. We are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan, protocols for the trial, and applicable regulatory requirements. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, for conducting and recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not, however, complete activities on schedule, or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. Furthermore the data that they generate may not be accurate or may, in extreme cases, be fraudulent.

Our ability to bring our future products to market depends on the quality and integrity of the data we present to regulatory authorities in order to obtain marketing authorizations. We cannot guarantee the authenticity or accuracy of such data, nor can we be certain that such data has not been fraudulently generated. The failure of these third parties to carry out their obligations would materially adversely affect our ability to develop and market new products and implement our strategies.

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

During 2004, we continued to implement our plans to expand into the dermatology market. We have completed and announced the preliminary results of a double-blinded, placebo-controlled 134-patient Phase III clinical trial to evaluate the safety and efficacy of Periostat to treat rosacea, and we purchased the rights to the topical drug delivery technology called Restoraderm. We also developed our relationship with Altana Inc. for the marketing and distribution of Pandel. We continue to seek additional product licensing opportunities to enhance our near-term offerings to the dermatology market. On April 22, 2004, we also announced the restructuring of our pharmaceutical sales organization into dedicated dental and dermatology sales forces focused on high-potential prescribers of our products.

While we have experience in the sales and marketing of dental products, we have limited experience in the dermatology market. This market is very competitive and some of our competitors have substantially greater resources than we have. Our future success will depend on, among other things, our ability to: (i) achieve market acceptance for any current 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.

At the same time, 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 of 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.

The success of our current technology platforms, and that of any other future technology platforms we may purchase or in-license, will depend on the quality and integrity of the technologies licensed or sold to us. Despite our due diligence and the safeguards we have in place, we cannot guarantee the effectiveness or integrity of such technologies, nor can we be certain that others do not have intervening rights in such technologies. If any of our in-licensed technologies proved ineffective, or if a third party successfully asserted any right to such technologies, our ability to develop new products and implement our strategies would be materially adversely affected.

Our Current Competitive Position in the Marketplace Depends on Successfully Enforcing and Defending Our Periostat Patents.

On October 1, 2004, we filed a complaint for patent infringement against IVAX and CorePharma in the United States District Court for the Eastern District of New York. In our complaint, we alleged that the submission of ANDAs by each of IVAX and CorePharma for 20 mg tablets of doxycycline hyclate infringed United States Patent RE 34,656, for which we are the exclusive licensee. We also alleged that any manufacture, importation, marketing and sale of generic 20 mg tablets of doxycycline hyclate by IVAX and CorePharma would infringe the RE 34,656 patent. We are seeking an injunction preventing IVAX and CorePharma from introducing 20 mg tablets of doxycycline hyclate in the United States. We cannot predict how this case will be decided.

As part of our strategy to maintain enforceability and strengthen our Periostat patents, in 2003, we filed requests for reexamination of the Periostat patents in the USPTO. As a result of the reexamination process, the USPTO has provided notification that it intends to issue a Reexamination Certificate confirming the patentability of certain amended claims of the RE 34,656 patent which we believe cover the use of Periostat. We can, however, give no assurances that the validity of this patent, or any of our patents, will be upheld in litigation. If a patent were found invalid, this would limit our right to exclude others from our markets, and may mean that we will face increased competition in the United States and in foreign countries. Specifically, if the RE 34,656 patent is found invalid, or determined not to cover generic versions of Periostat, competitors such as IVAX and CorePharma would be free to introduce generic versions of Periostat in the marketplace. We would not be able to maintain profitability during 2005 if a generic equivalent of Periostat is launched into

the market. As result, our business, financial condition, cash flows and results of operations would be materially adversely affected, we would have to reduce our headcount and our research and development activities would be delayed, interrupted or discontinued. We may also experience difficulty in managing our cash and in raising additional capital which may not be available to us on acceptable terms, or at all.

Our Future Competitive Position in the Marketplace Depends on Obtaining, Enforcing and Successfully Defending Our Patents.

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

Our patent positions, like those of other pharmaceutical firms, generally involve complex legal and factual questions. Even though we are currently prosecuting patent applications with United States and foreign patent offices, we do not know whether any of such applications will result in the issuance of additional patents. If any additional patents are issued, we do not know whether they will provide significant proprietary protection or will be circumvented or invalidated. 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. The failure to obtain and maintain patent protection limits our right to exclude others from our markets. As a result, we would face increased competition in the United States and in foreign countries, which would have a material adverse effect on our business, financial condition and results of operations.

There can be no assurance that patents to which we hold rights will not be challenged and held to be invalid. We may be required to bring expensive infringement actions to enforce our patents and protect our technology, particularly since our patent rights cover new treatments using tetracyclines, and generic tetracyclines have long been generally available for use as antibiotics. West-ward, Mutual, IVAX and CorePharma have already challenged our patents by filing ANDA's for generic equivalents of Periostat. Other generic manufacturers or others may follow suit. We are already involved in infringement actions and it is impossible to predict their outcome. We could become involved in additional infringement actions. Regardless of the outcome, defense or prosecution of patent disputes is expensive and time consuming and results in the diversion of substantial financial, management and other resources from our other activities. We may not have sufficient resources to fund or manage multiple or particularly complex litigations for unlimited periods. Our inability to defend our patents would have a material adverse effect on our business, financial condition and results of operations.

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 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.

We Depend Upon Certain Key Relationships to Generate Much of the Technology Required to Maintain Our Competitive Position in the Marketplace.

Our IMPACs technology is licensed from SUNY, and other academic and research institutions collaborating with SUNY. Under 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. 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.

If We Lose Our Sole Supplier of Doxycycline Hyclate or Our Current Manufacturer of Periostat, Our Sales of Periostat and Mutual's Branded Version of Periostat will be Interrupted, Halted or Less Profitable.

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 rely on a single supplier, Hovione International Limited, or Hovione, for doxycycline, the active ingredient in Periostat and Mutual's branded version of 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. Although Hovione maintains two manufacturing locations, if we are unable to procure a commercial quantity of doxycycline from Hovione on an ongoing basis at a competitive price, if Hovione fails to comply with cGMP, 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 and Mutual's branded version 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 and Mutual's branded version of 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, including the branded version of Periostat that we supply to Mutual. Any inability of PMRS to produce and supply product on agreed upon terms, including the inability of PMRS to comply with cGMP could result in delays in the supply of Periostat and could result in a default in our agreement with Mutual. This would in turn permit Mutual to manufacture and sell its own branded version of Periostat. The introduction of a generic 20 mg doxycycline hyclate tablet could also result in the termination of our agreement with PMRS, and 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. We cannot be certain that we will be able to enter into additional 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, our business, financial condition and results of operations would be materially adversely affected.

A Small Number of Wholesale Customers, Large Retail Chains, and Mutual, Account for the Majority of Our Sales, and the Loss of One of Them, or Changes in Their Purchasing Patterns or Business Model, Could Result in Reduced Sales and/or Higher Costs, Thereby Adversely Affecting Our Operating Results.

The majority of our sales are to a small number of wholesale drug distributors and Mutual. For the year ended December 31, 2004, sales to Cardinal Health, Inc., McKesson Corporation, Amerisource-Bergen

Corporation and Mutual, represented approximately 33%, 29%, 19% and 14%, respectively, of our aggregate net product sales. Our small number of customers, consolidation in the pharmaceutical wholesale industry or financial difficulties of these customers could result in situations which could temporarily increase returns of our products from our wholesalers or, as a result of wholesalers and Mutual reducing their respective inventory levels, delay the purchase of our products. In addition, wholesalers and Mutual may increase purchase levels in anticipation of future price increases. This may cause an unexpected increase in the level of trade inventories normally maintained by wholesalers.

Historically in the pharmaceutical industry, wholesalers have been speculative in their purchasing practices in anticipation of product price increases. To manage this process, we executed Inventory Management Agreements with our major wholesaler customers in 2003, which will expire in 2005. Under these agreements the wholesalers provide us with weekly retail demand information and current stocking levels for our products; additionally, they agree to manage the variability of their purchases within specified limits. In return we give the wholesalers the right to purchase a specific amount of inventory from us at the sales price in effect immediately prior to announced price increases. In recent months our wholesaler customers, as well as others in the industry, have begun to modify their business models from arrangements where they derived profits from the management of various discounts and rebates, to arrangements where they charge a fee for their services.

We have not yet reached agreement with our wholesaler customers concerning the terms of our future relationship. We cannot predict what the effect of any new relationship may be on our costs or our ability to manage trade inventory levels of Periostat and the branded version of Periostat exclusively marketed to Mutual. If trade inventory levels of Periostat and the branded version of Periostat become too high, or if prescription growth of Periostat and the branded version of Periostat, is lower than expected by the trade, wholesalers, large retail chains and Mutual could reduce their orders from us. This could result in reduced sales of Periostat and the branded version of Periostat, and adversely affect our quarterly operating results. Similarly, if the future fees charged by our wholesaler customers are significantly higher than the margins they achieve under our existing relationships, this could adversely affect our profitability and our operating results.

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

Our business may be adversely affected by potential product liability claims arising out of 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 (\$5.0 million for pediatric claims) covering Periostat and Mutual's branded version of Periostat, our product candidates and products for which we have licensing or co-promotion rights.

Our insurer, Chubb Group, has also notified us that our general product liability policy will not cover claims arising from our past sales of Vioxx, to the extent such claims are made after December 31, 2004. This does not affect our rights under the Co-Promotion Agreement with Merck, which provides for indemnification of us by Merck against any claims arising from manufacturing or design defects in the Vioxx product or for which we, as the seller of the product, may be strictly liable as a seller of an inherently dangerous product.

Our 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.

Changes in Stock Option Accounting Rules May have a Significant Adverse Affect on Our Operating Results.

We have a history of using broad based employee stock option programs to hire, incentivize and retain our workforce in a competitive marketplace. Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation," allows companies the choice of either using a fair value method of accounting for options that would result in expense recognition for all options granted, or using an intrinsic value method, as prescribed by Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to

Employees,” or APB 25, with a pro forma disclosure of the impact on net income (loss) of using the fair value option expense recognition method. We have elected to apply APB 25 and accordingly we generally have not recognized any expense with respect to employee stock options as long as such options are granted at exercise prices equal to the fair value of our common stock on the date of grant.

In December 2004, the Financial Accounting Standards Board issued “Share-Based Payment” (Statement 123R). Statement 123R requires that the compensation cost relating to share-based payment transactions be recognized in financial statements. That cost will be measured based on the grant-date fair value of the equity instruments issued. In determining the fair value of options and other equity-based awards, companies may use different valuation models that may involve extensive and complex analysis. Statement 123R will be effective for us no later than July 1, 2005, which is the first day of the third quarter of our 2005 fiscal year. We are in the process of reviewing Statement 123R to determine which model is more appropriate for us. While we continue to evaluate the effect that the adoption of Statement 123R will have on our financial position and results of operations, we currently expect that our adoption of Statement 123R will adversely affect our operating results to some extent in future periods. For example, if Statement 123, which also has a fair-value-based compensation methodology, had applied to our operating results for 2004, we would have recognized additional expense of approximately \$3.7 million, which would have decreased our diluted net earnings per common share allocable to common stockholders for 2004 from \$0.34 to \$0.09 per share.

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, 2001 through December 31, 2004, as reported on the Nasdaq National Market:

<u>Quarter Ended</u>	<u>High</u>	<u>Low</u>
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
March 31, 2004	\$14.16	\$10.07
June 30, 2004	\$13.21	\$ 8.70
September 30, 2004	\$ 9.49	\$ 6.23
December 31, 2004	\$ 7.49	\$ 5.37

Item 2. Properties.

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

Item 3. Legal Proceedings.

On April 8, 2004, we settled all pending litigation between us and Mutual. In the settlement, Mutual agreed and confessed to judgment that our Periostat patents are valid and would be infringed by the commercial manufacture, use, sale, importation or offer for sale of the generic version of Periostat for which Mutual had submitted its ANDA.

In connection with the settlement, we paid to Mutual \$2.0 million, which represented a portion of the anticipated fees and expenses that we would save as a result of the settlement of the pending actions with Mutual. We also entered into a License and Supply Agreement pursuant to which Mutual received a license to sell a branded version of Periostat. We will be the sole supplier of this product to Mutual, subject to certain conditions. The product will be sold to Mutual at prices below our average manufacturer's price for Periostat through May 15, 2007 or the earlier termination of such supply arrangements. Early termination may occur under certain circumstances, including the successful entry of a third party generic competitor to Periostat. We also agreed to provide price adjustment payments to Mutual if a generic version of Periostat becomes available on the market at a price lower than the selling price of Mutual's branded version of Periostat.

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 the 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 (the "FDA Litigation"). On July 23, 2003, the Court issued that injunction. On August 19, 2004 and September 10, 2004, respectively, IVAX and CorePharma intervened in the case, and moved to dissolve the injunction. We successfully opposed the dissolution of the injunction following a hearing on November 18, 2004, and the injunction remained in place throughout 2004. On January 20, 2005, however, the United States District Court for the District of Columbia reached its decision on the merits of the FDA Litigation, and dissolved the injunction prohibiting the FDA from approving any ANDAs submitted for any generic version of Periostat. We have lodged an appeal against this decision in the Court of Appeals for the District of Columbia Circuit.

On October 1, 2004, we filed a complaint for patent infringement against IVAX and CorePharma in the United States District Court for the Eastern District of New York. In our complaint, we alleged that the submission of ANDAs by each of IVAX and CorePharma for 20 mg tablets of doxycycline hyclate infringed United States Patent RE 34,656, for which we are the exclusive licensee. We also alleged that any manufacture, importation, marketing and sale of generic 20 mg tablets of doxycycline hyclate by IVAX and CorePharma would infringe the RE 34,656 patent. We are seeking an injunction preventing IVAX and CorePharma from introducing 20 mg tablets of doxycycline hyclate in the United States. As discussed above, during the pendency of this litigation, the United States District Court for the District of Columbia reached its decision in the FDA Litigation, and dissolved the injunction that had prevented the FDA from approving any ANDAs submitted for any generic version of Periostat. Consequently, we immediately applied to the United States District Court for the Eastern District of New York, seeking a temporary restraining order and a preliminary injunction preventing IVAX and CorePharma from introducing 20 mg tablets of doxycycline hyclate into the market in the United States until our patent claims have been resolved. Our motion was considered and discussed during a telephone conference with the Court on January 21, 2005. A full hearing on the merits of our motion was conducted on January 31, 2005. We are currently awaiting the Court's decision on our motion. We cannot predict how this case will be decided.

In addition, on November 19, 2004, we submitted a Petition for Stay of Action to the FDA asking it to refuse to approve any ANDA covering a generic version of Periostat, submitted by IVAX, CorePharma or any other party unless the bioequivalence study or studies in the ANDA include female subjects.

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 2004 and 2003, we incurred \$4.1 million and \$3.8 million, respectively, in legal defense, litigation and settlement costs, \$1.9 million 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, 2004, we have \$3.9 million in previously recognized 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 Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.*

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, 2003 through December 31, 2004 as reported on the Nasdaq National Market.

<u>Quarter Ended</u>	<u>High</u>	<u>Low</u>
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
March 31, 2004	\$14.16	\$10.07
June 30, 2004	\$13.21	\$ 8.70
September 30, 2004	\$ 9.49	\$ 6.23
December 31, 2004	\$ 7.49	\$ 5.37

As of March 3, 2005, the approximate number of holders of record of our common stock was 108.

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.

The following information relates to all securities of the Company sold by us during the year ended December 31, 2004 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 2004, 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>
25,000	\$5.59

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.

Item 6. *Selected Consolidated Financial Data.*

The selected consolidated financial data set forth below with respect to our consolidated statement of operations for each of the years in the three-year period ended December 31, 2004 and our consolidated balance sheets as of December 31, 2004 and 2003 are derived from and qualified by reference to our audited consolidated financial statements and the related notes thereto found at "Item 15. Exhibits and Financial Statement Schedules" herein. The consolidated statement of operations data for the years ended December 31, 2001 and 2000 and the consolidated balance sheet data as of December 31, 2002, 2001 and 2000 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 and Financial Statement Schedules" 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,				
	2004	2003	2002	2001	2000
	(Dollars in thousands except for per share data)				
Consolidated Statement of Operation Data:					
Revenues:					
Net product sales	\$ 51,739	\$ 49,038	\$ 42,111	\$ 31,358	\$ 20,501
Contract revenues	237	3,122	2,332	3,386	3,240
License revenues	170	699	176	488	530
Total revenues	52,146	52,859	44,619	35,232	24,271
Operating expenses:					
Cost of product sales	7,446	7,362	6,713	5,825	4,070
Research and development	8,843	5,462	4,394	3,764	3,128
Selling, general and administrative	31,765	33,668	32,699	34,010	25,746
Gain on sale of U.K. and European Dental assets	(2,980)	—	—	—	—
Operating income (loss)	7,072	6,367	813	(8,367)	(8,673)
Interest income	421	148	77	232	613
Interest expense	—	—	(5)	(17)	(15)
Other (expense) income	2	(3)	17	8	9
Income (loss) before income taxes and cumulative effect of change in accounting principle	7,495	6,512	902	(8,144)	(8,066)
Income taxes	967	85	—	—	—
Cumulative effect of change in accounting principle(1)	—	—	—	—	(764)
Net income (loss)	<u>\$ 6,528</u>	<u>\$ 6,427</u>	<u>\$ 902</u>	<u>\$ (8,144)</u>	<u>\$ (8,830)</u>
Net income (loss) allocable to common stockholders	<u>\$ 4,928</u>	<u>\$ 4,827</u>	<u>\$ (727)</u>	<u>\$ (9,824)</u>	<u>\$ (10,519)</u>
Basic net income (loss) per share allocable to common stockholders before cumulative effect of change in accounting principle(1)(2)	<u>\$ 0.35</u>	<u>\$ 0.40</u>	<u>\$ (0.06)</u>	<u>\$ (0.94)</u>	<u>\$ (1.12)</u>
Diluted net income (loss) per share allocable to common stockholders before cumulative effect of change in accounting principle(1)(2)	<u>\$ 0.34</u>	<u>\$ 0.38</u>	<u>\$ (0.06)</u>	<u>\$ (0.94)</u>	<u>\$ (1.12)</u>
Basic net income (loss) per share allocable to common stockholders(2)	<u>\$ 0.35</u>	<u>\$ 0.40</u>	<u>\$ (0.06)</u>	<u>\$ (0.94)</u>	<u>\$ (1.21)</u>
Diluted net income (loss) per share allocable to common stockholders(2)	<u>\$ 0.34</u>	<u>\$ 0.38</u>	<u>\$ (0.06)</u>	<u>\$ (0.94)</u>	<u>\$ (1.21)</u>
Shares used in computing basic per share amounts(2)	14,264,687	12,094,638	11,234,652	10,413,663	8,711,668
Shares used in computing diluted per share amounts(2)	14,500,637	12,836,364	11,234,652	10,413,663	8,711,668

	As of December 31,				
	2004	2003	2002	2001	2000
	(In thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and short-term investments	\$ 38,645	\$ 32,670	\$ 10,112	\$ 6,171	\$ 5,448
Working capital	39,714	32,010	5,992	6,194	5,308
Total assets	52,121	44,132	17,634	14,698	10,431
Note payable, less current portion	—	—	—	—	47
Accumulated deficit	(64,926)	(69,854)	(74,681)	(73,954)	(64,130)
Total stockholders' equity	\$ 41,215	\$ 33,956	\$ 8,352	\$ 7,127	\$ 5,264

- (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 allocable to common stockholders.

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

Our management's discussion and analysis of our financial condition and results of operations include the identification of certain trends and other statements that may predict or anticipate future business or financial results that are subject to important factors that could cause our actual results to differ materially from those indicated. See "Additional Factors That May Affect Future Results."

Overview

CollaGenex Pharmaceuticals, Inc. and subsidiaries, is a specialty pharmaceutical company currently focused on developing and marketing innovative proprietary medical therapies to the dental and dermatology markets. We currently market four pharmaceutical products to the dental market through our professional dental sales force, and we market one prescription product to the dermatology market through our professional dermatology sales force. Our dental products all treat periodontal disease and include Periostat®, Atridox®, Atrisorb FreeFlow® and Atrisorb-D® (the "Atrix Products"). We developed and launched Periostat in late 1998 and licensed the Atrix Products from Atrix Laboratories, Inc. (now known as QLT USA, Inc.) in August 2001. Our marketed dermatology product is Pandel®, a prescription corticosteroid we licensed from Altana, Inc. in May 2002. We also sell a branded version of Periostat to United Research Laboratories, Inc./ Mutual Pharmaceutical Company, Inc. ("Mutual") pursuant to a License and Supply Agreement with Mutual executed in April 2004 as part of a settlement of outstanding patent litigation. Mutual distributes this product through the major U.S. drug wholesalers.

In addition to our marketed products, we have a pipeline of products in clinical and pre-clinical development. These products are based on our two proprietary platform technologies, IMPACs™ and Restoraderm™. IMPACs (Inhibitors of Multiple Proteases and Cytokines) are a group of compounds that demonstrate a range of anti-inflammatory activities as well as the ability to inhibit the breakdown of connective tissue. Periostat is our first FDA-approved IMPACs product. Periostat-MR™ is a once-a-day, modified-release formulation of Periostat currently in a Phase III clinical trial for the treatment of adult periodontitis. Oracea™, which has the same active ingredient and modified delivery as Periostat-MR, is in two Phase III clinical trials for the treatment of rosacea, a dermatological condition. Col-3, a second generation IMPACs compound, has completed Phase II trials for the treatment of HIV-related Kaposi's sarcoma and is currently in a Phase II proof-of-concept clinical trial for the treatment of rosacea.

Our Restoraderm technology is a proprietary, foam-based, topical drug delivery technology that originated from a Swedish collaborator. We have acquired all right, title and interest to the Restoraderm technology and are committed to initiate the development of five products based on this technology before the end of 2005. We are currently developing Restoraderm products for the treatment of acne and psoriasis.

Our strategy is to become a leading, research and development-based specialty pharmaceutical company. We intend to continue to market our current products and develop and launch new products based on our two proprietary platform technologies. Our current focus is on the dental and dermatology markets, although we intend to seek partnerships with third parties to develop potential uses of our technology outside of our core focus.

In April 2004, we entered into a License and Supply Agreement as part of a settlement of all outstanding litigation with Mutual relating to our patents for Periostat. In the settlement, Mutual agreed and confessed to judgment that our Periostat patents are valid and would be infringed by Mutual's Abbreviated New Drug Application ("ANDA") for a generic form of Periostat. Under the License and Supply Agreement Mutual received a license to sell a branded version of Periostat. We will be the sole supplier of this product to Mutual, subject to certain conditions. The product will be sold to Mutual at prices below our average manufacturer's price for Periostat through May 15, 2007 or the earlier termination of such supply arrangements. Early termination may occur under certain circumstances, including the successful entry of a third party generic competitor to Periostat. We also agreed to provide price adjustment payments to Mutual if a generic version of Periostat becomes available on the market at a price lower than the selling price of Mutual's branded version of Periostat. During 2004, we made sales to Mutual of approximately \$7.0 million. We expect to earn gross

margins in the range of 88% to 90% of net sales on all future sales of product to Mutual, assuming the License and Supply Agreement is not terminated due to the entry of a third-party generic competitor.

We were founded in 1992 and completed an initial public offering of our common stock in 1996. We recorded our first profit in the third quarter of 2002. Although we achieved net income of \$6.5 million, \$6.4 million and \$902,000 for the years ended December 31, 2004, 2003 and 2002, respectively, we incurred losses in every other year since inception and have an accumulated deficit of \$64.9 million at December 31, 2004.

Results of Operations

Years Ended December 31, 2004 and December 31, 2003

Revenues

	<u>2004</u>	<u>Change</u>	<u>2003</u>
	(Dollars in thousands)		
Net Product Sales	\$51,739	5.5%	\$49,038
Contract Revenues	237	(92.4)%	3,122
License Revenues	<u>170</u>	<u>(75.7)%</u>	<u>699</u>
Total	<u>\$52,146</u>	<u>(1.3)%</u>	<u>\$52,859</u>

During the year ended December 31, 2004, net product sales included net sales of Periostat, Mutual's branded version of Periostat, the Atrix Products and Pandel. During the year ended December 31, 2003, net product sales included net sales of Periostat, the Atrix Products and Pandel. During 2004, we recorded \$7.0 million in sales to Mutual. Net product sales for the year ended December 31, 2004 increased over the prior year due to increases in the number of prescriptions for Periostat, including Mutual's branded version of Periostat, and Pandel as well as price increases in the products we sell to wholesalers offset in part by the lower average selling price recognized on sales to Mutual. During the year ended December 31, 2004, Mutual's branded version of Periostat accounted for approximately 20% of the tablets dispensed to patients who received and filled a prescription for Periostat.

Contract revenues for the year ended December 31, 2004 decreased 92.4% to \$237,000 from approximately \$3.1 million during the year ended December 31, 2003, primarily due to the expiration and/or mutual termination of our co-promotion agreements with Merck & Co., Inc., Novartis Consumer Health, Inc. and Sirius Laboratories, Inc. during 2003. The 2004 revenue consists of residual contract revenue from our expired agreement with Merck for Vioxx®.

We recorded \$170,000 and \$699,000 in licensing revenues for the years ended December 31, 2004 and December 31, 2003, respectively, relating to various international distribution agreements. Our 2004 license revenues included \$45,000 from the amortization of previously deferred upfront licensing fees that are being amortized over the expected performance periods of the agreements, \$96,000 from the acceleration of previously unamortized deferred upfront licensing fees related to European licensing agreements that were transferred to Alliance Pharma plc ("Alliance") as part of the sale of certain U.K. and European dental assets in October 2004, and \$29,000 in licensing revenue from our Canadian distribution partner. We recorded licensing revenues of \$699,000 during the year ended December 31, 2003. This amount included \$52,000 from the amortization of deferred up-front license fees over the expected performance periods of the agreements, \$222,000 from the acceleration of previously unamortized deferred up-front licensing fees relating to a licensing agreement that was terminated in 2003, and \$425,000 in milestone fees received from foreign marketing partners upon the achievement of certain milestones.

Cost of Product Sales

	<u>2004</u>	<u>Change</u>	<u>2003</u>
	<u>(Dollars in thousands)</u>		
Cost of Product Sales	\$7,446	1.1%	\$7,362
Percent of Net Product Sales	14.4%		15.0%

Cost of product sales includes product packaging, third-party royalties, amortization of product licensing fees, and the costs associated with the manufacturing, the acquisition of manufactured product, and storage and stability of our current products.

Cost of product sales were approximately \$7.4 million, or 14.4% of net product sales during the year ended December 31, 2004, compared to approximately \$7.4 million, or 15.0% of net product sales during the year ended December 31, 2003. As a percentage of net product sales, cost of net product sales decreased slightly compared to the year ended December 31, 2003, due to Periostat price increases and product mix that were partially offset by the lower average selling price recognized on sales to Mutual in 2004.

Research and Development

	<u>2004</u>	<u>Change</u>	<u>2003</u>
	<u>(Dollars in thousands)</u>		
Research and development	\$8,843	61.9%	\$5,462

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, report writing and regulatory compliance costs.

Research and development expenses increased approximately \$3.4 million, or 61.9%, to approximately \$8.8 million during the year ended December 31, 2004 from approximately \$5.5 million during the year ended December 31, 2003.

Development projects conducted during the year ended December 31, 2004 included:

- our continuing clinical and manufacturing development work for Oracea, our once-daily, modified formulation of doxycycline, 40 mg, for the treatment of rosacea, which accounted for total costs of approximately \$2.7 million;
- our continuing clinical and manufacturing development and formulation work for Periostat-MR, our once daily, modified formulation of doxycycline, 40 mg, for the treatment of adult periodontitis, which accounted for total costs of approximately \$2.2 million;
- in-process research and development charges associated with developing our Restoraderm technology, including milestone fees and formulation and stability testing costs for two potential products, which accounted for total costs of approximately \$868,000;
- the completion of a Phase III clinical trial to evaluate Periostat for the treatment of rosacea, which accounted for \$417,000 in expense; and
- our clinical and manufacturing development work for COL-3, a second generation IMPACs compound, totaling \$673,000.

Personnel and direct internal overhead expenses, including consulting and regulatory costs, incurred during the year ended December 31, 2004 were approximately \$2.0 million. We estimate that if Periostat-MR, Oracea and our Restoraderm acne and psoriasis products are developed to the point of market launch, the additional formulation and clinical development expenses and milestones fees would be approximately \$27.0 million. It is premature to estimate the future development costs relating to Col-3.

Development projects conducted during the year ended December 31, 2003 included:

- the manufacturing, development and formulation work for Periostat-MR and Oracea, which accounted for total costs of approximately \$269,000;
- stability testing and milestone fees for several potential products utilizing the Restoraderm technology, which accounted for total costs of approximately \$817,000;
- several Phase IV studies for Periostat in various dental applications, which accounted for total costs of approximately \$391,000; and
- a Phase III clinical trial to evaluate Periostat for the treatment of rosacea, which accounted for total costs of approximately \$2.0 million.

Personnel and direct internal overhead expenses, including consulting and regulatory costs, incurred during the year ended December 31, 2003 were approximately \$1.9 million.

Selling, General and Administrative

	<u>2004</u>	<u>Change</u>	<u>2003</u>
	(Dollars in thousands)		
Selling, General and Administrative	\$31,765	(5.7)%	\$33,668

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

Selling, general and administrative expenses decreased 5.7% to approximately \$31.8 million during the year ended December 31, 2004 from approximately \$33.7 million during the year ended December 31, 2003. The decrease in selling, general and administrative expenses during the year ended December 31, 2004 compared to the year ended December 31, 2003 is primarily due to reduced sales force expenses as a result of our April 2004 sales force restructuring and a significant decrease in marketing and promotional expenses associated with products subject to third-party co-promotion agreements that expired or were mutually terminated at the end of 2003. These savings were partially offset by a \$2.0 million payment to Mutual as part of a settlement of outstanding litigation as well as \$348,000 in restructuring costs associated with the April 2004 sales force restructuring.

Under our license agreement with State University of New York at Stony Brook ("SUNY"), we are entitled to deduct costs incurred to defend our patents from current and future royalties due to SUNY. As of December 31, 2004, the cumulative amount of such costs exceeded the cumulative amount of royalties due to SUNY by \$3.9 million. This excess is available to offset future royalties, if any, due to SUNY. During the year ended December 31, 2004, \$1.9 million of the Company's patent litigation costs of \$2.1 million (excluding payment made as part of the settlement with Mutual) were offset by royalties that otherwise would have been paid to SUNY. During the year ended December 31, 2003, \$1.8 million of the Company's patent litigation costs of \$3.1 million (excluding payment made as part of the settlement with West-ward Pharmaceutical Corporation ("West-ward")) were offset by royalties that otherwise would have been paid to SUNY.

Significant components of selling, general and administrative expenses incurred during the year ended December 31, 2004 included approximately \$15.4 million in direct selling and sales training expenses, approximately \$7.5 million in marketing expenses (including advertising and promotion expenditures for Periostat, the Atrix Products and Pandel) and approximately \$8.9 million in general and administrative expenses, which include business development, finance, legal and corporate activities. General and administrative expenses for the year ended December 31, 2004 also included the \$2.0 million payment to Mutual in connection with the settlement of all outstanding litigation. Significant components of selling, general and administrative expenses incurred during the year ended December 31, 2003 included approximately \$15.7 million in direct selling and sales training expenses, approximately \$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™), approximately \$8.9 million in general and administrative expenses, which include business development, finance, legal and corporate activities. General and administrative

expenses for the year ended December 31, 2003 also included a \$700,000 payment to West-ward in connection with the settlement of all outstanding litigation and a \$251,000 non-cash compensation expense related to the modifications of certain stock options held by Brian M. Gallagher, who left the Company in 2003 to pursue other interests.

Gain on Sale of U.K. and European Dental Assets

During 2004, we sold our U.K. and European dental assets to Alliance for net pretax proceeds of approximately \$3.0 million, and a provision of \$945,000 was made for anticipated U.K. income taxes due on this sale. In accordance with generally accepted accounting principles, the pretax gain on this sale of assets is included within operating income and the income tax provision is included within income taxes.

Other Income/Expense

	<u>2004</u>	<u>Change</u>	<u>2003</u>
	(Dollars in thousands)		
Interest income	\$421	184.5%	\$148

Interest income increased to \$421,000 for the year ended December 31, 2004 compared to \$148,000 for the year ended December 31, 2003. This increase was due primarily to higher average investment balances and investment yields in 2004.

Preferred Stock Dividend

Preferred stock dividends included in net income allocable to common stockholders were \$1.6 million during each of the years ended December 31, 2004 and December 31, 2003. Such preferred stock dividends were paid in cash and are the result of our obligations in connection with the issuance of our Series D preferred stock in May 1999.

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	<u>699</u>	<u>297.2%</u>	<u>176</u>
Total	<u>\$52,859</u>	<u>18.5%</u>	<u>\$44,619</u>

During the year ended December 31, 2003, net product sales included net product sales of Periostat, the Atrix Products and Pandel. During the year ended December 31, 2002, net product sales included net product sales of Periostat, the Atrix Products and Pandel (from July 1, 2002 to December 31, 2002). Our agreement with Novartis Consumer Health Inc. to co-promote Denavir[®] expired on September 30, 2003, and we and Novartis mutually decided not to renew our arrangement. 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 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 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. This was primarily due to increased contract revenues relating to our co-promotion activities with respect to Denavir and the AVAR product line. These increases

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. During 2003, our co-promotional agreements with Merck, Novartis and Sirius generated approximately \$3.1 million in revenue.

We recorded \$699,000 in total licensing revenues for the year ended December 31, 2003. This amount included \$52,000 from the amortization of deferred up-front license fees over the expected performance period of the agreements, \$222,000 from the acceleration of deferred up-front licensing fees relating to a licensing agreement that was terminated in 2003, and \$425,000 in milestone fees received from foreign marketing partners upon the achievement of certain milestones. For the year ended December 31, 2002, we recorded \$176,000 in total licensing revenues. This amount included \$59,000 from the amortization of deferred up-front license fees over the expected performance period of the agreements, \$47,000 from the acceleration of deferred up-front licensing fees relating to a licensing agreement that was terminated in 2002, and \$70,000 in 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>
	(Dollars in thousands)		
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>
	(Dollars in thousands)		
Research and development	\$5,462	24.3%	\$4,394

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:

- the manufacturing development and formulation work for Periostat-MR and Oracea, which accounted for total costs of approximately \$269,000;
- stability testing and milestone fees for several potential products utilizing the Restoraderm technology, which accounted for total costs of approximately \$817,000;
- several Phase IV studies for Periostat in various dental applications, which accounted for total costs of approximately \$391,000; and
- a Phase III clinical trial to evaluate Periostat for the treatment of rosacea, which accounted for total costs of approximately \$2.0 million.

Personnel and direct internal overhead expenses, including consulting and regulatory costs, incurred during the year ended December 31, 2003 were approximately \$1.9 million.

Development projects conducted during the year ended December 31, 2002 included:

- our formulation development work for a once-a-day formulation of Periostat and formulation and stability testing for several potential products utilizing the Restoraderm technology for total costs of approximately \$1.3 million;
- 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, which accounted for total costs of approximately \$173,000; and
- 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, which accounted for total costs of approximately \$927,000.

Personnel and direct internal overhead expenses, including consulting and regulatory costs, incurred during the year ended December 31, 2002 were approximately \$2.0 million.

Selling, General and Administrative

	<u>2003</u>	<u>Change</u>	<u>2002</u>
	(Dollars in thousands)		
Selling, General and Administrative	\$33,668	2.9%	\$32,699

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 2.9% to \$33.7 million during the year ended December 31, 2003 from \$32.7 million during the year ended December 31, 2002, primarily due to higher legal fees and settlement costs relating to patent litigation.

Significant components of selling, general and administrative expenses incurred during the year ended December 31, 2003 included approximately \$15.7 million in direct selling and sales training expenses, approximately \$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), approximately \$8.9 million in general and administrative expenses, which include business development, finance, legal and corporate activities. General and administrative expenses for the year ended December 31, 2003 also included a \$700,000 payment to West-ward in connection with the settlement of all outstanding litigation and a \$251,000 non-cash compensation expense related to the modifications of certain stock options held by Brian M. Gallagher, who left the Company in 2003 to pursue other interests. 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.

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 (Expense) Income	\$ (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).

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 were paid in shares of our common stock through May 11, 2002, and thereafter in cash, as a result of our obligations in connection with the issuance of our Series D preferred stock in May 1999.

Liquidity and Capital Resources

Cash Requirements/Sources and Uses of Cash

We require cash to fund our operating expenses, capital expenditures and dividend payments on our outstanding Series D preferred stock. We have historically funded our cash requirements primarily through the following:

- Public offerings and private placements of our preferred and common stock;
- Cash from operations; and
- Exercise of stock options and warrants.

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

- The presence or absence of generic competition, which will be influenced by the outcome and consequences of our litigation with IVAX Pharmaceuticals Inc. and CorePharma LLC;
- The effect of our arrangement with Mutual, including product payment terms and potential retroactive price adjustments;
- Revenues and profits from sales of Periostat, Mutual's branded version of Periostat and other products and contracted services;
- The success of our efforts to build a dermatology franchise;
- The success of our pre-clinical, clinical and development programs;
- Our ability to continue to meet the covenant requirements under our revolving credit facility with Silicon Valley Bank; and
- The receptivity of the capital markets to our future financings.

On June 7, 2004, we entered into a Loan Modification Agreement with Silicon Valley Bank to renew and amend our revolving credit facility, which had expired on March 15, 2004. The amended credit facility expires on May 31, 2006. Under the amended credit facility, we may borrow up to the lesser of \$5.0 million or 80% of eligible accounts receivable, as defined under the amended credit facility. The amount available to us is reduced by any outstanding letters of credit which may be issued under the amended credit facility in amounts totaling up to \$2.0 million. As we pay down amounts under any letter of credit, the amount available to us under the credit facility increases. As of December 31, 2004, we had an outstanding letter of credit approximating \$544,000 that serves as collateral for certain of our inventory purchase commitments, if any. We are not obligated to draw amounts under the amended credit facility and any borrowings shall bear interest, payable monthly, at the current prime rate. As of December 31, 2004, we had no borrowings outstanding.

At December 31, 2004, we had cash, cash equivalents and short-term investments of approximately \$38.6 million, an increase of \$5.9 million from the approximately \$32.7 million balance at December 31, 2003. This increase was primarily attributable to \$2.7 million in net cash flow from operations, \$3.0 million in net

proceeds from the sale of our U.K. and European dental assets, and the proceeds of stock option and warrant exercises, which were partially offset by the payment of preferred dividends. 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, commercial paper and government notes. Our working capital at December 31, 2004 was \$39.7 million, an increase of \$7.7 million from \$32.0 million at December 31, 2003. The increase was primarily attributable to \$6.5 million in net income, including a \$3.0 million pretax gain from the sale of our U.K. and European dental assets, and the proceeds of stock option and warrant exercises, offset by increases in accounts receivables and inventories relating to our agreement with Mutual and the payment of preferred dividends. During the year ended December 31, 2004, we invested approximately \$292,000 in capital expenditures and paid \$1.6 million in cash dividends to the holders of our Series D preferred stock.

Cash Flows/Cash Management

Investing activities during the year ended December 31, 2004 consisted primarily of the cash in-flows from the sale of our U.K. and European dental assets to Alliance, capital expenditures, purchase of in-process research and development and the purchase of short-term investments such as commercial paper and government notes.

Financing activities provided \$752,000 during the year ended December 31, 2004. The principal source of cash from financing activities was proceeds from employee stock option exercises, which were reduced by the payment of dividends to the holders of our Series D preferred stock.

We currently believe that projected sales of our marketed products combined with our working capital at December 31, 2004, will be sufficient to fund our operations, capital expenditures and preferred stock dividend requirements for at least the next twelve months. At this time, however, we cannot accurately predict the effect of certain developments on future product sales, such as our arrangement with Mutual, the possibility of generic competition, the effectiveness of our sales and marketing efforts and the outcome of our research and development efforts to demonstrate the utility of Periostat in indications beyond those already included in the FDA approved label. We expect to modestly increase our annual investment in research and development during 2005.

Contractual Obligations

Our major outstanding contractual obligations relate to cash dividends on our outstanding Series D preferred stock, operating leases for our office space and contractual commitments with our marketing partners for certain selling and promotional expenses associated with the products we are currently detailing.

Below is a table which presents our contractual obligations and commercial commitments as of December 31, 2004:

<u>Contractual Obligations</u>	<u>Payments Due by Period</u>				
	<u>Total</u>	<u>2005</u>	<u>2006 and 2007</u>	<u>2008 and 2009</u>	<u>2010 and after</u>
Operating Leases(1)	\$ 1,997,000	\$ 554,000	\$ 914,000	\$ 529,000	—
Co-Promotional Commitments	(2)	(2)	(2)	(2)	(2)
Cash Dividends on Series D Preferred Stock	\$10,640,000(3)	\$1,744,000(3)	\$4,008,000(3)	\$4,888,000(3)	(3)
Consulting Payments	\$ 304,000(4)	\$ 304,000(4)	—	—	—
Total Contractual Obligations	\$12,941,000	\$2,602,000	\$4,922,000	\$5,417,000	

(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. 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 \$337,000 per year.

- (2) 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.
- (3) 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. Beginning on the sixth anniversary of the date of the original issuance (May 12, 2005) of the Series D preferred stock dividends payable will increase by 1% per annum if the Series D preferred stock has not then been converted or redeemed.
- (4) 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.

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 use Shire technology and patents to develop prescription products for the treatment of various inflammatory disorders. Under the agreement, certain product development functions will be performed for us by Shire. We have committed to pay Shire milestone payments in cash or, at our option, in a combination of cash and our common stock, upon the achievement of certain clinical and regulatory milestones. These payments could total up to \$5.2 million in the aggregate. Under the agreement we must also pay Shire a percentage of net sales of any products utilizing any part of the licensed technology. We expect to make these payments in 2005 and 2006 if the outcome of our Phase III clinical trials for Periostat-MR and Oracea is favorable. We may terminate the agreement upon sixty days notice.

On August 19, 2004, we executed an Asset Purchase and Product Development Agreement with respect to Restoraderm technology (the "Purchase Agreement"). That Agreement superseded our Co-operation, Development and License Agreement executed in February 2002. Under the terms of the Purchase Agreement, we purchased all right, title and interest in the intellectual property and related rights to the Restoraderm topical drug delivery system, which we intend to develop for dermatological applications. Pursuant to the terms of the Purchase Agreement, the purchase price of the assets shall be up to \$1.0 million, subject to the achievement of certain milestones. We are also required to pay certain product development milestone payments in the aggregate amount of up to approximately \$2.0 million as well as royalty and sublicense fees upon product commercialization. As of December 31, 2004, approximately \$283,000 of these fees had been paid by us. We paid an additional \$150,000 in January 2005.

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 of America. 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, asset impairment and inventory obsolescence.

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. Certain sales revenue from our customers, including Mutual, is subject to agreements allowing limited rights of return, rebates and price protection. Accordingly, we make provisions that reduce reported revenue for estimated future returns, rebates and price

protection at the time the 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. If a generic version of Periostat, other than Mutual's branded version, becomes available on the market these estimates made for the returns, rebates and price protection for Periostat and Mutual's branded version of Periostat could vary materially from our current estimates and affect the results of operations, financial condition and our business in the period such generics become available on the market.

Our contract revenues, which were substantially terminated by December 31, 2003, were fee-based arrangements where revenue was earned as prescriptions were filled. Accordingly, since we never had title to the product being promoted, we had no significant obligations after we recognized this revenue.

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 or 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 upfront 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" and related interpretations. As such, compensation expense is recorded on fixed stock option grants only if the 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) would have varied from the reported net income (loss) as we would have recorded additional expenses in each period. See Note 2 to our Consolidated Financial Statements for the pro forma effect of applying SFAS No. 123 to our results of operations and earnings per share allocable to common stockholders.

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. 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. While the Company has been profitable for the past two years, uncertainty regarding patent litigation has prevented the Company from reaching the "more likely than not" conclusion required under the applicable literature to recognize deferred tax assets on our consolidated balance sheet.

Acquired Product Rights

With respect to our acquired product rights, we are required to test for asset impairment whenever events or circumstances indicate that the carrying value of an asset may not be recoverable. We apply SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," in order to determine whether or not an asset was impaired. This standard requires an impairment analysis when indicators of impairment are present.

If such indicators are present, the standard indicates that if the sum of the future expected cash flows from the asset, undiscounted and without interest charges, is less than the carrying value, an asset impairment must be recognized in the financial statements. The amount of the impairment is the difference between the fair value of the asset and the carrying value of the asset.

In making future cash flow analyses of our acquired product rights, the Company makes assumptions relating to the following:

- The intended use of the product rights and the expected future cash flows resulting directly from such use.
- Generic competitor activities and regulatory initiatives that affect our dental and dermatology franchise.
- Customer preferences and expected managed care reimbursement.

We believe that an accounting estimate relating to asset impairment is a critical accounting estimate because the assumptions underlying future cash flow estimates are subject to change from time to time and the recognition of an impairment, as a result of the availability of a generic alternative, could have a significant impact on our results of operations.

Inventory Obsolescence

We record an inventory obsolescence reserve for obsolete, excess and slow-moving inventory. In calculating our inventory obsolescence reserve, management analyzes historical data regarding customer demand for our product and generic alternatives if they should become available. Management believes that its accounting estimate related to inventory obsolescence for our current products could vary materially if a generic alternative becomes available for sale. As such, the demand of our current products could become variable and changes in our reserve for inventory obsolescence could materially affect our financial position and results of operations.

Critical accounting estimates and the related assumptions are evaluated periodically as conditions warrant, and changes to such estimates are recorded as new information or changed conditions require revision.

Recently Issued Accounting Standards

In December 2004, the Financial Accounting Standards Board issued SFAS No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123R"), which replaces SFAS No. 123, "Accounting for Stock Issued to Employees" and supercedes APB Opinion No. 25. SFAS 123R requires all share-based payments to employees, including grants of employee stock options and purchases under the employee stock purchase plan and liabilities that are based on the fair value of the Company's equity instruments or that may be settled by the issuance of such equity instruments, to be recognized in the financial statements based on their fair values. The pro forma disclosures previously permitted under SFAS 123, no longer will be an alternative to financial statement recognition. We are required to adopt SFAS 123R no later than our third quarter of fiscal 2005. Under SFAS 123R, we must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at date of adoption. The transition methods include prospective and retroactive adoption options. Under the retroactive options, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The prospective method requires that compensation expense be recorded at the beginning of the first quarter of adoption of SFAS 123R for all unvested stock options and restricted stock based upon the previously disclosed SFAS 123 methodology and amounts. The retroactive methods would record compensation expense beginning with the first period restated for all unvested stock options and restricted stock. We expect the adoption of SFAS 123 will have a material impact on our results of operations and earnings per share. We are evaluating the requirements of SFAS 123R and have not yet determined the method of adoption and we have not determined whether this adoption will result in amounts that are similar to the current pro forma disclosures under SFAS No. 123 in Note 2 to our Consolidated Financial Statements.

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs — An amendment of ARB No. 43, Chapter 4" ("SFAS 151"). SFAS 151 amends the guidance in ARB No. 43, Chapter 4, "Inventory Pricing," to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). Among other provisions, the new rule requires that items such as idle facility expense, extensive spoilage, double freight, and rehandling costs be recognized as current-period charges regardless of whether they meet the criterion of "so abnormal" as stated in ARB No. 43. Additionally, SFAS No. 151 requires that the allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. SFAS No. 151 is effective for fiscal years beginning after June 15, 2005 and is required to be adopted by us in the first quarter of 2006. We are currently in the process of evaluating the impact that SFAS No. 151 will have on our results of operations and financial position.

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

We had cash and cash equivalents and short-term investments at December 31, 2004 which are exposed to the impact of interest rate changes and our interest income fluctuates as 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, 2004. Our short-term investments in commercial paper and government notes are carried at fair value.

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 and financial statement schedules filed herewith is found at "Item 15. Exhibits and Financial Statement Schedules."

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

Not applicable.

Item 9A. *Controls and Procedures.*

1. Disclosure 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 of December 31, 2004. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act of 1934 is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes 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, 2004, our disclosure controls and procedures were effective.

2. Internal Controls Over Financial Reporting

(a) Management's Annual Report on Internal Control Over Financial Reporting

The management of CollaGenex is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934 as a process designed by, or under the supervision of,

the company's principal executive and principal financial officers and effected by the company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

CollaGenex' management, including the supervision and participation of the Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2004. In making this assessment, the Company's management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in "Internal Control-Integrated Framework."

Based on our assessment, management has concluded that the Company's internal control over financial reporting is effective based on those criteria as of December 31, 2004.

The Company's independent registered public accounting firm has issued its report on our assessment and effectiveness of the Company's internal control over financial reporting. This report appears below.

(b) Report of the Independent Registered Public Accounting Firm

Report of Independent Registered Public Accounting Firm

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

We have audited management's assessment, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting that CollaGenex Pharmaceuticals, Inc. and subsidiaries maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). CollaGenex Pharmaceuticals, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that,

in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that CollaGenex Pharmaceuticals, Inc. and subsidiaries maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on criteria established in Internal Control — Integrated Framework issued by COSO. Also, in our opinion, CollaGenex Pharmaceuticals, Inc. and subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control — Integrated Framework issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of CollaGenex Pharmaceuticals, Inc. and subsidiaries as of December 31, 2004 and 2003, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2004, and our report dated March 9, 2005 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG LLP

Philadelphia, Pennsylvania
March 9, 2005

(c) Changes in Internal Control Over Financial Reporting

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, 2004 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. There have been no significant changes in internal controls subsequent to the assessment by the Company's chief executive officer and chief financial officer.

Item 9B. Other Information.

Not applicable.

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 2005 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 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 2005 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement. The information specified in Item 402(k) and (l) of Regulation S-K and set forth in our definitive proxy statement for the 2005 Annual Meeting of Stockholders is not incorporated by reference.

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 2005 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 2005 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 2005 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

PART IV

Item 15. *Exhibits and Financial Statement Schedules.*

(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 48.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized this 10th day of March, 2005.

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>
<u>/s/ Colin W. Stewart</u> Colin W. Stewart	President, Chief Executive Officer and Director (Principal Executive Officer)	March 10, 2005
<u>/s/ Nancy C. Broadbent</u> Nancy C. Broadbent	Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)	March 10, 2005
<u>/s/ Brian M. Gallagher</u> Brian M. Gallagher, Ph.D.	Director	March 10, 2005
<u>/s/ Peter R. Barnett, D.M.D.</u> Peter R. Barnett, D.M.D.	Director	March 10, 2005
<u>/s/ Robert C. Black</u> Robert C. Black	Director	March 10, 2005
<u>/s/ James E. Daverman</u> James E. Daverman	Chairman of the Board and Director	March 10, 2005
<u>/s/ Robert J. Easton</u> Robert J. Easton	Director	March 10, 2005
<u>/s/ Robert A. Beardsley, Ph.D.</u> Robert A. Beardsley, Ph.D.	Director	March 4, 2005
<u>/s/ W. James O'Shea</u> W. James O'Shea	Director	March 4, 2005

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
3.1(a)	Amended and Restated Certificate of Incorporation.
3.2(r)	Amended and Restated Bylaws.
3.3(k)	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(p)	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(p)	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 David Pfeiffer.
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.
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(c)	Distribution Services Agreement dated August 15, 1998 between Cord Logistics, Inc. and the Company.
10.13(d)	Stock Purchase Agreement dated March 19, 1999, between the Company, OCM Principal Opportunities Fund, L.P. and other Purchasers set forth therein.
10.14(e)	Lease Agreement dated March 15, 1999 between the Company and Newton Venture IV Associates, effective May 15, 1999.
10.15(f)	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(g)	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.
10.17(h)	Loan and Security Agreement dated March 19, 2001, between the Company and Silicon Valley Bank.

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
†10.18(i)	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(j)	Letter Agreement dated as of June 26, 2001 by and between the Company and Pharmaceutical Manufacturing Research Services, Inc.
10.20(k)	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(k)	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(l)	License Agreement dated August 24, 2001 by and between CollaGenex Pharmaceuticals, Inc. and Atrix Laboratories, Inc.
†10.23(l)	Stock Purchase Agreement dated August 24, 2001 by and between CollaGenex Pharmaceuticals, Inc. and Atrix Laboratories, Inc.
†10.24(m)	First Addendum December 10, 2001 to the Supply Agreement dated January 23, 1995 by and between CollaGenex, Inc. and Hovione International Limited.
10.25(n)	Common Stock Purchase Agreement dated February 14, 2002 by and between CollaGenex Pharmaceuticals, Inc. and Kingsbridge Capital Limited.
10.26(n)	Warrant dated February 14, 2002 issued to Kingsbridge Capital Limited.
†10.27(o)	Wholesale Service Agreement effective as of November 1, 2001, by and between CollaGenex Pharmaceuticals, Inc. and National Specialty Services, Inc.
†10.28(o)	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(o)	Exclusive Distribution Agreement dated as of March 1, 2002, by and between CollaGenex Pharmaceuticals, Inc. and Cord Logistics, Inc.
10.30(o)	First Loan Modification Agreement dated as of March 22, 2002 by and between CollaGenex Pharmaceuticals, Inc. and Silicon Valley Bank.
10.31(o)	Second Loan Modification Agreement dated as of March 27, 2002 by and between CollaGenex Pharmaceuticals, Inc. and Silicon Valley Bank.
†10.32(q)	Agreement by and between Altana Inc. and CollaGenex Pharmaceuticals, Inc., dated May 24, 2002.
10.33(r)	Form of Change of Control Agreement executed with each of Colin Stewart, Nancy C. Broadbent, David Pfeiffer and Andrew Powell.
†10.34(t)	Letter Agreement dated as of September 12, 2002 by and between the Company and Pharmaceutical Manufacturing Research Services, Inc.
10.35(s)	Transition Agreement and Release dated March 18, 2003 by and between Brian Gallagher and CollaGenex Pharmaceuticals, Inc.
10.36(s)	Consulting Agreement dated March 18, 2003 by and between Brian Gallagher and CollaGenex Pharmaceuticals, Inc.
10.37(u)	Form of Incentive Bonus Agreement executed with David F. Pfeiffer.
†10.38(v)	License and Supply Agreement dated April 8, 2004 by and among Mutual Pharmaceutical Company, Inc. United Research Laboratories, Inc. and the Company.
10.39(w)	Fourth Loan Modification Agreement, dated June 7, 2004, by and between Silicon Valley Bank and the Company.
10.40(x)	Nonstatutory Stock Option Agreement dated September 23, 2004 by and between Andrew Powell and the Company.
10.41(x)	Asset Purchase and Product Development Agreement dated August 19, 2004 by and between Thomas Skold and the Company.

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
10.42*	Nonstatutory Stock Option Agreement dated December 7, 2004 by and between Robert A. Beardsley, Ph.D. and the Company.
10.43*	Sale of Assets Agreement dated November 3, 2004 by and among CollaGenex International Limited, Alliance Pharmaceuticals Limited and Alliance Pharma plc.
10.44*	Non-Employee Director Compensation Summary.
10.45*	Executive Officer Compensation Summary.
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 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.
- (d) 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.
- (e) 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.
- (f) 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.
- (g) 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.
- (h) 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.
- (i) 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.
- (j) 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.
- (k) 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.
- (l) 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.
- (m) 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.
- (n) 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.

- (o) 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.
- (p) 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.
- (q) 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.
- (r) 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.
- (s) 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.
- (t) Incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 2002, which was filed with the Securities and Exchange Commission on March 31, 2003.
- (u) 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.
- (v) Incorporated by reference to the Company's Current Report on Form 8-K, dated April 8, 2004, which was filed with the Securities and Exchange Commission on April 8, 2004.
- (w) Incorporated by reference to the Company's Current Report on Form 8-K, dated June 7, 2004, which was filed with the Securities and Exchange Commission on June 7, 2004.
- (x) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2004, which was filed with the Securities and Exchange Commission on November 9, 2004.

COLLAGENEX PHARMACEUTICALS, INC.
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Report of Independent Registered Public Accounting Firm

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

We have audited the accompanying consolidated balance sheets of CollaGenex Pharmaceuticals, Inc. and subsidiaries as of December 31, 2004 and 2003, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2004. In connection with our audits of the consolidated financial statements, we also have audited the consolidated financial statement schedule, "Valuation and Qualifying Accounts." 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 the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the 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, 2004 and 2003, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles. 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 aspects, the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of CollaGenex Pharmaceuticals, Inc. and subsidiaries' internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 9, 2005 expressed an unqualified opinion on management's assessment of, and the effective operation of, internal control over financial reporting.

/s/ KPMG LLP

Philadelphia, Pennsylvania
March 9, 2005

**COLLAGENEX PHARMACEUTICALS, INC.
AND SUBSIDIARIES**

**Consolidated Balance Sheets
December 31, 2004 and 2003**

	<u>2004</u>	<u>2003</u>
	<small>(Dollars in thousands, except per share data)</small>	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 11,889	\$ 32,670
Short-term investments	26,756	—
Accounts receivable, net of allowances of \$483 and \$481 in 2004 and 2003, respectively	6,983	5,786
Inventories	2,692	1,672
Prepaid expenses and other current assets	<u>2,096</u>	<u>1,732</u>
Total current assets	50,416	41,860
Equipment and leasehold improvements, net	498	496
Acquired product rights, net	1,164	1,749
Other assets	<u>43</u>	<u>27</u>
Total assets	<u>\$ 52,121</u>	<u>\$ 44,132</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	4,105	3,729
Accrued expenses	5,797	5,321
Preferred dividends payable	<u>800</u>	<u>800</u>
Total current liabilities	<u>10,702</u>	<u>9,850</u>
Deferred revenue	<u>204</u>	<u>326</u>
Commitments and contingencies (Notes 6 and 12)		
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 2004 and 2003, (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 2004 and 2003	2	2
Common stock, \$0.01 par value; 25,000,000 shares authorized, 14,385,877 and 13,842,200 shares issued and outstanding in 2004 and 2003, respectively	144	138
Additional paid-in capital	106,016	103,670
Accumulated other comprehensive loss	(21)	—
Accumulated deficit	<u>(64,926)</u>	<u>(69,854)</u>
Stockholders' equity	<u>41,215</u>	<u>33,956</u>
Total liabilities and stockholders' equity	<u>\$ 52,121</u>	<u>\$ 44,132</u>

See accompanying notes to consolidated financial statements.

**COLLAGENEX PHARMACEUTICALS, INC.
AND SUBSIDIARIES**

**Consolidated Statements of Operations
Years ended December 31, 2004, 2003 and 2002**

	<u>2004</u>	<u>2003</u>	<u>2002</u>
	(Dollars in thousands, except per share data)		
Revenues:			
Net product sales	\$ 51,739	\$ 49,038	\$ 42,111
Contract revenues	237	3,122	2,332
License revenues	<u>170</u>	<u>699</u>	<u>176</u>
Total revenues	<u>52,146</u>	<u>52,859</u>	<u>44,619</u>
Operating expenses:			
Cost of product sales	7,446	7,362	6,713
Research and development	8,843	5,462	4,394
Selling, general and administrative — other	31,765	33,668	32,699
Gain on sale of UK and European Dental assets (note 11)	<u>(2,980)</u>	<u>—</u>	<u>—</u>
Total operating expenses	<u>45,074</u>	<u>46,492</u>	<u>43,806</u>
Operating income	7,072	6,367	813
Other income (expense):			
Interest income	421	148	77
Interest expense	—	—	(5)
Other, net	<u>2</u>	<u>(3)</u>	<u>17</u>
Income before income taxes	7,495	6,512	902
Income taxes	<u>967</u>	<u>85</u>	<u>—</u>
Net income	6,528	6,427	902
Preferred stock dividends	<u>1,600</u>	<u>1,600</u>	<u>1,629</u>
Net income (loss) allocable to common stockholders	<u>\$ 4,928</u>	<u>\$ 4,827</u>	<u>\$ (727)</u>
Basic net income (loss) per share allocable to common stockholders	<u>\$ 0.35</u>	<u>\$ 0.40</u>	<u>\$ (0.06)</u>
Diluted net income (loss) per share allocable to common stockholders	<u>\$ 0.34</u>	<u>\$ 0.38</u>	<u>\$ (0.06)</u>
Weighted average shares used in computing per share amounts:			
Basic	<u>14,264,687</u>	<u>12,094,638</u>	<u>11,234,652</u>
Diluted	<u>14,500,637</u>	<u>12,836,364</u>	<u>11,234,652</u>

See accompanying notes to consolidated financial statements.

**COLLAGENEX PHARMACEUTICALS, INC.
AND SUBSIDIARIES**

**Consolidated Statements of Stockholders' Equity
Years ended December 31, 2004, 2003 and 2002**

	Series D Cumulative Convertible Preferred Stock		Common Stock		Common Stock to be Issued	Additional Paid-In Capital	Accumulated Other Comprehensive Income (loss)	Accumulated Deficit	Total Stockholders' Equity	Total Comprehensive Income
	Number of Shares	Par Value	Number of Shares	Par Value						
	(Dollars in thousands)									
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	\$ 902
Balance, December 31, 2002	200,000	2	11,377,631	114	—	82,917	—	(74,681)	8,352	\$ 902
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	\$ 6,427
Balance, December 31, 2003	200,000	2	13,842,200	138	—	103,670	—	(69,854)	33,956	\$ 6,427
Exercise of common stock options and warrants	—	—	543,677	6	—	2,346	—	—	2,352	
Cash dividends declared on Series D cumulative convertible preferred stock	—	—	—	—	—	—	—	(1,600)	(1,600)	
Net income	—	—	—	—	—	—	—	6,528	6,528	\$ 6,528
Net unrealized loss on short-term investments	—	—	—	—	—	—	(21)	—	(21)	
Total comprehensive income	—	—	—	—	—	—	—	—	—	\$ 6,507
Balance, December 31, 2004	200,000	\$ 2	14,385,877	\$ 144	\$ —	\$ 106,016	—	\$(64,926)	\$ 41,215	\$ 6,507

See accompanying notes to consolidated financial statements.

**COLLAGENEX PHARMACEUTICALS, INC.
AND SUBSIDIARIES**

**Consolidated Statements of Cash Flows
Years ended December 31, 2004, 2003 and 2002**

	2004	2003	2002
	(Dollars in thousands)		
Cash flows from operating activities:			
Net income	\$ 6,528	\$ 6,427	\$ 902
Adjustments to reconcile net income to net cash provided by operating activities:			
Noncash compensation expense	—	251	—
Depreciation and amortization expense	875	954	524
Accounts receivable provisions	2	42	43
Gain on sale of UK and European dental assets (note 11)	(2,980)	—	—
Charge for in-process research and development	300	—	—
Change in assets and liabilities:			
Accounts receivable	(1,199)	(2,713)	1,874
Inventories	(1,020)	(257)	(13)
Prepaid expenses and other assets	(380)	(688)	156
Accounts payable	376	(258)	(163)
Accrued expenses	326	1,314	681
Deferred revenue	(122)	(235)	(53)
Net cash provided by operating activities	2,706	4,837	3,951
Cash flows from investing activities:			
Capital expenditures	(292)	(305)	(298)
Net proceeds from the sale of UK and European dental assets (note 11)	2,980	—	—
Acquisition of product rights	—	(900)	(800)
Purchase of in-process research and development	(150)	—	—
Purchase of short-term investments	(26,777)	—	—
Net cash used in investing activities	(24,239)	(1,205)	(1,098)
Cash flows from financing activities:			
Net proceeds from issuance of common stock	2,352	20,526	1,341
Payment of preferred dividends	(1,600)	(1,600)	(218)
Repayment of long-term debt	—	—	(35)
Net cash provided by financing activities	752	18,926	1,088
Net (decrease) increase in cash and cash equivalents	(20,781)	22,558	3,941
Cash and cash equivalents at beginning of year	32,670	10,112	6,171
Cash and cash equivalents at end of year	\$ 11,889	\$32,670	\$10,112
Supplemental schedule of noncash investing and financing activities:			
Common stock dividends issued or issuable on preferred stock	\$ —	\$ —	\$ 1,451
Accrued liability for licenses	\$ 150	\$ —	\$ 900
Cash dividends declared but not paid on preferred stock	\$ 800	\$ 800	\$ 800
Issuance of warrants to purchase common stock in connection with equity line	\$ —	\$ —	\$ 248
Supplemental disclosure of cash flow information:			
Cash paid during the year for interest	\$ —	\$ —	\$ 5
Cash paid during the year for income taxes	\$ 25	\$ 197	\$ —

See accompanying notes to consolidated financial statements.

**COLLAGENEX PHARMACEUTICALS, INC.
AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements
December 31, 2004, 2003 and 2002
(Dollars in thousands, except per share data)**

(1) Business

CollaGenex Pharmaceuticals, Inc. and subsidiaries ("CollaGenex" or the "Company") was incorporated in Delaware on January 10, 1992. The Company is a specialty pharmaceutical company focused on developing and marketing 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 periodontitis, 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"). The Company also sells a branded version of Periostat to United Research Laboratories, Inc./Mutual Pharmaceutical Company, Inc. ("Mutual") pursuant to a licensing agreement with Mutual executed in April 2004 that was part of a settlement of outstanding patent litigation. Mutual distributes this product through the major U.S. drug wholesalers and retail chains.

During 2002 and 2003, the Company also co-promoted Vioxx[®] under an agreement with Merck and Co. ("Merck") and Denavir[®] under an agreement with Novartis Consumer Health, Inc. ("Novartis") to dental professionals on a contract basis. In March 2003, the Company was engaged in an agreement with Sirius Laboratories, Inc. ("Sirius") to co-promote Sirius' AVAR[™] product line and the Company's Pandel product line to dermatologists in the United States. The co-promotion agreements with Merck, Novartis and Sirius expired or were mutually terminated as of December 31, 2003. The Company continues to earn nominal residual revenues under its non-compete provisions from Merck through 2005.

(2) Summary of Significant Accounting Policies

Principles of Consolidation

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.

Cash, Cash Equivalents and Short-term Investments

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. Cash equivalent investments are held at amortized cost, which approximates fair value. The Company's short-term investments are primarily composed of money market funds, commercial paper and government notes. At December 31, 2004, all of the Company's short-term investments, carried at fair value, were classified as available-for-sale with unrealized gains and losses included as a separate component of equity. The gross unrealized loss on short-term investments was \$21 at December 31, 2004.

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, 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.

**COLLAGENEX PHARMACEUTICALS, INC.
AND SUBSIDIARIES**

Notes to Consolidated Financial Statements — (Continued)

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 are calculated using the straight-line method over the estimated useful lives of the assets or the related lease term, whichever is shorter, and are generally three to ten years. Expenditures for repairs and maintenance are expensed as incurred.

Segment Information

The Company operates as one business that is managed by a single management team reporting to the chief executive officer. The Company does not prepare discrete financial information with respect to separate product or product candidate 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. Short-term investments are carried at fair value.

Net Product Sales

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, Denavir and the AVAR products were fee-based arrangements and recognized according to the provisions of each collaborative agreement. The Company did not take title to the products being promoted under these arrangements. These arrangements were terminated during 2003. Contract revenues recorded during 2004 represent residual contract revenues for Vioxx.

License Revenue

Milestone revenue from license arrangements is recognized upon completion of the milestone event 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, "Revenue Recognition" (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 2004, 2003, and 2002, respectively, the Company recorded \$140, \$52 and \$59 in license revenues that were deferred upon the implementation of SAB 101 and previously recognized as license revenues under the historical revenue recognition policy prior to the adoption of SAB 101. The Company's 2004 license revenues included \$96 of previously unamortized upfront licensing fees related to European licensing agreements that were transferred to Alliance Pharma plc ("Alliance") as part of the sale of certain U.K. and European dental assets in November 2004 (see note 11).

**COLLAGENEX PHARMACEUTICALS, INC.
AND SUBSIDIARIES**

Notes to Consolidated Financial Statements — (Continued)

Advertising Costs

The Company records advertising expense when incurred. Such amounts are charged to selling, general and administrative expenses in the consolidated statements of operations for 2004, 2003 and 2002 were \$24, \$139 and \$3,091, respectively.

Research and Development

Research and development expenses consist primarily of personnel costs, in-process research and development charges and 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 tax rates and laws expected to 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 that 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 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. The Company has elected to account for stock-based compensation under Accounting Principles Board (APB) Opinion No. 25, "Accounting for Stock Issued to Employees", and related interpretations. 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 common 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 (if any), 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.

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 method of accounting in accordance with SFAS No. 123, as amended by SFAS No. 148, "Accounting For

**COLLAGENEX PHARMACEUTICALS, INC.
AND SUBSIDIARIES**

Notes to Consolidated Financial Statements — (Continued)

Stock Based Compensation — Transition and Disclosures and Amendment of SFAS 123” which assumes the fair value method of accounting had been adopted using the assumptions described in note 7:

	<u>2004</u>	<u>2003</u>	<u>2002</u>
Net income (loss) allocable to common stockholders:			
As reported	\$ 4,928	\$ 4,827	\$ (727)
Add: Stock-based employee compensation expenses included in net income (loss) allocable to common stockholders	—	251	—
Less: Stock-based employee compensation under fair value based method	<u>(3,679)</u>	<u>(5,015)</u>	<u>(3,735)</u>
Pro forma net income (loss)	<u>\$ 1,249</u>	<u>\$ 63</u>	<u>\$ (4,462)</u>
Basic net income (loss) per share allocable to common stockholders:			
As reported	<u>\$ 0.35</u>	<u>\$ 0.40</u>	<u>\$ (0.06)</u>
Pro forma net income (loss)	<u>\$ 0.09</u>	<u>\$ 0.01</u>	<u>\$ (0.40)</u>
Diluted net income (loss) per share allocable to common stockholders:			
As reported	<u>\$ 0.34</u>	<u>\$ 0.38</u>	<u>\$ (0.06)</u>
Pro forma net income (loss)	<u>\$ 0.09</u>	<u>\$ 0.01</u>	<u>\$ (0.40)</u>

Concentration of Credit and Other Risks

The Company invests its excess cash in money market funds with major U.S. financial institutions, commercial paper and government notes. The Company has established investment guidelines focused on protecting the safety and liquidity of this invested cash.

The Company currently contracts with a single source for the domestic manufacturing of Periostat tablets and has an 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 2004, four customers accounted for 33%, 29%, 19% and 14% of net product sales, respectively. These same customers accounted for 32%, 30%, 26% and 8% of gross accounts receivable balances as of December 31, 2004. During 2003, three customers accounted for 43%, 31% and 20% of net product sales, respectively. These same customers accounted for 49%, 28% and 18% of the gross accounts receivable balance as of December 31, 2003. During 2002, three customers accounted for 32%, 24% and 19% of net product sales, respectively.

During the years ended December 31, 2004, 2003 and 2002, Periostat and Mutual’s branded version of Periostat accounted for approximately 88%, 82% and 82% of the Company’s total net revenues, respectively.

Impairment of Long-Lived Assets

The Company evaluates 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 an asset should be evaluated for possible impairment, the Company reviews the realizability of the long-lived assets by comparing the asset’s projected undiscounted net cash flows to its carrying value.

**COLLAGENEX PHARMACEUTICALS, INC.
AND SUBSIDIARIES**

Notes to Consolidated Financial Statements — (Continued)

Impairment, if any, is recognized as the difference between the asset carrying value and its fair value. No such adjustments were recorded in 2004, 2003 or 2002.

Net Income (Loss) Per Share

Basic income per share (EPS) is calculated by dividing net 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 and/or convertible securities were converted into common stock.

As of December 31, 2002, the Company had outstanding stock options and stock warrants that were not included in the calculation of diluted net per share allocable to common stockholders because doing so would have been anti-dilutive. During the years ended December 31, 2004, 2003 and 2002, the Company had approximately 2,000,000 of potential common stock shares from convertible preferred stock that were not included in the calculation of diluted net income (loss) per share allocable to common stockholders because doing so would have been anti-dilutive. There were no common stock equivalents used in the calculation of diluted loss per share in 2002. For the years ended December 31, 2004 and 2003, common stock equivalents were 235,950 and 741,726, respectively, as a result of in-the-money stock options and warrants calculated using the treasury method.

Recently Issued Accounting Standards

In December 2004, the Financial Accounting Standards Board issued SFAS No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123R"), which replaces SFAS No. 123, "Accounting for Stock Issued to Employees" and supercedes APB Opinion No. 25. SFAS 123R requires all share-based payments to employees, including grants of employee stock options and purchases under the employee stock purchase plan and liabilities that are based on the fair value of the Company's equity instruments or that may be settled by the issuance of such equity instruments, to be recognized in the financial statements based on their fair values. The pro forma disclosures previously permitted under SFAS 123, no longer will be an alternative to financial statement recognition. The Company is required to adopt SFAS 123R no later than its third quarter of fiscal 2005. Under SFAS 123R, the Company must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at date of adoption. The transition methods include prospective and retroactive adoption options. Under the retroactive options, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The prospective method requires that compensation expense be recorded at the beginning of the first quarter of adoption of SFAS 123R for all unvested stock options and restricted stock based upon the previously disclosed SFAS 123 methodology and amounts. The retroactive methods would record compensation expense beginning with the first period restated for all unvested stock options and restricted stock. We expect the adoption of SFAS 123 will have a material impact on our results of operations and earnings per share. We are evaluating the requirements of SFAS 123R and have not yet determined the method of adoption and we have not determined whether this adoption will result in amounts that are similar to the current pro forma disclosures under SFAS No. 123 in Note 2 to these consolidated financial statements.

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs — An amendment of ARB No. 43, Chapter 4" ("SFAS 151"). SFAS 151 amends the guidance in ARB No. 43, Chapter 4, "Inventory Pricing," to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). Among other provisions, the new rule requires that items such as idle facility expense, extensive spoilage, double freight, and rehandling costs be recognized as current-period charges regardless of whether they meet the criterion of "so abnormal" as stated in ARB No. 43. Additionally,

**COLLAGENEX PHARMACEUTICALS, INC.
AND SUBSIDIARIES**

Notes to Consolidated Financial Statements — (Continued)

SFAS No. 151 requires that the allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. SFAS No. 151 is effective for fiscal years beginning after June 15, 2005 and is required to be adopted by the Company in the first quarter of 2006. The Company is currently in the process of evaluating the impact that SFAS No. 151 will have on the results of operations and financial position of the Company.

Reclassification

Certain amounts in the 2003 and 2002 consolidated financial statements have been reclassified to conform to the 2004 presentation.

(3) Composition of Certain Financial Statement Captions

Inventories

Inventories at December 31, 2004 and 2003 consist of the following:

	<u>2004</u>	<u>2003</u>
Raw materials	\$ 395	\$ 396
Work-in-process	394	52
Finished goods	<u>1,903</u>	<u>1,224</u>
	<u>\$2,692</u>	<u>\$1,672</u>

Equipment and Leasehold Improvements

Equipment and leasehold improvements at December 31, 2004 and 2003 consist of the following:

	<u>2004</u>	<u>2003</u>	<u>Useful Life</u>
Computer and office equipment	\$ 1,365	\$ 1,133	3-5 years
Exhibit equipment	496	451	5 years
Leasehold improvements	60	45	Shorter of 10 years or lease term
	<u>1,921</u>	<u>1,629</u>	
Less: accumulated depreciation and amortization	<u>(1,423)</u>	<u>(1,133)</u>	
	<u>\$ 498</u>	<u>\$ 496</u>	

Acquired Product Rights

Acquired product rights at December 31, 2004 and 2003 consist of the following:

	<u>2004</u>	<u>2003</u>
Acquired product rights	\$ 2,700	\$2,700
Less: accumulated amortization	<u>(1,536)</u>	<u>(951)</u>
	<u>\$ 1,164</u>	<u>\$1,749</u>

**COLLAGENEX PHARMACEUTICALS, INC.
AND SUBSIDIARIES**

Notes to Consolidated Financial Statements — (Continued)

Amortization expense, which is included in cost of product sales, was \$585, \$586 and \$366 in 2004, 2003 and 2002, respectively. Expected amortization of acquired product rights is as follows:

2005	\$ 586
2006	100
2007	100
2008	100
2009	100
Thereafter	<u>178</u>
	<u>\$1,164</u>

Accrued Expenses

Accrued expenses at December 31, 2004 and 2003 consist of the following:

	<u>2004</u>	<u>2003</u>
Contracted development and manufacturing costs	\$1,648	\$ 835
Sales and marketing costs	212	202
Payroll and related costs	1,731	1,925
Professional and consulting fees	159	922
Royalties	212	189
Deferred revenue	54	52
Foreign taxes	945	85
Product returns	592	827
Miscellaneous taxes	99	139
Other	<u>145</u>	<u>145</u>
	<u>\$5,797</u>	<u>\$5,321</u>

(4) Stockholders' Equity

The Company's Board of Directors may, without further action by the Company's stockholders, direct the issuance and determine the rights, preferences and limitations of one or more series of shares of preferred stock. 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 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 then 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 paid dividends in cash at a rate of 8.0% per annum. Beginning May 12, 2005, the dividend rate will increase 100 basis points per year if the preferred stock has not yet been converted into common stock. Dividends totaling \$1,600, \$1,600 and \$1,629 were declared in 2004, 2003 and 2002, respectively.

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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), 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 the Company issues new equity securities or convertible securities at a price per share or having a conversion price per share lower than the conversion price of the preferred stock at that time (see below and note 5).

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 issued an aggregate of 400,000 warrants that were exercisable for up to three years into 400,000 shares of the Company's common stock at an exercise price of \$6.00 per share. The consideration received for such warrants is included in the aggregate proceeds received in the financing. During 2004, all 400,000 of these warrants were exercised into 189,043 shares of the Company's common stock. The Company also issued 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, to its financial advisor in this financing. 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, 2004. 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 5).

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.

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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 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, 2004.

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 there under. 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 per share. All Rights expire on September 26, 2007 unless earlier redeemed. At December 31, 2004, 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 October 2003, the Company sold 2,000,000 shares of its common stock in a public offering 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.

(5) Acquisition/Licensing/Co-Promotion Agreements

On August 19, 2004, the Company executed an Asset Purchase and Product Development Agreement (the "Purchase Agreement") relating to its Restoraderm technology that superseded its Co-operation, Development and License Agreement executed in February 2002. Under the terms of the Purchase Agreement, the Company purchased all right, title and interest in the intellectual property and related rights to the Restoraderm™ topical drug delivery system. The Company intends to develop Restoraderm for dermatological applications. In accordance with the terms of the Purchase Agreement, the purchase price of the assets will be up to \$1,000 subject to the achievement of certain milestones. The Company is also required to pay product development milestone payments in the aggregate amount of up to approximately \$2,000 and royalty and sublicense fees, if applicable, upon product commercialization. During the year-ended December 31,

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2004, the Company incurred approximately \$300 in research and development expenses related to the asset purchase and approximately \$133 related to the product development milestones, which was charged to research and development in the consolidated statement of operations. The purchase was charged to in-process research and development since the Restoraderm technology has not achieved technical feasibility at this time.

Pursuant to a Co-Promotion Agreement the Company executed with Merck & Co., Inc. in September 1999, the Company received the exclusive right to co-promote Vioxx[®], a prescription strength non-steroidal anti-inflammatory drug. 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 such Co-Promotion Agreement which expired on December 31, 2003. The Company will continue to earn nominal residual contract revenues through 2005 from this agreement. The Co-Promotion Agreement also provides for indemnification of the Company by Merck against any claims arising from manufacturing or design defects in the product or for which the Company, as the promoter of the product, may be strictly liable as if it had been a seller of an inherently dangerous product. During the year-ended December 31, 2004, the Company recorded \$237 in residual contract revenues under this agreement.

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 \$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. On an annual basis commencing with fiscal year 2003, the Company is required to make marketing expenditures to promote the Atrix dental products equal to the lesser of \$4,000 or 30% of the Company's contribution margin, as defined in the agreement, for the promotion of a specific Atrix product that the Company markets plus the lesser of \$2,000 or 30% of the Company's contribution margin, as defined in the agreement, for the promotion of a separate Atrix product that the Company markets. These annual requirements were met by the Company in 2003 and 2004.

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 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 its agreement, the Company paid Altana an aggregate sublicense fee of \$1,700, of which \$800 was paid in September 2002 and \$900 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

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Notes to Consolidated Financial Statements — (Continued)

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. for the marketing and distribution of Periostat in Italy. 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.

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

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.

(6) Line of Credit

On June 7, 2004, the Company entered into a Loan Modification Agreement with Silicon Valley Bank to renew and extend its revolving credit facility. The credit facility had expired on March 15, 2004. The amended credit facility expires on May 31, 2006. Under the amended credit facility, the Company may borrow up to the lesser of \$5,000 or 80% of eligible accounts receivable, as defined under the amended credit facility. The amount available to the Company is reduced by any outstanding letters of credit which may be issued under the amended credit facility in amounts totaling up to \$2,000. As the Company pays down amounts under any letter of credit, the amount available to it under the credit facility increases. As of December 31, 2004, the Company had an outstanding letter of credit approximating \$544 that served as collateral for certain future inventory purchase commitments of the Company, if any. The Company is not obligated to draw down any amounts under the amended credit facility and any borrowings shall bear interest, payable monthly, at the current prime rate. As of December 31, 2004 and 2003, the Company had no borrowings outstanding.

(7) Stock Option Plans

The Company has three stock-based compensation plans:

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 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 value on the measurement date. Incentive 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 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.

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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 value on the date of grant. Such options vest 20% per annum commencing one year from the grant date.

During 2004, 2003 and 2002, certain existing members of the Board of Directors were granted 116,907, 74,500 and 62,136 options, respectively, at a weighted average fair value exercise price of \$9.10, \$10.80 and \$6.60 per share, respectively. These grants were issued under the 1996 Plan. Such options vest 25% per annum, commencing one year from the grant date.

At December 31, 2004, there were 533,819 shares available for grant under the 1996 Plan and 75,000 under the Nonemployee Director Plan.

The following table summarizes stock option activity for 2002 through 2004:

	<u>Options</u>	<u>Weighted Average Exercise Price Per Share</u>
Balance, December 31, 2001	2,452,609	\$ 9.15
Granted	616,086	7.91
Exercised	(31,050)	4.70
Cancelled	<u>(82,475)</u>	<u>9.90</u>
Balance, December 31, 2002	2,955,170	8.91
Granted	899,350	10.23
Exercised	(374,374)	4.52
Cancelled	<u>(47,142)</u>	<u>10.38</u>
Balance, December 31, 2003	3,433,004	9.72
Granted	744,007	9.12
Exercised	(354,634)	6.19
Cancelled	<u>(551,154)</u>	<u>10.95</u>
Balance, December 31, 2004	<u>3,271,223</u>	<u>\$ 9.76</u>

As of December 31, 2004, the following options were outstanding and exercisable by price range as follows:

<u>Range of Exercise Prices</u>	<u>Outstanding</u>			<u>Exercisable</u>	
	<u>Number of Options</u>	<u>Weighted Average Remaining Contractual Life (in Years)</u>	<u>Weighted Average Exercise Price Per Share</u>	<u>Number of Options</u>	<u>Weighted Average Exercise Price Per Share</u>
\$ 0.33 - \$ 2.00	26,500	0.3	\$ 0.59	26,500	\$ 0.59
\$ 4.50 - \$ 6.99	622,553	7.2	\$ 5.82	335,975	\$ 5.43
\$ 7.01 - \$ 8.88	453,620	6.9	\$ 8.06	291,120	\$ 8.05
\$ 9.00 - \$11.88	1,693,720	7.0	\$10.10	677,037	\$ 9.91
\$12.00 - \$24.25	474,830	4.5	\$15.84	459,330	\$15.77
	<u>3,271,223</u>	<u>6.6</u>	<u>\$ 9.76</u>	<u>1,789,962</u>	<u>\$10.13</u>

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The weighted average fair values of stock options granted to employees during 2004, 2003 and 2002 were \$6.75, \$6.39 and \$6.07 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:

	<u>2004</u>	<u>2003</u>	<u>2002</u>
Expected life in years —			
Employees and directors	7.02	7.00	7.00
Risk-free interest rate	3.87%	3.52%	4.30%
Volatility	80%	81%	83%
Expected dividend yield	—%	—%	—%

On September 18, 2002, the Company executed agreements with the current 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, 2004, there were 76,000 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 recorded compensation expense of \$29, 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.

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.

On December 8, 2003, the Company granted stock options to Colin W. Stewart, its 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 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; this did not occur during 2004.

(8) 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 and for loss and credit carry forwards using currently enacted tax rates. The provision for income taxes is as follows:

	<u>Year Ended December 31,</u>		
<u>Current</u>	<u>2004</u>	<u>2003</u>	<u>2002</u>
Federal	\$ 22	\$80	\$—
Foreign	945	—	—
State	—	5	—
	<u>\$967</u>	<u>\$85</u>	<u>\$—</u>

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Reconciliations of the income tax expense from the Federal statutory rates for 2004, 2003 and 2002 are as follows:

	Year Ended December 31,					
	2004		2003		2002	
Statutory Federal income tax	\$ 2,541	34.0%	\$ 2,214	34.0%	\$ 307	34.0%
Adjustments resulting from:						
Foreign income taxed at different rates	16	0.2	—	—	—	—
State taxes, net of Federal benefit ...	—	—	3	—	16	1.8
Permanent items and others	87	1.1	(316)	(4.8)	221	24.5
Decrease in valuation allowance	<u>(1,677)</u>	<u>(22.4)</u>	<u>(1,816)</u>	<u>(27.9)</u>	<u>(544)</u>	<u>(60.3)</u>
Total income tax expense	<u>\$ 967</u>	<u>12.9%</u>	<u>\$ 85</u>	<u>1.3%</u>	<u>\$ —</u>	<u>—%</u>

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liability at December 31, 2004 and 2003 are presented below:

	2004	2003
Deferred tax assets:		
Depreciation and amortization	\$ 356	\$ 244
Net operating loss carryforwards	20,184	21,737
Tax credit carryforwards	1,043	973
Accrued expenses	921	1,190
Deferred revenue	<u>96</u>	<u>134</u>
Total gross deferred assets	22,600	24,277
Less valuation allowance	<u>(22,600)</u>	<u>(24,277)</u>
Net deferred taxes	<u>\$ —</u>	<u>\$ —</u>

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, 2004 and 2003. While the Company has been profitable for the past two years, uncertainty regarding patent litigation has prevented the Company from reaching the "more likely than not" conclusion required under the applicable literature to recognize deferred tax assets on its consolidated balance sheet.

The net change in the valuation allowance for the years ended December 31, 2004 and 2003 was a decrease of approximately \$1,677 and \$1,816, respectively, related primarily to utilization of net operating losses in 2004 and 2003.

At December 31, 2004, 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 carryforwards will begin expiring in 2010 and 2006, respectively, if not utilized. Included in the Company's net operating loss carryforward are deductions relating to the exercise of non-qualified stock options in the amount of \$7,926, which tax benefit will be credited to additional paid-in capital to the extent such tax assets

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are realized in the future. The Company also has research and development tax credit carryforwards of approximately \$893 available to reduce Federal income taxes which begin expiring in 2007.

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, 2004, approximately \$38,000 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.

(9) 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 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 patents underlying the technology license are deducted from royalties paid to SUNY (See note 14). 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 \$1,933, \$1,832 and \$1,563 in 2004, 2003 and 2002, respectively.

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

(10) Sales Force Restructuring

On April 22, 2004, the Company announced the restructuring of the Company's pharmaceutical sales organization into dedicated dental and dermatology sales forces. The restructuring is intended to increase the Company's sales focus on high-prescribing dentists and dermatologists while reducing the Company's cost base. The Company incurred a \$348 restructuring charge included in SG&A during the year ended December 31, 2004. As of December 31, 2004, approximately \$323 of these restructuring costs had been paid by the Company.

(11) Sale of U.K. and European Dental Assets

On November 3, 2004, CollaGenex International Ltd ("CIL"), a wholly-owned U.K. subsidiary of the Company, sold its U.K. and European dental assets to Alliance, a U.K. specialty pharmaceuticals company, for net proceeds of \$2,980. This agreement provided for the sale by CIL to Alliance of certain trademark rights, U.K. and European governmental marketing authorizations, distribution agreements and other intangible assets relating to the sale or potential sale of Periostat in the U.K., Europe, Israel, South Africa, New Zealand and Australia. The agreement also granted Alliance an option to acquire a license to register and market Periostat-MR™, a once-daily, modified release form of Periostat, for adult periodontitis in the same territories. The Company has retained all rights to Periostat-MR for all other clinical indications. The Company also entered into a Supply Agreement with Alliance pursuant to which the Company will supply Periostat in bulk tablet form to Alliance at a negotiated fair value transfer price.

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The Company recorded net proceeds of \$2,980 from the sale during the year ended December 31, 2004. The net proceeds represent the \$3,300 payment from Alliance less professional fees incurred in connection with the transaction. As a result of the transaction, the Company also recognized \$96 in previously deferred license revenues during the year ended December 31, 2004. The Company also recognized \$74 in net product sales related to a bulk shipment of Periostat to Alliance during the year ended December 31, 2004.

(12) Commitments and Contingencies

The Company maintains various operating leases, primarily for office space and equipment. As of December 31, 2004, future minimum payments under noncancellable operating leases are as follows:

2005	\$ 554
2006	554
2007	360
2008	334
Thereafter	<u>195</u>
Total	<u>\$1,997</u>

Rent expense for the years ended December 31, 2004, 2003 and 2002 totaled \$520, \$327 and \$356, respectively.

During 2003, the Company entered into a three-year operating lease agreement for certain sales force 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 5), beginning in 2003, the Company is required to make certain annual minimum expenditures equal to the lesser of \$4,000 or 30% of the Company's contribution margin, as defined in the agreement, relating to the promotion of specific Atrix product that the Company markets plus the lesser of \$2,000 or 30% of the Company's contribution margin, as defined in the agreement, relating to the promotion of a separate Atrix product that the Company markets. The Company met these spending requirements in 2004 and 2003.

On June 10, 2002, the Company executed a Development and Licensing Agreement with Shire Laboratories, Inc. ("Shire") pursuant to which the Company was granted an exclusive worldwide license (including the right to sublicense) to use Shire's drug delivery technology to develop, make, have made, use, supply, export, import, register and sell products for the treatment of various inflammatory disorders. The Company committed to make certain future payments to Shire, 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. Assuming the successful development of products currently in development using the Shire technology, these future payments would be \$5,200 in the aggregate. The Company will also pay a royalty on future net sales of products, if any, utilizing any part of the technology. The Company may terminate the agreement upon sixty days notice.

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 and, until December 2005, will act as a consultant to the Company. The Company paid \$324 and \$20 in consulting fees to Dr. Gallagher for the years ended December 31, 2004 and 2003, respectively, and expects to pay \$304 in consulting fees in 2005. In 2003, the Company also recognized a non-cash stock compensation charge of approximately \$251 relating to certain modifications of Dr. Gallagher's stock option agreements.

**COLLAGENEX PHARMACEUTICALS, INC.
AND SUBSIDIARIES**

Notes to Consolidated Financial Statements — (Continued)

(13) Legal Settlements and Proceedings

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 adult periodontitis, which the Company believed would infringe patents covering the Company’s Periostat product. On November 7, 2003, the Company settled all pending litigation between the Company and West-ward. In the settlement, 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. In connection with this settlement, the Company agreed to pay a portion of West-ward’s actual legal expenses in the amount of \$700, which was recorded in 2003.

In July 2003, the Company commenced an action against United Research Laboratories/Mutual Pharmaceuticals Inc. (“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 alleged infringement of patents covering the Company’s Periostat product. On April 8, 2004, the Company announced that it had settled all pending litigation between the Company and Mutual. In the settlement, Mutual agreed and confessed to judgment that the Company’s Periostat patents are valid and would be infringed by the commercial manufacture, use, sale, importation or offer for sale of the generic version of Periostat for which Mutual had submitted its Abbreviated New Drug Application, or ANDA. The Company paid to Mutual \$2,000, which represented a portion of the anticipated fees and expenses that the Company would save as a result of the settlement of the pending actions with Mutual. This charge was recorded in 2004.

In connection with the settlement, the Company and Mutual entered into a License and Supply Agreement pursuant to which Mutual received a license to sell a branded version of Periostat. The Company will be the sole supplier of this product to Mutual, subject to certain conditions. The product will be sold to Mutual at prices below the Company’s average manufacturer’s price for Periostat through May 15, 2007 or the earlier termination of such supply arrangements. Early termination may occur under certain circumstances, including the successful entry of a third party generic competitor to Periostat.

The Company also agreed to provide price adjustment payments to Mutual if a generic version of Periostat becomes available on the market at a price lower than the selling price of Mutual’s branded version of Periostat. If a generic product had been introduced at December 31, 2004 at an initial price equivalent to 60% of the wholesale acquisition price of Periostat, the Company would have been obligated to provide price adjustment payments to Mutual of approximately \$2,000 to \$2,300, based on the estimated number of bottles in Mutual’s inventory and the inventory of Mutual’s customers at December 31, 2004.

On October 1, 2004, the Company filed a complaint for patent infringement against Ivax Pharmaceuticals, Inc. (“IVAX”) and CorePharma LLC (“CorePharma”) in the United States District Court for the Eastern District of New York. In the Company’s complaint, the Company alleged that the submission of ANDAs by each of IVAX and CorePharma for 20 mg tablets of doxycycline hyclate infringed United States Patent RE 34,656, for which the Company is the exclusive licensee. The Company also alleged that any manufacture, importation, marketing and sale of generic 20 mg tablets of doxycycline hyclate by IVAX and CorePharma would infringe the RE 34,656 patent. In addition, the Company applied to the United States District Court for the Eastern District of New York, seeking a temporary restraining order and a preliminary injunction preventing IVAX and CorePharma from introducing 20 mg tablets of doxycycline hyclate into the market in the United States until its patent claims have been resolved. The Company’s motion was considered and discussed during a telephone conference with the Court on January 21, 2005. A full hearing on the merits of the motion was conducted on January 31, 2005.

**COLLAGENEX PHARMACEUTICALS, INC.
AND SUBSIDIARIES**

Notes to Consolidated Financial Statements — (Continued)

(14) Legal Expenses to Defend Periostat Patents

Under the Company's license agreement with SUNY covering Periostat, the Company is entitled to deduct costs incurred to defend its patents, including the \$2,700 in settlement payments to Mutual and West-Ward, from current and future royalties due to SUNY on net sales of products based on the SUNY technology. During the year ended December 31, 2004, the Company incurred \$4,116 (which included the \$2,000 Mutual settlement) in legal defense, litigation and settlement costs, of which \$1,933 was deducted from royalties payable to SUNY and reduced the Company's general and administrative expenses during this period. For the year ended December 31, 2003, the Company incurred \$3,757 (which included the \$700 Westward settlement) in legal defense, litigation and settlement costs respectively, of which \$1,750 was deducted from royalties payable to SUNY during this period. The cumulative legal patent defense, litigation and settlement costs incurred to date exceed the amount of the royalties payable to SUNY, earned during the litigation period, as of December 31, 2004 by \$3,931. These amounts, which have been expensed, will be available to offset future royalties earned by SUNY, if any, on net sales of products based on the SUNY technology.

(15) 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, 2004, 2003 and 2002, the Company made a discretionary contribution of \$100 to the Plan.

(16) 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.

(17) Quarterly Financial Data (Unaudited)

The tables below summarize the Company's unaudited quarterly operating results for 2004 and 2003:

	Three Months Ended			
	March 31, 2004	June 30, 2004	September 30, 2004	December 31, 2004
Total revenues	\$13,406	\$14,445	\$11,075	\$13,220
Gross margin on product sales	11,327	12,320	9,454	11,192
Net income (loss)	(34)	1,998	1,125	3,439
Net income allocable to common stockholders	(434)	1,598	725	3,039
Basic and diluted net income (loss) per share allocable to common stockholders(1)	\$ (0.03)	\$ 0.11	\$ 0.05	\$ 0.21

**COLLAGENEX PHARMACEUTICALS, INC.
AND SUBSIDIARIES**

Notes to Consolidated Financial Statements — (Continued)

	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(1)	\$ 0.07	\$ 0.10	\$ 0.07	\$ 0.14
Diluted net income per share allocable to common stockholders(1)	\$ 0.07	\$ 0.10	\$ 0.06	\$ 0.14

(1) Quarterly figures do not summate to annualized figure due to rounding.

COLLAGENEX PHARMACEUTICALS, INC. AND SUBSIDIARIES

FINANCIAL STATEMENT SCHEDULE

**Valuation and Qualifying Accounts
Years Ended December 31, 2004, 2003 and 2002**

<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>		
			<u>(In thousands)</u>		
Accounts Receivable Allowance:					
2004	\$481	\$3,755	\$—	\$3,753	\$483
2003	\$475	\$2,693	\$—	\$2,687	\$481
2002	\$530	\$2,706	\$—	\$2,761	\$475

Board of Directors

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

Peter R. Barnett, D.M.D.
President
Star Ranch Dental Spa

Robert A. Beardsley, Ph.D.
President and Chief Executive Officer
Kereos, Inc.

Robert C. Black
Retired President
U.S. Pharmaceuticals Division
AstraZeneca, Inc.

Robert J. Easton
Chairman
Easton Associates, LLC

Brian M. Gallagher, Ph.D.
Former Chairman, President
and Chief Executive Officer
CollaGenex Pharmaceuticals, Inc.

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

Klaus P. Theobald, M.D., Ph.D.
Senior Vice President
and Chief Medical Officer

David F. Pfeiffer
Senior Vice President, Sales and Marketing

Andrew Powell, J. D.
Vice President, General Counsel and
Corporate Secretary

Corporate Information

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

Independent Auditors

KPMG LLP
1601 Market Street
Philadelphia, PA 19103
Phone: 267-256-7000

Legal Counsel

Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109
Phone: 617-526-6000

Transfer Agent

American Stock Transfer & Trust Company
59 Maiden Lane
New York, NY 10038
Phone: 212-936-5100

Annual Meeting

The Annual Meeting of Shareholders will be held on Wednesday, May 25, 2005 at 8:30 a.m. at the Philadelphia Marriott Downtown Hotel, 1201 Market Street, Philadelphia, PA 19107.

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 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 3, 2005, there were approximately 108 holders of record of the company's common stock, which do 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, 2003 through December 31, 2004 as reported on the NASDAQ National Market.

2004	High	Low	2003	High	Low
March 31	\$14.16	\$10.07	March 31	\$11.03	\$6.66
June 30	\$13.21	\$8.70	June 30	\$13.27	\$8.62
September 30	\$9.49	\$6.23	September 30	\$15.84	\$10.50
December 31	\$7.49	\$5.37	December 31	\$11.82	\$8.90

Safe Harbor

Statements contained or incorporated by reference in this Annual Report that are not based on historical fact are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Exchange Act. These forward-looking statements regarding future events and our future results are based on current expectations, estimates, forecasts and projections, and the beliefs and assumptions of our management. We cannot assure investors that our expectations and assumptions will prove to have been correct. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements. Such factors that could cause or contribute to such differences include those factors discussed in our Annual Report on Form 10-K for the year ended December 31, 2004 under the section "Additional Factors That May Affect Future Results" as well as other documents that may be filed by us from time to time with the Securities and Exchange Commission. We undertake no intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.



COLLAGENEX
PHARMACEUTICALS

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