



04027215

PE
12-31-03

IDEA GENERATION

RECD S.E.C.

APR 22 2004

1086

DRUG FORMULATION

CLINICAL DEVELOPMENT

REGULATORY AFFAIRS

PROCESSED

APR 23 2004

THOMSON
FINANCIAL

CORPORATE DEVELOPMENT

PENWEST develops pharmaceutical products based on innovative oral drug delivery technologies. The foundation of our technology platform is **TIMERx®**, an extended release delivery system that is adaptable to soluble and insoluble drugs and that is flexible for a variety of controlled release profiles. We have also developed two additional oral drug delivery systems, **Geminex®** and **SyncroDose™**. **Geminex** is a dual drug delivery system that is designed to provide independent release of different active ingredients contained in a drug, and **SyncroDose** is a drug delivery system that is designed to release the active ingredient of a drug at the desired site and time in the digestive tract.

OPERATING HIGHLIGHTS

COMPLETED SALE OF EXCIPIENT BUSINESS. In February 2003, the sale of the Company's excipient business was completed. Penwest received \$41.75 million in gross proceeds and focused the business on drug development.

FDA ACCEPTED NDA FOR OXYMORPHONE ER IN FEBRUARY 2003. Oxymorphone ER is an extended release formulation of oxymorphone being developed with Endo Pharmaceuticals and incorporates the TIMERx technology. The product will compete in an approximately \$3.3 billion moderate to severe pain market.

RAISED \$52.7 MILLION OF GROSS PROCEEDS IN A COMMON STOCK OFFERING IN AUGUST 2003. Proceeds from this offering will assist in funding the research, development, and commercialization of the Company's products and technologies.

APPROVABLE LETTER FROM FDA FOR OXYMORPHONE ER GRANTED TO ENDO PHARMACEUTICALS IN OCTOBER 2003. This letter represents an important step in advancing oxymorphone ER toward final approval. In the letter, the FDA asked Endo to address certain questions, provide additional clarification and information, and conduct some form of additional trial to further confirm the safety and efficacy before the FDA would approve Endo's NDA for oxymorphone ER.

FINANCIAL HIGHLIGHTS

(amounts in thousands, except per share data)	2003	2002	2001
Revenues	\$ 4,678	\$ 5,537	\$ 5,796
Research & product development	\$ 20,590	\$ 16,955	\$ 16,190
Gain on sale and earnings from discontinued operations	\$ 10,071	\$ 1,929	\$ 833
Net loss	\$ (15,935)	\$ (17,099)	\$ (15,981)
Loss per share	\$ (0.96)	\$ (1.11)	\$ (1.15)
Weighted average shares outstanding	16,678	15,462	13,905
Cash and short term investments	\$ 63,893	\$ 3,686	\$ 21,138
Shareholders' equity	\$ 67,696	\$ 31,423	\$ 45,624

DEAR FELLOW SHAREHOLDERS The past year was one of important advances in Penwest's overall strategic development.

In 2003 we finalized steps to fully focus on drug development, increased our capabilities in the drug development process and took decisive actions to expand our product pipeline using our proprietary oral drug delivery technologies. Importantly, we made significant progress in developing the resources and expertise necessary to generate and develop our own product concepts.

STRATEGIC DIRECTION The year began with the completion in February of the sale of our excipient business to Josef Rettenmaier Holding GmbH & Co. KG. This transaction allowed us to focus all of our energies and resources on executing our drug development strategy, while generating approximately \$40 million in cash to fund the further development of our product pipeline.

We strongly believe that the best way for our company to build long-term value is to use our drug formulation technologies and expertise to develop new products that provide benefits to patients with unmet medical needs. By controlling the drug development process, we believe we can better manage development timelines and retain more value for our shareholders.

Our drug delivery expertise is our clear competitive advantage in executing our drug development strategy. Our drug delivery technologies — TIMERx[®], the foundation of our

technology platform, as well as Geminex[®] and SyncroDose[™] — enable us to turn existing drugs which can be improved with better delivery profiles into new product opportunities for Penwest. By applying our delivery technologies to these existing drugs, we can develop improved formulations — and ultimately better solutions for patients.

MODEL FOR THE FUTURE Perhaps the best way to illustrate where our company is headed is to briefly describe our work this past year on PW2101, our product for the treatment of hypertension. PW2101 is the reformulation of a branded product with current annual sales in the U.S. of approximately \$1 billion. We developed the idea for this product ourselves, formulated it using our TIMERx delivery technology, designed a regulatory strategy and are now completing the development work.

During the fourth quarter of 2003, we completed the final pivotal trial for this product, and announced in the first quarter of 2004 that we met the primary endpoints in that trial. We intend to out-license this product and are currently in discussions with potential marketing partners. With due diligence underway and terms of an agreement being discussed, we anticipate completing a deal in the first half of 2004. We expect to submit a new drug application, or NDA, with the FDA in the second half of 2004.

TOD R. HAMACHEK Chairman and CEO



In addition, we are planning to make an NDA filing for a lower strength formulation of this product during the first quarter of 2005. The development of the lower strength requires an additional clinical trial. We are working with the FDA on study design and endpoints.

PROGRESS ON OXYMORPHONE ER In 2003, we also took several important steps in the regulatory approval process for oxymorphone ER, an extended release formulation of oxymorphone that incorporates the TIMERx technology. Oxymorphone ER is being developed for the treatment of moderate to severe chronic pain.

In February 2003, the FDA accepted Endo's NDA filing for oxymorphone ER. In October 2003, our partner, Endo received an approvable letter for oxymorphone ER. The receipt of this letter was an important step in the process toward launching the product. In the letter, the FDA requested that Endo address certain questions, provide additional clarification and information, and conduct some form of additional clinical trials to further confirm the safety and efficacy of this product. Endo is working with the FDA to clarify the issues raised in the letter, such as whether additional trials will be required, and to determine the appropriate action. While receiving the letter was encouraging, we are disappointed that the nature of the FDA approvable letter makes it difficult to predict the timing of approval by the FDA and the ultimate launch of the product.

PIPELINE GROWTH Consistent with our strategic focus, the development of our product pipeline was a priority in 2003, and we continue to be excited about the products we are developing. We have identified several therapeutic categories that are of particular interest to us, including pain, cardiovascular and the central nervous system (CNS), and have several product concepts in these areas. We also see potential in developing combination therapies. We believe the FDA is becoming more receptive to combination therapies, and our Geminex drug delivery technology lends itself well to the dual delivery of drugs.

We are especially pleased about the products in the early part of the pipeline, with several interesting product concepts that are targeted at utilizing drug delivery to solve unmet medical needs. We will share more of the details about these product candidates if they continue through more advanced stages of development.

CONTINUED FINANCIAL STRENGTH In 2003, we continued to strengthen the company financially. Penwest's market capitalization almost doubled since the end of 2002, and our cash position increased to just under \$64 million at year end 2003. We continued to make significant strategic investments in R&D to advance the development of PW2101 and other products in the pipeline, as well as to invest in the development of new technologies. We believe that this has positioned the Company for continued growth and funding of the continued development of our product pipeline.

THE RIGHT TEAM The year's advancements were possible only due to the commitment and hard work of our talented, experienced people. During the year, we made personnel adjustments to ensure that we have the proper combination of talent and resources to successfully execute our business strategy. Our team, some of whom you will meet in the following pages, is made up of talented scientists, medics, regulatory specialists and market research experts.

Our distinguished Scientific Advisory Board plays a critical role in supporting our work. Our Scientific Advisory Board advises us on our drug product concepts, drug delivery research and technology development, and consults with senior management on strategic issues related to new scientific progress, future trends in medicine, market opportunities, regulatory guidelines, and overall business development.

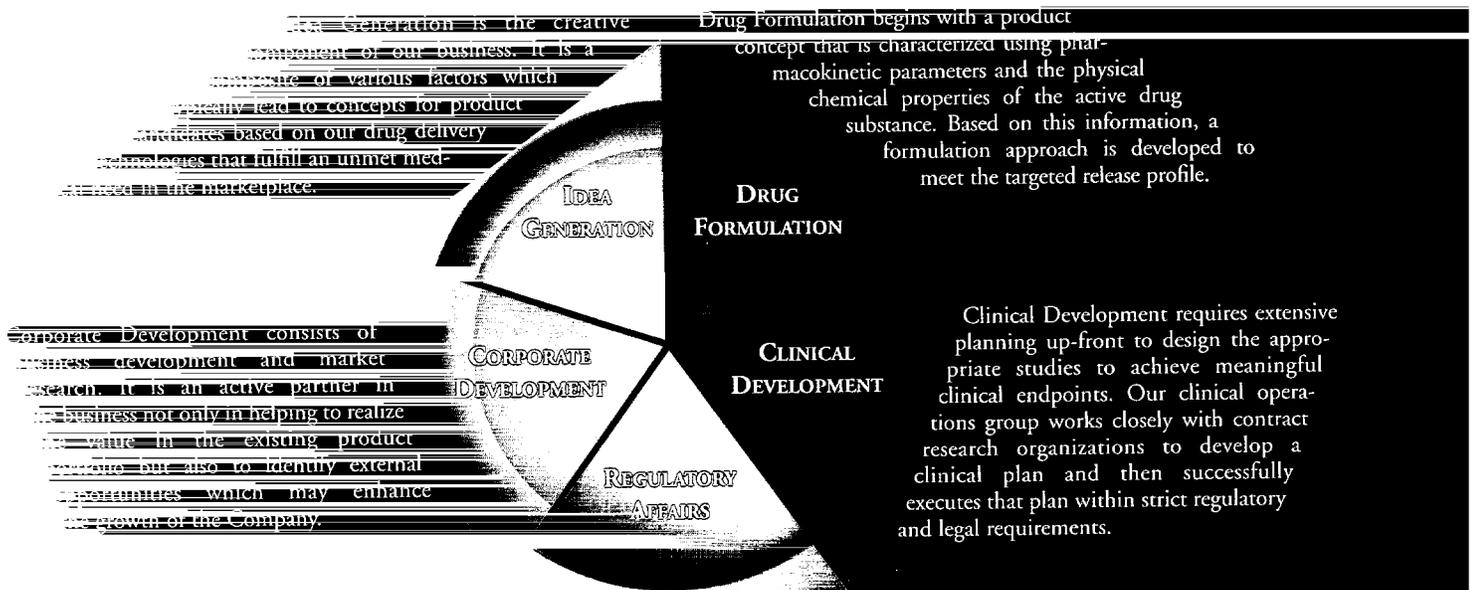
OUR COMMITMENT TO YOU Honesty and integrity are at the heart of everything we do at Penwest. As responsible stewards of our company's business and assets, our Board of Directors and management are always mindful of and act in accordance with our responsibility to our shareholders. We are committed to strong corporate governance, including ensuring that our financial reporting is accurate, complete and transparent. We are also committed to complying fully with the letter and spirit of the provisions of the Sarbanes-Oxley Act of 2002, as well as the rules and regulations of the Securities and Exchange Commission and NASDAQ. Since our inception we have had a Board of Directors with a majority of independent directors as well as an independent lead director. We have adopted a Code of Ethics within the Company as well as the other required charters.

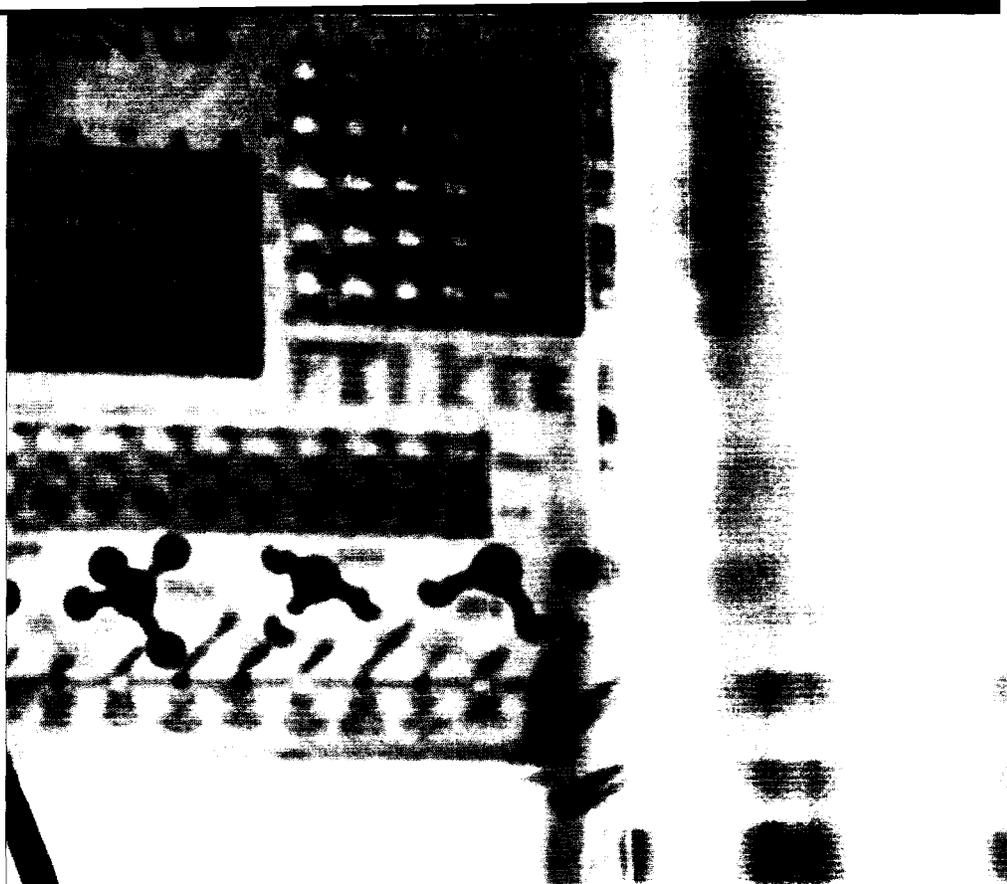
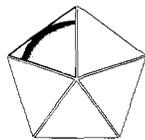
Looking ahead, we plan to build on our accomplishments of the past year. In the coming year, we expect to focus on obtaining final FDA approval of oxymorphone ER, filing an NDA with the FDA for PW2101, and continuing to advance our early stage product pipeline, anticipating that some products will enter Phase II by year-end. With these as our highest priorities, we intend to continue to execute our drug development strategy to build long-term shareholder value.



Tod R. Hamachek
Chairman and CEO
Penwest Pharmaceuticals Co.

PENWEST





IDEA GENERATION is the creative component of our business; it begins with understanding the opportunities within the marketplace as well as the competitive strengths of the Company. It is a composite of various factors which typically lead to concepts for product candidates. At Penwest, we focus our product development activities on existing compounds that are able to be reformulated, using one of our proprietary drug delivery technologies, to address an unmet need in the marketplace. These existing compounds can either be developed for the current medical indication or gain an entirely new indication.

Ideas come from the collaborative efforts among many disciplines within the Company: medical, pharmaceutical development, marketing, and regulatory, as well as our scientific advisors. Once an idea is generated, it is screened for various criteria: ability to reformulate and develop clinically, whether an identifiable regulatory pathway exists, whether there is freedom to operate from a patent perspective, the commercial opportunity, and strategic fit within the Company. Once ideas are screened, those which appear attractive are evaluated against other opportunities, and decisions are made with regard to the product pipeline with the ultimate goal of balancing risk and returns within the portfolio.

THOMAS R. SCIASCIA, M.D.
Vice President, Clinical Operations
and Chief Medical Officer

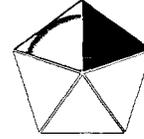
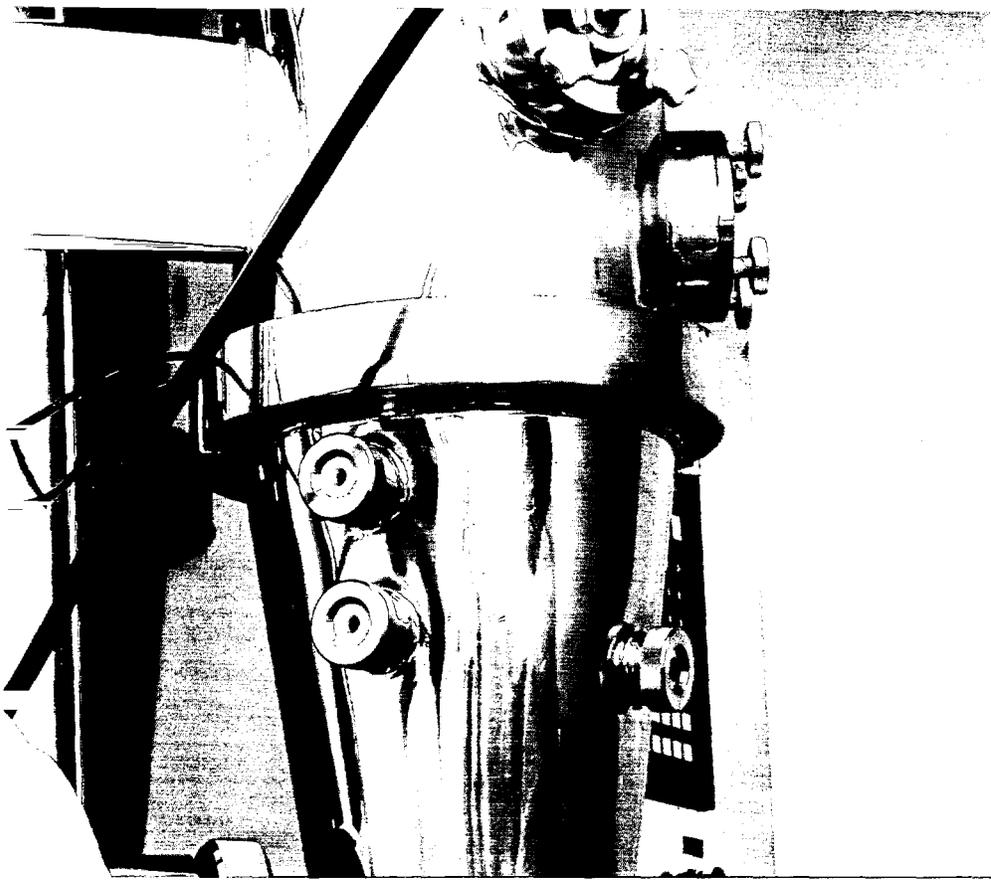
Dr. Sciascia joined Penwest in 2001 and has been instrumental in generating many of the product concepts in Penwest's product pipeline. His clinical experience comes from positions held at Quintiles, Inc. as Medical Director and Boston University School of Medicine where he held an academic title of Assistant Professor of Neurology. In that capacity he was actively involved in the management of neurological patients as well as supervising medical students and neurology resident staff physicians. In addition, he was involved in evaluating patients in the electrodiagnostic laboratories. Tom received his medical degree from Columbia University College of Physicians and Surgeons and a Bachelor's of Science degree from the Massachusetts Institute of Technology.





DANIEL SZETO, PH.D.
Director, Pharmaceutical Analysis

Dr. Szeto joined Penwest in 2002 with more than 20 years of experience in managing analytical research and methods development for solid, liquid and sterile products in the pharmaceutical industry. Daniel plays a vital role in the overall drug development process at Penwest. Daniel's analytical background comes from positions held at Elan Pharmaceuticals, Avant Immunotherapeutics, Carter Wallace, Inc. and Berlex Laboratories. He holds a Ph.D. degree in Medicinal Chemistry from the State University of New York at Buffalo and a M.S. degree in Pharmaceutics from Rutgers University.



Penwest 2003 Annual Report

DRUG FORMULATION begins with the medical and marketing departments defining the product concept, including the dose and targeted release rate of the drug. Our formulators then characterize the pharmacokinetic parameters and the physical chemical properties of the active drug substance and use this information to design a formulation approach to meet the targeted release profile. The formulation approach is based upon our extensive knowledge of the key variables of our drug delivery technologies. Several prototype formulations are then developed and tested in our laboratories (in-vitro) in various conditions relative to the targeted profile. Based upon this in-vitro work, a few formulations are selected for optimization and are scaled-up for manufacturing of pilot clinical batches. These formulations are then dosed in pilot scale proof-of-principle trials to determine the rate and extent of absorption, and in certain cases pharmacodynamic parameters, which can be indicators of efficacy, are measured. Based on the results of these pilot studies, the product is either reformulated or scaled up to be advanced into the clinic for further development of the product.



Jacque joined Penwest 2 years ago bringing with her 14 years of clinical trial experience. Her background in clinical development comes from positions held at Forest Laboratories and DUSA Pharmaceuticals. Jacque has been instrumental in managing the clinical development plan for our hypertension product — PW2101. She holds an Associate of Science degree from Dean College.

(LEFT)

JACQUELINE KURITZKY

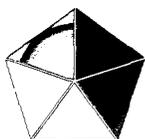
Associate Director, Clinical Studies

(RIGHT)

THEODORE J. JAWORSKI, PH.D.

Director of Pharmacokinetics

Dr. Jaworski joined Penwest in 2003 bringing with him over 13 years of pharmacokinetic and drug metabolism experience. He plays an important role in providing pharmacokinetic expertise for clinical trials, formulation development and evaluation of new product concepts at Penwest. Prior to joining Penwest, Ted was the Director of Clinical Pharmacology at PPD Development. Previously he was also with CytRx Corporation where he was Director of Preclinical Development and at Pharmakon Research International, Inc. where he was a Pharmacokineticist. Ted earned his Ph.D. and B.S.P. from the University of Saskatchewan.

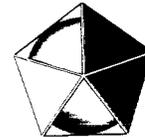
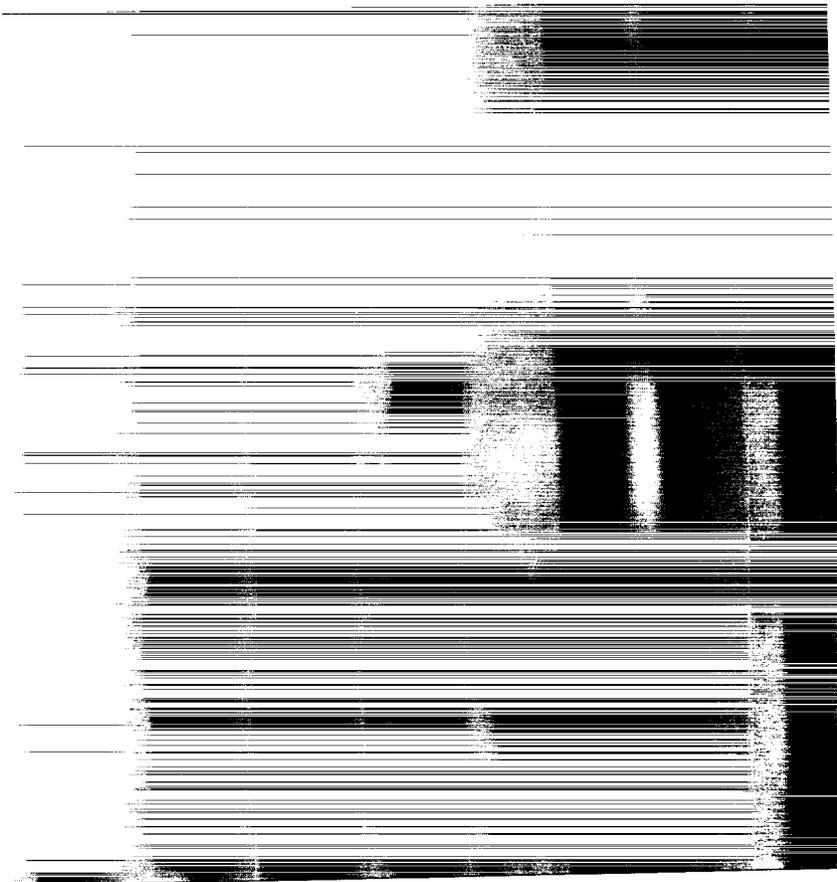




CLINICAL DEVELOPMENT is execution focused. It requires extensive planning up-front to design the appropriate studies to achieve meaningful clinical endpoints as well as to provide insight into potential risks in future development work. Clinical development requires a solid organizational structure, both internal and external, as well as the necessary tools and procedures to execute development within strict regulatory and legal requirements.

At Penwest we outsource much of the clinical development work to contract research organizations (CRO's) that may have specific expertise in a therapeutic category. In this way, CRO's become our partners in helping us think through the clinical development plan, and then successfully execute that plan. Although CRO's play an important role in this process, our clinical operations group manages the development efforts through active involvement in the planning of clinical trials, the monitoring of studies, and the interpretation of data upon the completion of the trials. This level of supervision requires technically knowledgeable individuals that are focused on successfully completing the development plan as well as challenging what is best for the overall development program and, in turn, for the Company.





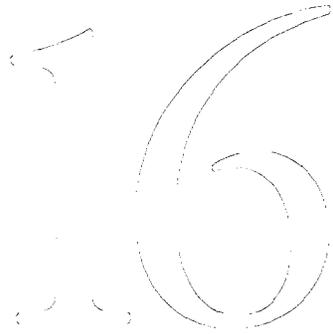
Penwest 2003 Annual Report

REGULATORY AFFAIRS is an integral component of both the drug development and new product evaluation efforts at Penwest. This department carries out critical functions related to our ongoing drug development programs including ensuring that the Company is aware of and in compliance with all FDA regulations, mapping the steps required to move products towards approval, communicating and negotiating with the FDA on the Company's behalf, as well as overseeing the compilation and submission of Penwest's drug applications.

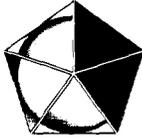
Regulatory's primary role in the product selection process is to identify candidates that can be moved rapidly through development and approval, yet which still satisfy established business and marketing objectives. By developing an in depth knowledge and understanding of existing regulations, maintaining an awareness of emerging legal, political, and scientific trends, as well as dialoguing directly with the FDA, Regulatory Affairs seeks to discover alternative and less burdensome strategies for bringing pharmaceutical products to market.

ANNA WYSOWSKYJ
Vice President, Regulatory Affairs

Anna joined Penwest in 2002 with more than 20 years of pharmaceutical regulatory experience. Anna's expertise in regulatory affairs has made her a significant member of Penwest's management team. Her knowledge in regulatory affairs comes from her involvement in numerous drug approvals, first while at Bayer Corporation and later at Bausch & Lomb Pharmaceutical Division. She holds an MBA from the University of New Haven and a Bachelor's degree from Yale University.



Penwest 2003 Annual Report



CORPORATE DEVELOPMENT which consists of business development and market research, plays a strategic role in Penwest's growth by creating value through both internal and external collaborations.

Internally, market research works with various disciplines throughout the Company to identify attractive market segments and product opportunities in which oral drug delivery may solve an unmet need in the marketplace. As these product candidates progress through various stages of development, marketing provides input with regard to various factors such as product indication, labeling and packaging.

Externally, business development seeks partners for both out-licensing and in-licensing opportunities. Since Penwest does not currently sell its own drug products, we seek to partner our products with pharmaceutical marketing partners who have expertise in a particular therapeutic category and who we believe can help us maximize the drug's commercial value. We are also currently seeking opportunities for in-licensing of either products that enhance our product portfolio or drug delivery technologies that complement our current oral technologies. Corporate Development is an active partner in the business not only in helping to realize the value in the existing product portfolio but also in identifying external opportunities that have the potential to enhance the growth of the Company.



FRED BANTI
Vice President,
Corporate Development

Fred joined Penwest in January 2003 with more than 20 years experience in the pharmaceutical industry. He began his pharmaceutical career in the area of cardiovascular pharmacology at Revlon Health Care and then joined Rorer Group (now Aventis), where he held positions of increasing responsibility in R&D, Project Management, Market Research, and Business Development and Licensing. Following Rorer, he joined Pharmacia as Global Head, Infectious Disease Licensing. After Pharmacia, he was Vice President, Business Development and Licensing at Novartis Oncology. Fred earned a B.S. degree in Biology from Fairfield University and an M.S. degree in Organizational Planning from the University of Pennsylvania.

BOARD OF DIRECTORS

PAUL E. FREIMAN

Paul E. Freiman is President and Chief Executive Officer of Neurobiological Technologies, Inc. (NTI). He is the former Chairman and Chief Executive Officer of Syntex Corporation (Syntex), where he had a long and successful career and was instrumental in the sale of Syntex to Roche Holdings for \$5.3 billion. He is credited with much of the marketing success of Syntex's lead product, Naprosyn, and was responsible for moving the product to over-the-counter status, marketed by Proctor & Gamble as Aleve. Mr. Freiman currently serves as chairman of the boards of Digital Gene Technologies, Inc., a private genomics company, and SciGen Pte. Ltd. Mr. Freiman currently serves on the boards of Calypte Biomedical Corporation, Alexza Molecular Delivery Corp., PHYTOS Inc. and Otsuka America Pharmaceuticals, Inc. He has been chairman of the Pharmaceutical Research and Manufacturers of America Association (PhRMA) and has also chaired a number of key PhRMA committees. Mr. Freiman holds a B.S. degree from Fordham University and an honorary doctorate from the Arnold & Marie Schwartz College of Pharmacy.

JERE E. GOYAN, PH.D.

Dr. Goyan is President of Goyan and Hart Associates. He is Chairman of the Board of SciClone Pharmaceuticals and PharmQuest, Inc., a member of the Boards of Sllil Pharmaceuticals, VasoGenix, Institute for World Health and until November 2003 a member of the Board of Emisphere Technology. Dr. Goyan was President and COO of Alteon, Inc. from 1993 to 1998. From 1979 to 1981, Dr. Goyan served as Commissioner of the Food and Drug Administration. He is currently Dean Emeritus and Professor Emeritus of the School of Pharmacy, University of California, San Francisco after serving as Dean from 1967 to 1992 and Professor from 1956 to 1992. Dr. Goyan is a member of numerous associations and served as President of the American Association of Colleges of Pharmacy in 1978 and of the American Association of Pharmaceutical Scientists in 1990. He has received meritorious awards from the University of California, San Francisco, the American Pharmaceutical Association, the Department of Health and Human Services and others. He obtained a Bachelor of Science degree from the School of Pharmacy, University of California, San Francisco in 1952 and his Doctor of Philosophy, Pharmaceutical Chemistry, from the University of California, Berkeley in 1957.

TOD R. HAMACHEK

Mr. Hamachek is Chief Executive Officer and Chairman of the Board of Penwest Pharmaceuticals Co. Prior to that, he served as President, Chief Executive Officer and Director of Penford Corporation. He is also a director of Northwest Natural and The Seattle Times. Mr. Hamachek holds an M.B.A. from the Harvard Business School and a B.A. from Williams College.

ROLF H. HENEL

Mr. Henel currently serves as an advisor to the health care industry and is a partner in Naimark & Associates, a health care consulting firm. He is a director of SciClone Pharmaceuticals and Draxis Health Inc., a Canadian company. He is the retired President of Cyanamid International Lederle Division. He holds an MBA from New York University and a BA from Yale.

ROBERT HENNESSEY

Mr. Hennessey is the retired Chairman, President and CEO of Genome Therapeutics Corporation and currently serves on its Board. Additionally, he was previously an independent consultant of Hennessey & Associates, Ltd. Prior to that, Mr. Hennessey was Senior Vice President of Corporate Development for Sterling Drug, Inc. and also served in various executive assignments at Merck & Co., Inc., SmithKline Beecham PLC, and Abbott Laboratories. Mr. Hennessey is also a director of Repligen Corporation. Mr. Hennessey holds an M.A. and an A.B. from the University of Connecticut.

JOHN N. STANIFORTH, PH.D.

Dr. Staniforth is Chief Scientific Officer of Vectura Ltd, a UK biosciences company. Dr. Staniforth serves as a scientific advisor to a number of international pharmaceutical companies and has extensive teaching and research experience. He is an Honorary Professor of the University of Bath in England and has past associations with a number of US universities as well as Monash University in Australia. His research in the field of powder technology has been widely published and he is the recipient of numerous research awards. Dr. Staniforth is a Churchill Fellow and has been elected Fellow of a number of scientific societies around the world, including the American Association of Pharmaceutical Sciences. Dr. Staniforth has been affiliated with Penwest as a consultant since its inception and is the co-inventor of its flagship technology platform, TIMERx. Dr. Staniforth is also the recipient of the 2003 AstraZeneca Industrial Achievement Award.

ANNE M. VANLENT

Ms. VanLent is currently Executive Vice President and Chief Financial Officer for Barrier Therapeutics, Inc. an emerging specialty pharmaceutical company in the field of dermatology. Prior to joining Barrier in May 2002, Ms. VanLent was a founder of The Technology Compass Group, LLC, a healthcare/technology consulting firm. From mid-1997 through October 2001, Ms. VanLent was with Sarnoff Corporation, a privately-held research and development company which creates and commercializes electronic, biomedical, and information technologies, where her last position held was Executive Vice President, Portfolio Management, overseeing creation of spin-off companies and patent and licensing activities. Ms. VanLent served as President of AMV Associates, an emerging growth healthcare consulting firm from March 1994 through August 1997, and as Senior Vice President and Chief Financial Officer of The Liposome Company, Inc., a biotechnology company, from 1985 through 1993. She currently serves as a director of a private fuel cell development company. Ms. VanLent received a B.A. in Physics from Mount Holyoke College.

FORM | 10-K

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-K

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

For the Fiscal Year Ended December 31, 2003

OR

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

For the transition period from _____ to _____

Commission File Number 000-23467

PENWEST PHARMACEUTICALS CO.

(Exact name of registrant as specified in its charter)

Washington
(State or other jurisdiction of
incorporation or organization)

91-1513032
(IRS Employer Identification No.)

39 Old Ridgebury Road
Suite 11
Danbury, Connecticut
(Address of principal Executive Offices)

06810-5120
(Zip Code)

(Registrant's telephone number, including area code): **(877) 736-9378**

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT:

None

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT:

Common Stock, \$.001 par value
(Including Associated Preferred Stock Purchase Rights)

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

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

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

The aggregate market value of the Registrant's Common Stock held by non-affiliates as of June 30, 2003 was approximately \$381 million based on the last sale price of the Registrant's Common Stock on the Nasdaq National Market. The number of shares of the Registrant's Common Stock outstanding as of February 29, 2004 was 18,446,648.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of our definitive Proxy Statement relating to the 2004 Annual Meeting of Shareholders to be held on June 2, 2004 is incorporated by reference into Part III of this Form 10-K.

PENWEST PHARMACEUTICALS CO.

INDEX TO FORM 10-K

	<u>Page</u>
PART I	
Item 1. Business	1
Item 2. Properties	13
Executive Officers of the Registrant	13
PART II	
Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	14
Item 6. Selected Financial Data	15
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations	16
Item 7a. Quantitative and Qualitative Disclosures About Market Risk	35
Item 8. Financial Statements and Supplementary Data	35
Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	35
Item 9a. Controls and Procedures	35
PART III	
Item 10. Directors and Executive Officers of the Registrant	35
Item 11. Executive Compensation	36
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	36
Item 13. Certain Relationships and Related Transactions	36
Item 14. Principal Accountant Fees and Services	36
PART IV	
Item 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K	36
Signatures	38

PART I

ITEM 1: BUSINESS

Overview

We develop pharmaceutical products based on innovative proprietary oral drug delivery technologies. The foundation of our technology platform is **TIMERx**, an extended release delivery system that is adaptable to soluble and insoluble drugs and that is flexible for a variety of controlled release profiles. We have also developed two additional oral drug delivery systems, **Geminex** and **SyncroDose**. **Geminex** is a dual drug delivery system that is designed to provide independent release of different active ingredients contained in a drug. **SyncroDose** is a drug delivery system that is designed to release the active ingredient of a drug at the desired site and time in the digestive tract.

Our proprietary **TIMERx** drug delivery technology is utilized in four products that were developed with collaborators and have been approved and are for sale in various countries. In addition, we have a number of product candidates in our drug development pipeline. The most advanced of these is oxymorphone ER, an extended release formulation of oxymorphone, a narcotic analgesic being developed for the treatment of moderate to severe pain. We are developing oxymorphone ER with Endo Pharmaceuticals, Inc. In October 2003, the United States Food and Drug Administration, or FDA, issued to Endo an approvable letter for oxymorphone ER. In the letter, the FDA requested that Endo address certain questions, provide additional clarification and information, and conduct some form of additional clinical trials to further confirm the safety and efficacy of oxymorphone ER before the FDA would approve Endo's New Drug Application, or NDA, for oxymorphone ER. Endo has stated it expects to meet with the FDA during the first quarter of 2004 to clarify the issues raised in the letter, review the necessity for additional trials and discuss its responses to the approvable letter. We anticipate that Endo will receive information at that meeting about the final path to regulatory approval and whether any additional trials will be required by the FDA. We are also developing **PW2101**, a branded product for the treatment of hypertension, which we have formulated using our **TIMERx** technology. We completed a pivotal clinical trial of this product candidate in the fourth quarter of 2003, and anticipate releasing results of this study in the first quarter of 2004. We expect to file an NDA for this product by the end of 2004.

Prior to February 27, 2003, we also developed, manufactured and distributed branded pharmaceutical excipients, which are the inactive ingredients in tablets and capsules, primarily consisting of binders, disintegrants and lubricants. On February 27, 2003, we sold substantially all of the assets used in our excipient business to subsidiaries and affiliates of Josef Rettenmaier Holding GmbH & Co. KG. We received \$39.5 million in cash and a promissory note for \$2.25 million in consideration for the excipient business.

Our Strategy

Our strategy is to develop pharmaceutical products utilizing our innovative extended release oral drug delivery technologies.

- *Leverage our drug delivery technologies into a portfolio of product candidates for development.* We believe that we have significant expertise in drug formulation and in oral drug delivery technologies. Our proprietary drug delivery technologies, **TIMERx** extended release, **Geminex** dual delivery and **SyncroDose** chronotherapeutic delivery, are applicable to a wide range of drugs with different physical and chemical properties including water soluble and insoluble drugs as well as high dose and low dose drugs. Using these technologies, we can formulate drugs with precise release profiles. In selecting product candidates for development, we focus on opportunities in which our drug delivery technologies can provide benefits to patients and result in branded, proprietary products. We do not limit the products we develop by therapeutic area.

- *Expand our product development pipeline to include drugs in various stages of development.* We intend to aggressively add product candidates into our development pipeline and control more of the clinical development process than we have in the past. Historically, we have formulated product candidates and then relied upon third party collaborators to complete the remainder of the clinical development program and market the drugs. Although we still expect that we will out-license a portion of our product portfolio prior to regulatory submission, we intend to develop a greater portion of our products on our own. We believe that by controlling development we will be better able to control the development timelines of our product candidates and retain more of their economic value. We expect to continue to seek collaborators earlier in the process for product candidates for which we believe that the development process is too expensive or too risky and for product candidates that require specialized marketing input.
- *Increase participation in the funding of drug development to capture an increased share of the economic value of the product if and when it is marketed.* Developing pharmaceutical products is expensive. If we develop products on our own or jointly with third parties, we will need to devote significant resources to the costs of development of the products. However, we believe that by assuming a larger role in the funding of a product's development, we will be able to receive a greater share of any returns from the product.
- *Expand the core drug delivery technologies.* Our expertise is in oral drug delivery technologies and drug formulation. We intend to continue to develop our core technologies as well as to seek to develop, in-license or acquire new technologies that are synergistic with our product development capabilities.
- *Establish collaborations for development, manufacturing and marketing.* We expect that we will continue to seek to enter into collaborations to develop some of our products. In addition, because we do not anticipate establishing manufacturing or sales and marketing capabilities within the next few years, we also expect that we will seek to enter into collaborations for the manufacturing and the selling and marketing of our products. We are a party to a number of collaborative agreements including agreements with Endo, Mylan Pharmaceuticals Inc. and Sanofi-Synthelabo S.A.

Drug Delivery Technologies

TIMERx Extended Release Delivery Systems

We developed our TIMERx delivery system to address the limitations of other oral extended release delivery systems. We believe that the TIMERx system has advantages over other oral drug delivery technologies, as it is readily manufactured, adaptable to soluble and insoluble drugs and flexible for a variety of controlled release profiles. Pharmaceutical products containing TIMERx have been approved and are being marketed, and we are developing additional products in our pipeline using TIMERx.

The patented TIMERx drug delivery system is based on a hydrophilic matrix combining a heterodispersed mixture primarily composed of two polysaccharides, xanthan and locust bean gums, in the presence of dextrose. These gums are also used in our Geminex and SyncroDose drug delivery systems. The physical interaction between these components works to form a strong, binding gel in the presence of water. Drug release is controlled by the rate of water penetration from the gastrointestinal tract into the TIMERx gum matrix, which expands to form a gel and subsequently releases the active drug substance. The TIMERx system can precisely control the release of the active drug substance in a tablet by varying the proportion of the gums, together with the tablet coating and the tablet manufacturing process. Drugs using TIMERx technology are formulated by combining the active drug substance, the TIMERx drug delivery system and additional excipients, and compressing such materials into a tablet.

Geminex Dual Release Technology

We developed our patented Geminex dual release technology to provide for the independent release of the same active ingredient or different active ingredients contained in one pharmaceutical product at different rates. The release of the active ingredients can each involve two different controlled release profiles, or involve controlled release and immediate release profiles. The technology is based on a bi-layer tablet that utilizes TIMERx in the controlled release layer. We are utilizing Geminex technology in several product candidates that are currently in the formulation stage.

SyncroDose Drug Delivery

We developed our patented SyncroDose drug delivery system to deliver drugs chronotherapeutically in the body or to deliver a drug within a specific site in the gastrointestinal tract. SyncroDose is a technology based on our underlying TIMERx platform. We believe that there are several disease states that can benefit from chronotherapeutic delivery including: arthritis, cardiovascular disorders, asthma, neurological disorders and site specific diseases. The SyncroDose technology utilizes the TIMERx gum matrix in the coating combined with the active and various other excipients in the core.

Products

Marketed and Approved Products

To date, several drug formulations utilizing the TIMERx system have received regulatory approval:

- Cystrin CR, an extended release version of oxybutynin for the treatment of urge urinary incontinence, is being marketed in Finland by Schering Oy.
- Siofedipine XL, an extended release version of nifedipine for the treatment of angina, is being marketed in the United Kingdom and Italy by Sanofi-Synthelabo.
- Cronodipin, an extended release version of nifedipine for the treatment of angina, was licensed to Merck S.A. Industries Quimicas for marketing in Brazil.

In December 1999, the FDA approved the 30 mg strength of Nifedipine XL, a generic version of Procardia XL that is used for the treatment of hypertension and angina. The 30 mg strength of Nifedipine XL is not being marketed in the United States by our collaborator Mylan. In March 2000, Mylan signed a supply and distribution agreement with Pfizer, Inc. to market a generic version of all three strengths, 30 mg, 60 mg and 90 mg, of Pfizer's Procardia XL. In connection with that agreement, Mylan agreed to pay us a royalty on net sales of Pfizer's 30 mg strength of generic Procardia XL. The royalties are comparable to those called for in our original agreement with Mylan for Nifedipine XL. Mylan has retained the marketing rights to the 30 mg strength of Nifedipine XL.

Products in Our Pipeline

We also have a number of TIMERx products in our development pipeline. The table below summarizes each of the principal products in this pipeline, including the therapeutic use, the development status and our collaborator, if any, for each product:

<u>PRODUCT</u>	<u>INDICATION</u>	<u>DEVELOPMENT STATUS</u>	<u>COLLABORATOR</u>
OXYMORPHONE ER	Moderate to Severe Pain	Approvable Letter	Endo Pharmaceuticals
PW3101	Asthma	Approvable Letter	IVAX Corporation
PW2101	Hypertension	Phase III	Internal Development
PW2134	Edema/Congestive Heart Failure	Phase I	Internal Development
PW2134 Combo	Hypertension	Phase I	Internal Development
PW4102	Central Nervous System	Phase I	Internal Development
PW4142	Acute Chronic Benign Pain	Phase I	Internal Development
PW4155	Acute Benign Pain	Phase I	Internal Development

Oxymorphone ER

The most advanced of the products in our development pipeline is an extended release formulation of oxymorphone incorporating TIMERx technology, which we are developing with Endo. Oxymorphone ER, a narcotic analgesic, is being developed for twice a day dosing in patients with moderate to severe pain. Oxymorphone, which is currently given in the parenteral and suppository dosage form, is marketed by Endo and had sales in the United States in 2003 of approximately \$536,000. Oxymorphone ER, if successfully developed, would represent the first oral extended release version of oxymorphone and would compete in the moderate to severe long acting opioid market with products such as MS Contin, Purdue Pharma's OxyContin and Johnson & Johnson's Duragesic patch, which had aggregate sales in the United States in 2003 of approximately \$3.3 billion.

Endo, which is responsible for conducting the clinical trials and seeking regulatory approval of the product, submitted the NDA to the FDA in December 2002. In October 2003, the FDA issued to Endo an approvable letter for oxymorphone ER. In the letter, the FDA requested that Endo address certain questions, provide additional clarification and information, and conduct some form of additional clinical trials to further confirm the safety and efficacy of oxymorphone ER, before the FDA would approve Endo's NDA for oxymorphone ER. Endo has stated it expects to meet with the FDA during the first quarter of 2004 to clarify the issues raised in the letter, review the necessity for additional trials and discuss its responses to the approvable letter. We anticipate that Endo will receive information at that meeting about the final path to regulatory approval and whether any additional trials will be required by the FDA.

PW3101

PW3101 is an oral asthma product that we are developing in collaboration with IVAX Corporation based on our TIMERx technology. PW3101 is a reformulation of a branded product that is marketed for oral asthma. The branded product had U.S. sales of approximately \$20 million in 2003. IVAX filed

an NDA for PW3101 in late 2002. IVAX received an approvable letter from the FDA for PW3101 in the second half of 2003 and resubmitted the NDA to the FDA in the first quarter of 2004.

PW2101

PW2101 is a formulation of a competitive product candidate to a branded product that is marketed for hypertension. This product is being developed utilizing our TIMERx technology. The branded product had U.S. sales of approximately \$1 billion in 2003. We intend to file a 505(b)2 NDA with the FDA for PW2101 by the end of 2004. We are also developing a lower strength of PW2101. In order to obtain marketing approval of this lower strength dosage form, we will need to conduct additional clinical trials. We believe that we can complete these additional trials and submit an NDA for the lower strength dosage form in early 2005. We are currently seeking a marketing partner for PW2101 and expect to out-license the marketing rights by mid-2004.

Phase I Products

We are currently conducting pilot scale biostudies of several product candidates. In these studies, we are seeking to obtain proof of principal data in humans. If the pilot scale biostudies of any of these product candidates shows proof of principal and the commercial returns appear attractive, we will most likely seek to advance the product candidate into further clinical trials on our own. The decision to develop the product candidate on our own will be based on our available resources after consideration of a number of factors, including the size of the potential market, competitors in the potential market, the availability of intellectual property protection, the regulatory pathway and the development status of our other product candidates.

Collaborative Arrangements

We enter into collaborative agreements with pharmaceutical companies to develop, market or manufacture products developed with our drug delivery technologies.

We currently have two primary types of collaborative agreements. In revenue sharing collaborative agreements, we jointly fund research and development with our collaborator, and we receive no up-front licensing fees or milestone payments. In these arrangements, we share in a pre-determined percentage of the net operating profits. Technology licensing collaborative agreements involve the straight licensing of our technology to a collaborator. We have no obligation to fund the ongoing clinical development or marketing costs of the product. Under these collaborative agreements, we receive up-front license fees and milestone payments. In addition, under all our current collaborative arrangements, we are entitled to receive royalties on our collaborators' sales of the products covered by such collaborative arrangements and payments for the purchase of formulated TIMERx material. Our principal collaborative arrangements are described below.

In the future, we expect that our collaborative agreements are likely to involve the licensing of an NDA to a marketing partner after we complete the development of a product and submit the application to the FDA. Under this type of collaborative agreement, we anticipate that we would receive up-front license fees, milestone payments and royalties.

Revenue Sharing Collaborative Agreements

Endo Pharmaceuticals, Inc.

In September 1997, we entered into a strategic alliance agreement with Endo with respect to the development of oxymorphone ER, an extended release formulation of oxymorphone based on our TIMERx technology. This agreement was amended and restated in April 2002. Endo is a fully integrated specialty pharmaceutical company with a market leadership position in pain management.

Endo has a broad product line, including established brands such as Percodan, Percocet and Lidoderm. Endo is registered with the United States Drug Enforcement Administration as a developer, manufacturer and marketer of controlled narcotic substances.

Under our agreement with Endo, our responsibilities and the responsibilities of Endo with respect to oxymorphone ER are determined by a committee comprised of an equal number of members from each of Endo and us, which we refer to as the Alliance Committee. During the development of the product, we formulated oxymorphone ER, and Endo conducted all clinical studies and prepared and filed all regulatory applications. We have agreed to supply TIMERx material to Endo, and Endo has agreed to manufacture and market oxymorphone ER in the United States. The manufacture and marketing of oxymorphone ER outside of the United States may be conducted by Endo, us or a third party, as determined by the Alliance Committee.

Prior to March 17, 2003, we shared with Endo the costs involved in the development of oxymorphone ER. On March 17, 2003, we notified Endo that we were discontinuing our participation in the funding of the development and marketing of oxymorphone ER effective April 17, 2003. We took this action because we believed that our strategic focus should be on funding other products in our development pipeline. As a result of this termination of funding, Endo has the right to complete the development of oxymorphone ER and recoup the portion of development costs incurred by Endo that otherwise would have been funded by us. Endo may recoup such development costs through a temporary adjustment in the royalty rate payable to us, which will return to its pre-adjustment level once Endo has recovered such costs. Endo may also allow us to reimburse Endo directly for the unfunded amounts. We estimate that through December 31, 2003, these unfunded development costs approximated \$6.7 million. We expect these costs to increase as Endo continues to invest in oxymorphone ER. We have agreed with Endo that the party marketing oxymorphone ER will pay the other party royalties initially equal to 50% of the net realization as defined in the agreement between Endo and us, subject to adjustment for unfunded development costs. This percentage will decrease if the aggregate U.S. net realization exceeds pre-determined thresholds. In general, the royalty payable by the marketing party to the other party will not drop below 40%. However, the royalty will be reduced by one-third in limited circumstances, including termination of the agreement based on uncured material breaches of the agreement by the royalty receiving party and specified bankruptcy and insolvency events involving the royalty receiving party. Under the agreement, Endo will purchase formulated TIMERx material for use in oxymorphone ER exclusively from us at specified prices, and include these purchases in cost of goods sold of the product prior to determining net realization.

Technology Licensing Collaborative Agreements

Mylan Pharmaceuticals Inc.

In August 1994, we entered into product development and supply agreements with Mylan with respect to the development of Nifedipine XL, a generic version of Procardia XL based on our TIMERx technology. Procardia XL is a branded drug for the treatment of hypertension and angina that utilizes nifedipine as its active ingredient. Under the agreement, we were responsible for the formulation, manufacture and supply of TIMERx material for use in the product, and Mylan was responsible for conducting all bioequivalence studies, preparing all regulatory applications and submissions, and manufacturing and marketing the Nifedipine XL in North America. In December 1999, the FDA approved the 30 mg strength of Nifedipine XL.

On March 2, 2000, Mylan announced that it had signed a supply and distribution agreement with Pfizer to market a generic version of all three strengths, 30 mg, 60 mg and 90 mg, of Pfizer's Procardia XL. In connection with that agreement, Mylan decided not to market Nifedipine XL and agreed to pay us a royalty on all future net sales of the 30 mg strength of Pfizer's generic Procardia XL. The royalty percentage was comparable to the percentage called for in our original agreement with Mylan for

Nifedipine XL. Mylan has retained the marketing rights for the 30 mg strength of Nifedipine XL. Mylan's sales in the United States in 2003 of the 30 mg dosage strength version of Pfizer's generic Procardia XL totaled approximately \$36.8 million. The term of this agreement continues until such time as Mylan permanently ceases to market generic Procardia XL. In 2003, 2002 and 2001, royalties from Mylan accounted for approximately 88%, 87% and 82%, respectively, of our total revenue.

Other Agreements

We are a party to the following additional technology licensing collaborative agreements involving our TIMERx technology:

- *Sanofi-Synthelabo S.A.* Our agreement with Sanofi-Synthelabo relates to Slofedipine XL, an extended release version of nifedipine for the treatment of angina. Slofedipine XL was approved in the United Kingdom in 1998 and Italy in 2000. Sanofi-Synthelabo is marketing Slofedipine XL in both countries.
- *Schering Oy.* Our agreement with Schering Oy relates to Cystin CR, an extended release version of oxybutynin for the treatment of urge urinary incontinence. Schering began marketing Cystin CR in Finland after receiving approval for the product in 1997.
- *E. Merck.* Our agreement with E. Merck relates to an extended release version of nifedipine for the treatment of angina that was licensed to Merck S.A. Industries Quimicas for marketing in Brazil.
- *IVAX Corporation.* Our agreement with IVAX relates to the development of PW3101 for the treatment of asthma.
- *Ranbaxy Laboratories Ltd.* Our agreement with Ranbaxy relates to the development of an extended release version of nifedipine for the treatment of angina.

Research and Development

We conduct research and development activities on the development of product candidates utilizing our drug delivery technologies and on the development of additional drug delivery technologies. Our research and development expenses in 2003, 2002, and 2001 were \$20.6 million, \$17.0 million and \$16.2 million. These expenses do not include amounts incurred by our collaborators in connection with the development of products under our collaboration agreements such as expenses for full-scale bioequivalence studies development, clinical trials performed by our collaborators, expenses incurred on oxymorphone ER subsequent to April 17, 2003, or our collaborators' share of funding.

Manufacturing

We currently have no internal manufacturing capabilities. Generally, our collaborators manufacture the pharmaceutical products, and we are responsible for supplying them with bulk TIMERx. We have outsourced the commercial manufacture of TIMERx materials to a third-party pharmaceutical company, Draxis Pharmaceuticals, Inc., under a manufacturing agreement that expires in September 2004. The agreement will automatically renew for successive one-year periods, unless either party gives notice of its intent not to renew the contract at least six months prior to the end of the then-current term. During the year, we also completed initial validation work on a second contract manufacturer. However, there is some additional follow-up work required before the site is fully validated. We believe that there are a limited number of manufacturers that operate under cGMP regulations capable of manufacturing our TIMERx materials. There can be no assurance that Draxis or any other third parties upon which we rely for supply of our TIMERx material will perform, and any failures by third parties may delay development or the submission of products for regulatory approval,

impair our collaborators' ability to commercialize products as planned and deliver products on a timely basis, or otherwise impair our competitive position, which could have a material adverse effect on our business, financial condition and results of operations.

Our TIMERx technology is based on a hydrophilic matrix combining a heterodispersed mixture primarily composed of two polysaccharides, xanthan and locust bean gums, in the presence of dextrose. We purchase these gums from a primary supplier. Although we have qualified alternate suppliers with respect to these gums and to date we have not experienced difficulty acquiring these materials, there can be no assurance that interruptions in supplies will not occur in the future or that we will not have to obtain substitute suppliers. Any of these events could have a material adverse effect on our ability to manufacture bulk TIMERx for delivery to our collaborators, which could have a material adverse effect on our business, financial condition and results of operations.

In those cases where we are developing products on our own and have not entered into any collaboration agreements with respect to such products, we rely on third party contract manufacturers. For instance, Patheon, Inc. manufactured PW2101 for use in our clinical trials and also manufactured the commercial batches for stability studies. We believe there are many companies which are capable of manufacturing these products.

Marketing and Distribution

Pursuant to our collaborative agreements, our collaborators have, or are expected to have, responsibility for the marketing and distribution of any pharmaceuticals developed based on our drug delivery technologies. Because we do not currently market any pharmaceuticals without a collaborator, we have not developed any sales force with respect to such products. As a result, we are substantially dependent on the efforts of our collaborators to market the products. In selecting a collaborator for a drug candidate, some of the factors we consider include the collaborator's market presence in the therapeutic area targeted by the drug candidate and the collaborator's sales force and distribution network.

Patents and Proprietary Rights

We believe that patent and trade secret protection of our drug delivery technology is important to our business and that our success will depend in part on our ability to maintain existing patent protection, obtain additional patents, maintain trade secret protection and operate without infringing the proprietary rights of others.

Patents and Protection of Proprietary Information

As of February 29, 2004, we owned 31 U.S. and 177 foreign patents relating to our controlled release drug delivery technology. The U.S. patents principally cover our TIMERx technology and new technologies based on the TIMERx technology, including the combination of the xanthan and locust bean gums, the oral solid dosage form of TIMERx and the method of preparation, as well as the application of TIMERx technology to various active drug substances, including both methods of treatment and methods of preparation. All these patents will expire between 2008 and 2020. Based on a patent review conducted in 2003, the most important patents relating to our TIMERx technology begin to expire in 2014.

The issuance of a patent is not conclusive as to its validity or as to the enforceable scope of the claims of the patent. There is no assurance that our patents or any future patents we obtain will prevent other companies from developing non-infringing similar or functionally equivalent products or from successfully challenging the validity of our patents. Furthermore, there is no assurance that:

- any of our future processes or products will be patentable;

- any pending or additional patents will be issued in any or all appropriate jurisdictions;
- our processes or products will not infringe upon the patents of third parties; or
- we will have the resources to defend against charges of infringement by, or protect our own patent rights against, third parties.

Our inability to protect our patent rights, or infringement by us of the patent or proprietary rights of others, could have a material adverse effect on our business, financial condition and results of operations.

We also rely on trade secrets and proprietary knowledge, which we generally seek to protect by confidentiality and non-disclosure agreements with employees, consultants, licensees and pharmaceutical companies. There can be no assurance, however, that these agreements have or in all cases will be obtained, that these agreements will not be breached, that we will have adequate remedies for any breach or that our trade secrets will not otherwise become known by competitors.

There has been substantial litigation in the pharmaceutical industry with respect to the manufacture, use and sale of new products that are the subject of conflicting patent rights. Some of the controlled release products that we are developing with our collaborators are generic versions of brand name controlled release products that are covered by one or more patents. Under the Waxman-Hatch Act, when an applicant files an ANDA with the FDA for a generic version of a brand name product covered by an unexpired patent listed with the FDA, the applicant must certify to the FDA that such patent will not be infringed by the applicant's product or that such patent is invalid or unenforceable. Notice of such certification must be given to the patent owner and the sponsor of the NDA for the brand name product. If a patent infringement lawsuit is filed within 45 days of the receipt of such notice, the FDA will conduct a substantive review of the ANDA, but will not grant final marketing approval of the generic product until a final judgment on the patent suit is rendered in favor of the applicant or until 30 months (or such longer or shorter period as a court may determine) have elapsed from the date of the certification, whichever is earlier. Should a patent owner commence a lawsuit with respect to alleged patent infringement by us or our collaborators, the uncertainties inherent in patent litigation make the outcome of such litigation difficult to predict. Our collaborators are responsible for all legal costs under Waxman-Hatch lawsuits. We evaluate the probability of patent infringement litigation with respect to our collaborators' ANDA submissions on a case by case basis. The delay in obtaining FDA approval to market our products as a result of litigation, whether or not we are successful, could have a material adverse effect on our business, financial condition and results of operations.

Trademarks

TIMERx and Geminex are our registered trademarks. SyncroDose is also our trademark. Other tradenames and trademarks appearing in this annual report on Form 10-K are the property of their respective owners.

Government Regulation

FDA Regulation of Pharmaceutical Products

All pharmaceutical manufacturers are subject to extensive regulation by the federal government, principally the FDA, and, to a lesser extent, by state and local governments. The Federal Food, Drug and Cosmetic Act, or the FDCA, and other federal statutes and regulations govern or influence the development, testing, manufacture, safety, labeling, storage, record keeping, approval, advertising, promotion, sale and distribution of prescription products. Pharmaceutical manufacturers are also subject to specific record keeping and reporting requirements, establishment registration, product listing and FDA inspections.

Drugs can be approved by the FDA based on three types of marketing applications: an NDA, an ANDA or a license application under the Public Health Service Act. A full NDA must include complete reports of preclinical, clinical and other studies to prove adequately that the product is safe and effective for its intended use. The FDCA also provides for NDA submissions that may rely in whole or in part on publicly available clinical and other data on safety and efficacy under section 505(b)(2) of the FDCA. These types of NDAs may be appropriate for certain drugs containing previously approved active ingredients but differing with regard to other characteristics such as indications for use, dosage form or method of delivery.

As an initial step in the FDA regulatory approval process for an NDA, preclinical studies are typically conducted in animal models to assess the drug's efficacy and to identify potential safety problems. The results of these studies must be submitted to the FDA as part of an Investigational New Drug Application, which must be reviewed by the FDA before proposed clinical testing can begin. Typically, clinical testing involves a three-phase process. Phase I trials are conducted with a small number of subjects and are designed to provide information about both product safety and the expected dose of the drug. Phase II trials are designed to provide additional information on dosing and preliminary evidence of product efficacy. Phase III trials are large scale studies designed to provide statistical evidence of efficacy and safety in humans. The results of the preclinical testing and clinical trials of a pharmaceutical product are then submitted to the FDA in the form of an NDA for approval to commence commercial sales. Preparing such applications involves considerable data collection, verification, analysis and expense. In responding to an NDA, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not satisfy its regulatory approval criteria.

This regulatory process can require many years and the expenditure of substantial resources. Data obtained from preclinical testing and clinical trials are subject to varying interpretations, which can delay, limit or prevent FDA approval. In addition, changes in FDA approval policies or requirements may occur or new regulations may be promulgated which may result in delay or failure to receive FDA approval.

Some products containing our TIMERx formulation will require the filing of an NDA. The FDA will not accept ANDAs when the delivery system or duration of drug availability differs significantly from the Listed Drug. However, we may be able to rely on existing publicly available safety and efficacy data to support section 505(b)(2) NDAs for controlled release products when such data exists for an approved immediate release version of the same chemical entity. However, there can be no assurance that the FDA will accept such section 505(b)(2) NDAs, or that we will be able to obtain publicly available data that is useful. The section 505(b)(2) NDA process is a highly uncertain avenue to approval because the FDA's policies on section 505(b)(2) NDAs have not yet been fully developed. There can be no assurance that an application submitted under section 505(b)(2) will be approved, or will be approved in a timely manner.

Although the FDA has approved the ANDA filed by our collaborator Mylan for the 30 mg dosage strength of a generic version of Procardia XL and Endo has received an approvable letter for oxymorphone ER and Ivax for PW3101, there can be no assurance that applications filed by our collaborators with respect to other products will receive FDA approval on a timely basis.

Sponsors of ANDAs and section 505(b)(2) NDAs, with the exception of applications for certain antibiotic drugs, must include, as part of their applications, certifications with respect to certain patents on Listed Drugs that may result in significant delays in obtaining FDA approvals. Sponsors who believe that patents that are listed in an FDA publication entitled "Approved Drug Products With Therapeutic Equivalence Evaluations" are invalid, unenforceable, or not infringed, must notify the patent owner. If the patent owner initiates an infringement lawsuit against the sponsor within 45 days of the notice, the FDA's final approval of the ANDA or section 505(b)(2) NDA may be delayed for a period of thirty months or longer. This delay may also apply to other ANDAs or 505(b)(2) NDAs for the same Listed Drug. Moreover, the approval of an ANDA involved in such a patent lawsuit may under certain circumstances require a further delay in the final approval of other ANDAs for the same Listed Drug for an additional 180 days. In addition, recent court decisions have raised the possibility that, under some circumstances, ANDAs other than the first ANDA for a Listed Drug may be delayed indefinitely and thereby effectively denied approval if the drug that is the subject of the first ANDA is not brought to market.

ANDAs and section 505(b)(2) NDAs are also subject to so-called market exclusivity provisions that delay the submission or final approval of the applications. The submission of ANDAs and section 505(b)(2) NDAs may be delayed for five years after approval of the Listed Drug if the Listed Drug contains a new active molecular entity. The final approval of ANDAs and section 505(b)(2) NDAs may also be delayed for three years where the Listed Drug or a modification of the Listed Drug was approved based on new clinical investigations. The three-year marketing exclusivity period would potentially be applicable to Listed Drugs with novel drug delivery systems.

Sponsors of drug applications affected by patents may also be adversely affected by patent term extensions provided under the FDCA to compensate for patent protection lost due to time taken in conducting FDA required clinical studies or during FDA review of data submissions. Patent term extensions may not exceed five additional years nor may the total period of patent protection following FDA marketing approval be extended beyond 14 years. In addition, by virtue of the Uruguay Round Agreements Act of 1994 that ratified the General Agreement on Tariffs and Trade, certain brand name drug patent terms have been extended to 20 years from the date of filing of the pertinent patent applications (which can be longer than the former 17-year patent term starting from the date of patent issuance). Patent term extensions may delay our ability and the ability of our collaborators to use our proprietary technology in the future, market new controlled release products, file section 505(b)(2) NDAs referencing approved products, or file ANDAs based on Listed Drugs when those approved products or Listed Drugs have acquired patent term extensions.

Manufacturers of marketed drugs must conform to the FDA's cGMP standard or risk sanctions such as the suspension of manufacturing or the seizure of drug products and the refusal to approve additional marketing applications. The FDA conducts periodic inspections to implement these rules. There can be no assurance that a manufacturer's facility will be found to be in compliance with cGMP or other regulatory requirements. Failure to comply could result in significant delays in the development, testing and approval of products manufactured at such facility, as well as increased costs.

Noncompliance with applicable requirements can also result in total or partial injunctions against production and/or distribution, refusal of the government to enter into supply contracts or to approve NDAs, ANDAs or biologics applications, criminal prosecution and product recalls. The FDA also has the authority to revoke for cause drug or biological approvals previously granted.

Other Regulations. We are governed by federal, state and local laws of general applicability, such as laws regulating working conditions and environmental protection. Oxymorphone ER and other drugs that we are developing are subject to regulations under the Controlled Substances Act and related statutes.

Competition

The pharmaceutical industry is highly competitive and is affected by new technologies, governmental regulations, health care legislation, availability of financing, litigation and other factors. Many of our competitors have longer operating histories and greater financial, technical, marketing, legal and other resources than us and some of our collaborators. In addition, many of our competitors have significantly greater experience than we have in conducting clinical trials of pharmaceutical products, obtaining FDA and other regulatory approvals of products, and marketing and selling approved products. We expect that we will be subject to competition from numerous other entities that currently operate or intend to operate in the pharmaceutical and specialty pharmaceutical industry.

The key competitive factors affecting the success of our drug delivery products are likely to include, among other things:

- the safety and efficacy of our products;
- the relative speed with which we can develop products;
- generic competition for any product that we develop;
- our ability to differentiate our products; and
- external factors affecting pricing.

Most of our products under development are extended release versions of existing immediate release drugs. Our products will face competition from existing products with the same indication, as well as other products that may be developed in the future. For example, if oxymorphone ER receives marketing approval, it will compete against MS Contin, Purdue Pharma's OxyContin and Johnson & Johnson's Duragesic patch, as well as any generic competitors to those products. If PW2101 receives marketing approval, it will compete against the extended release product being marketed by the original developer of the branded product and any approved generic competitors. In addition, PW2101 would also compete against other drugs that have been developed for the treatment of hypertension.

Employees

As of February 29, 2004, we employed approximately 71 people, of whom 46 were primarily involved in research and development activities, and 25 were primarily involved in selling, general and administrative activities. As of February 29, 2004, none of our employees were covered by collective bargaining agreements. We consider our employee relations to be good.

Information Available on the Internet

Our internet address is www.penwest.com. We make available free of charge through our web site, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to these reports filed or furnished pursuant to Section 12(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file such materials with the Securities and Exchange Commission. We also include on our website our corporate governance guidelines, our code of business conduct and ethics, and the charters for our audit committee, our compensation committee and our nominating and corporate governance committee. In addition, we intend to disclose on our website 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 SEC and the Nasdaq.

ITEM 2: PROPERTIES

Our corporate offices, comprising approximately 11,000 square feet, are located in Danbury, Connecticut. We lease these offices under a lease that expires on January 31, 2006, with renewal options through December 30, 2006. We are currently negotiating for additional office space in this same building. If acquired, we expect that the additional space will have the same cost per square foot as the existing lease, and that the lease term may extend to December 2006, plus renewal options.

We also have research facilities, comprising approximately 14,000 square feet, in Patterson, New York, which we owned prior to the sale of our excipient business. Under our agreement with Rettenmaier, we have the right to occupy this laboratory and office space until February 2005 on a rent-free basis and then pursuant to three successive one-year options at a rental rate of \$12 per square foot.

The space we currently lease is adequate for our current needs, but we are beginning to plan for the additional laboratory space that we will need when our Patterson lease expires.

EXECUTIVE OFFICERS OF THE REGISTRANT

The following table sets forth the names, ages and positions of our executive officers.

<u>NAME</u>	<u>AGE</u>	<u>TITLE</u>	<u>DATES</u>
Tod R. Hamachek	58	Chairman of the Board and Chief Executive Officer	1997—current
		President and Chief Executive Officer of Penford Corp., our former parent company	1985—1997
Anand R. Baichwal, Ph.D.	49	Senior Vice President, Research & New Technology Development and Chief Scientific Officer	1997—current
		Vice President, Technology of Penwest Pharmaceuticals Co., a division of Penford Corp.	1994—1997
Jennifer L. Good	39	Senior Vice President, Finance and Chief Financial Officer	1997—current
		Corporate Controller of Penford Corp., our former parent company	1993—1997
Thomas Sciascia	50	Vice President, Clinical Operations and Chief Medical Officer	2001—current
		Medical Director of Quintiles, Inc., a provider of contract product development and commercialization services	1997—2000
Ferdinand Banti	46	Vice President, Corporate Development	2003—current
		Vice President, Business Development of Novartis Oncology, a pharmaceuticals and consumer health company	2001—2002
		Senior Director, Infectious Disease Licensing of Pharmacia Corp., a developer, manufacturer and seller of pharmaceutical products	1999—2001

PART II

ITEM 5: MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock, \$.001 par value, is listed with and trades on the Nasdaq National Market under the symbol "PPCO." The high and low sale prices of our common stock during 2003 and 2002 are set forth below. These prices reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

	<u>HIGH</u>	<u>LOW</u>
PERIOD 2003		
Quarter Ended March 31	\$17.05	\$ 8.60
Quarter Ended June 30	\$24.66	\$15.35
Quarter Ended September 30	\$25.02	\$19.19
Quarter Ended December 31	\$24.03	\$13.69
PERIOD 2002		
Quarter Ended March 31	\$19.75	\$17.20
Quarter Ended June 30	\$20.99	\$17.00
Quarter Ended September 30	\$17.25	\$ 7.89
Quarter Ended December 31	\$10.98	\$ 7.01

On February 29, 2004 there were 787 shareholders of record.

We have never paid cash dividends on our common stock. We presently intend to retain earnings, if any, for use in the operation of our business, and therefore do not anticipate paying any cash dividends in the foreseeable future.

ITEM 6: SELECTED FINANCIAL DATA

The following selected financial data are derived from our consolidated financial statements. The data should be read in conjunction with the consolidated financial statements, related notes, and other financial information included herein.

	YEAR ENDED DECEMBER 31,				
	2003	2002	2001	2000	1999
	(IN THOUSANDS, EXCEPT FOR PER SHARE DATA)				
STATEMENT OF OPERATIONS DATA:					
Revenues (a)	\$ 4,678	\$ 5,537	\$ 5,796	\$ 8,780	\$ 1,914
Cost of revenues (a)	169	170	243	2,678	371
Gross profit	4,509	5,367	5,553	6,102	1,543
Selling, general and administrative	10,361	7,568	6,358	5,500	6,025
Research and product development	20,590	16,955	16,190	12,103	6,474
Loss from continuing operations before cumulative effect of change in accounting principle	(26,006)	(19,028)	(16,814)	(11,459)	(11,327)
Earnings from discontinued operations, net of income tax expense	177	1,929	833	2,983	3,646
Gain on sale of discontinued operations	9,894	—	—	—	—
Total discontinued operations	10,071	1,929	833	2,983	3,646
Loss before cumulative effect of change in accounting principle	(15,935)	(17,099)	(15,981)	(8,476)	(7,681)
Cumulative effect of change in accounting principle (b)	—	—	—	(310)	—
Net loss	<u>\$(15,935)</u>	<u>\$(17,099)</u>	<u>\$(15,981)</u>	<u>\$ (8,786)</u>	<u>\$ (7,681)</u>
Basic and diluted loss per share before cumulative effect of change in accounting principle:					
Continuing operations	\$ (1.56)	\$ (1.23)	\$ (1.21)	\$ (0.93)	\$ (1.02)
Discontinued operations	0.60	0.12	0.06	0.24	0.33
Cumulative effect of change in accounting principle per share	—	—	—	(0.02)	—
Net loss per share	<u>\$ (0.96)</u>	<u>\$ (1.11)</u>	<u>\$ (1.15)</u>	<u>\$ (0.71)</u>	<u>\$ (0.69)</u>
Weighted average shares of common stock outstanding	<u>16,678</u>	<u>15,462</u>	<u>13,905</u>	<u>12,330</u>	<u>11,103</u>

	DECEMBER 31,				
	2003	2002	2001	2000	1999
	(IN THOUSANDS)				
BALANCE SHEET DATA:					
Cash and cash equivalents	\$25,307	\$ 1,629	\$11,529	\$ 1,291	\$ -204
Marketable securities	38,586	2,057	9,609	—	—
Working capital	60,697	26,355	27,059	11,129	7,713
Total assets	78,503	50,220	59,613	42,294	38,120
Long-term debt	—	—	—	—	6,700
Accumulated deficit	(94,433)	(78,025)	(60,926)	(44,945)	(36,159)
Shareholders' equity	\$67,696	\$ 31,423	\$45,624	\$ 31,017	\$ 22,509

- (a) Reclassification recorded of amounts in 1999 for the adoption of EITF No. 00-10 "Accounting for Shipping and Handling Fees and Costs."
- (b) Cumulative effect of adopting Staff Accounting Bulletin No. 101 ("SAB No. 101") in 2000.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

We develop pharmaceutical products based on innovative oral drug delivery technologies. The foundation of our technology platform is TIMERx, an extended release delivery system that is adaptable to soluble and insoluble drugs, and that is flexible for a variety of controlled release profiles. We have also developed two additional oral drug delivery systems, Geminex and SyncroDose. Geminex is a dual drug delivery system that is designed to provide independent release of different active ingredients contained in a drug. SyncroDose is a drug delivery system that is designed to release the active ingredient of a drug at the desired site and time in the digestive tract.

Our proprietary controlled release drug delivery technology is utilized in four products that were developed with collaborators and have been approved in various countries. In addition, we have a number of product candidates in our drug development pipeline. The most advanced of these is oxymorphone ER, an extended release formulation of oxymorphone, a narcotic analgesic being developed for the treatment of moderate to severe pain. We are developing oxymorphone ER with Endo Pharmaceuticals, Inc. In October 2003, Endo received an approvable letter from the FDA for oxymorphone ER. In the letter, the FDA requested that Endo address certain questions, provide additional clarification and information, and conduct some form of additional clinical trials to further confirm the safety and efficacy of oxymorphone ER, before the FDA would approve Endo's NDA for oxymorphone ER. Endo has stated it expects to meet with the FDA during the first quarter of 2004 to clarify the issues raised in the letter, review the necessity for additional trials and discuss its responses to the approvable letter. We anticipate that Endo will receive information at that meeting about the final path to regulatory approval and whether any additional trials will be required by the FDA. We are also developing PW2101, a branded product for the treatment of hypertension that we have formulated using our TIMERx technology. In the fourth quarter of 2003, we completed a pivotal clinical trial of this product candidate and anticipate releasing results of this study in the first quarter of 2004. We expect to file an NDA for this product by the end of 2004.

Prior to February 27, 2003, we also developed, manufactured and distributed branded pharmaceutical excipients, which are the inactive ingredients in tablets and capsules, primarily consisting of binders, disintegrants and lubricants. On February 27, 2003, we sold substantially all of the assets used in our excipient business to subsidiaries and affiliates of Josef Rettenmaier Holding GmbH & Co. KG. We received \$39.5 million in cash and a promissory note for \$2.25 million in consideration for the excipient business. We received \$1.0 million of the \$2.25 million promissory note in April 2003 with the balance due in May 2004. We used approximately \$5.5 million of proceeds of the sale of our excipient business to repay outstanding debt. Commencing in the first quarter of 2003, we reported the operating results of the excipient business as a discontinued operation. As a result of the sale of the excipient business, our audited consolidated financial statements included in this annual report on Form 10-K present our excipient business as a discontinued operation for all periods presented.

On August 5 and August 6, 2003, we completed the sale of a total of 2,507,762 shares of common stock through a private placement to selected institutional investors, resulting in net proceeds to us, after fees and expenses, of approximately \$49.3 million. As part of this transaction, we granted the institutional investors additional rights to purchase up to an additional 501,552 shares of common stock at a price of \$26.00 per share. These additional investment rights expired on December 9, 2003 without being exercised.

We have incurred net losses since 1994. As of December 31, 2003, our accumulated deficit was approximately \$94.4 million. We expect operating losses and negative cash flows to continue until substantial sales of products commercialized utilizing TIMERx technology occur. A substantial portion

of our revenues through February 27, 2003 were generated from sales of our pharmaceutical excipient product line. During 2001, 2002, and 2003 through the date that we sold our excipient business, sales of our excipient products generated positive cash flows from operations, although as a whole we had negative cash flows from operations. Our revenues for 2003 were generated primarily from Mylan royalties and shipments of bulk TIMERx. Our future profitability will depend on several factors, including:

- the successful commercialization of TIMERx controlled release products, including in particular oxymorphone ER;
- royalties from Mylan's sales of Pfizer's 30 mg generic version of Procardia XL; and
- the level of our investment in research and development activities.

Our strategy includes a significant commitment to spending on research and development targeted at identifying and developing modified release products that can be formulated using our drug delivery technologies. We also expect to expend significant resources on the development of new drug delivery technologies, both internally and through in-licenses or acquisitions. Our spending in the area of new technology however, is discretionary and is subject to identifying appropriate opportunities, as well as the availability of funds from our operations, cash resources, collaborative research and development arrangements and external financing.

Our results of operations may fluctuate from quarter to quarter depending on if and when oxymorphone ER is approved, the amount and timing of royalties on Mylan's sales of Pfizer's 30 mg generic version of Procardia XL, volume and timing of shipments of formulated bulk TIMERx, and on variations in payments under our collaborative agreements, including payments upon the achievement of specified milestones.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. We base our estimates on historical experience and on various other factors that we believe to be reasonable under the circumstances. We regard an accounting estimate underlying our financial statements as a "critical accounting estimate" if the nature of the estimate or assumption is material due to the level of subjectivity and judgment involved or the susceptibility of such matter to change and if the impact of the estimate or assumption on our financial condition or performance may be material. On an ongoing basis, we evaluate these estimates and judgments. Actual results may differ from these estimates under different assumptions or conditions. While our significant accounting policies are fully described in Note 2 to our consolidated financial statements included in this annual report, we regard the following as critical accounting estimates.

Revenue Recognition

Revenues received from non-refundable upfront licensing fees are recognized ratably over the development period of the collaboration agreement, when this period involves development risk associated with the incomplete stage of a product's development or over the estimated or contractual licensing and supply term when there exists an obligation to supply inventory for manufacture. Non-refundable milestone fees received for the development funding of a product are partially recognized upon receipt based on our proportionate development efforts achieved to date relative to the total expected development efforts and the remainder is generally recognized ratably over the remaining expected development period. The proportionate development efforts achieved are measured

by estimating the percentage of work completed that is required of us in the development effort for the product. This estimate is primarily derived from the underlying project plans and timelines, developed by qualified personnel who work closely on such projects. In particular, we review output measures such as job specifications and tasks completed, compared to all such job specifications and tasks outlined for a particular project. Job specifications vary with each project and primarily include development activities regarding initial formulation work, manufacturing scale-up, proof-of-principle biostudies, clinical development and regulatory matters. Other contractual fees received in connection with a collaborator's launch of a product are also recognized ratably over the estimated or contractual licensing and supply term. Product royalty fees are recognized when earned, as reported by our collaborators, and are generally subject to review or audit.

Research and Development Expenses

Research and development expenses consist of costs associated with products being developed internally as well as products being developed under collaboration agreements and include related salaries, benefits and other personnel related expenses, clinical trial costs, and contract and other outside service fees. Research and development costs are expensed as incurred. Certain reimbursements of costs, generally related to drug formulation on feasibility studies, are netted against research and development expense. A significant portion of our development activities are outsourced to third parties, including contract research organizations and contract manufacturers in connection with the production of clinical materials, or may be performed by our collaborators. These arrangements may require estimates to be made of related service fees or our share of development costs. These arrangements may also require us to pay termination costs to the third parties for reimbursement of costs and expenses incurred in the orderly termination of contractual services.

These estimates involve identifying services, which have been performed on our behalf, and estimating the level of service performed and associated cost incurred for such service as of each balance sheet date in our consolidated financial statements. In connection with such service fees, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual levels of service incurred by such service providers. In the event that we do not identify specific costs which have begun to be incurred or we under- or over-estimate the level of services performed or the costs of such services, our reported expenses for such period could be too low or too high. The date on which services commence, the level of services performed on or before a given date, and the cost of such services are often judgmental. We make these judgments based upon the facts and circumstances known to us in accordance with generally accepted accounting principles.

Deferred Taxes—Valuation Allowance

We record a valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realized. While we may consider any potential future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for the valuation allowance, in the event we were to determine that we would be able to realize our deferred tax assets in the future in excess of our net recorded amount, an adjustment to the deferred tax asset would increase income in the period such determination was made. At December 31, 2003, we had recorded full valuation allowances totaling approximately \$26.5 million against our net deferred tax assets.

Impairment of Long-Lived Assets

For purposes of recognizing and measuring impairment to our long-lived assets, including intangible assets such as our intellectual property, we assess the recoverability of the carrying amount of these assets whenever facts and circumstances indicate that the carrying amount may not be fully recoverable. We measure the impairment related to long-lived assets by the amount by which the carrying amount of the assets exceeds the fair value of the assets. In assessing the recoverability of our intangible assets, we must make assumptions regarding estimated future cash flows and other factors to

determine the fair value of the respective assets. Estimated cash flow assumptions include profitability projections provided by our marketing partners or developed internally, based upon historical revenues or projected market share for new products. If these estimates or their related assumptions change in the future, we may be required to record impairment charges for these assets.

Results of Operations for Years Ended December 31, 2003, 2002 and 2001

Revenues

	<u>2003</u>	PERCENTAGE (DECREASE) FROM 2002	<u>2002</u>	PERCENTAGE (DECREASE) FROM 2001	<u>2001</u>
	(IN THOUSANDS, EXCEPT PERCENTAGES)				
Product Sales	\$ 455	(26)%	\$ 619	(24)%	\$ 814
Royalty and Licensing Revenues	<u>4,223</u>	<u>(14)%</u>	<u>4,918</u>	<u>(1)%</u>	<u>4,982</u>
Total Revenues	\$4,678	(16)%	\$5,537	(4)%	\$5,796

The decreases in total revenues in 2003 and 2002 from the prior year were the result of decreases during each period for both components of our total revenues, product sales revenues, and royalty and licensing revenues. Our product sales consist of sales of formulated bulk TIMERx. Our royalty and licensing revenues primarily consist of royalties from Mylan.

The decrease in product sales in 2003 was primarily due to the timing of a shipment to a European customer of formulated bulk TIMERx that did not occur until the first quarter of 2004. The decrease in product sales in 2002 was primarily due to decreased orders for formulated bulk TIMERx from a European customer, believed to be due to their lower sales as a result of additional generic entrants to the marketplace.

In 2003, 2002 and 2001, royalties and licensing revenues consisted primarily of the royalties from Mylan on their sales of Pfizer's 30 mg generic Procardia XL. Royalties and licensing revenues decreased in 2003 and 2002 primarily due to pricing pressure from additional generic competition.

Selling, General and Administrative Expense

Selling, general and administrative expenses increased by 37% in 2003 to \$10.4 million as compared with \$7.6 million for 2002. The increase was primarily due to increased professional fees associated with a strategic review of our product pipeline, an increase in rent and lease expense related to office space, and increased personnel costs to support our business development and market research capabilities. The increase also reflects certain selling, general and administrative expenses that were incurred after February 27, 2003, the date of the sale of our excipient business, which were previously allocated to the excipient business but did not cease with the sale and were fully absorbed in continuing operations for the balance of 2003.

Selling, general and administrative expenses increased by 19% in 2002 to \$7.6 million as compared with \$6.4 million in 2001. The increase was primarily due to an increase in our share of marketing expenses on oxymorphone ER, increased compensation expense primarily due to hiring additional personnel and increased business insurance costs.

Research and Product Development Expense

	2003	PERCENTAGE INCREASE (DECREASE) FROM 2002	2002	PERCENTAGE INCREASE (DECREASE) FROM 2001	2001
	(IN THOUSANDS, EXCEPT PERCENTAGES)				
Oxymorphone ER	\$ 1,947	(78)%	\$ 8,914	3%	\$ 8,657
PW2101	9,443	420%	1,815	32%	1,372
Research and New Technology					
Development	2,344	6%	2,213	61%	1,378
Phase I Products and Internal Costs	6,856	71%	4,013	(16)%	4,783
Total Research and Product Development Expense	<u>\$20,590</u>	<u>21%</u>	<u>\$16,955</u>	<u>5%</u>	<u>\$16,190</u>

In the preceding table, research and development expenses are set forth in the following four categories:

- *Oxymorphone ER*—These expenses reflect our direct external expenses relating to the development of oxymorphone ER. These expenses consist primarily of payments to third parties, including payments to Endo for our share of development costs under our collaboration agreement with Endo;
- *PW2101*—These expenses reflect our direct external expenses relating to the development of PW2101. These expenses consist primarily of payments to third parties in connection with clinical trials and the manufacturing of products prior to regulatory approval for clinical use and for commercial use;
- *Research and New Technology Development*—These expenses reflect both our direct external expenses and our internal expenses relating to the development of new drug delivery technologies. These direct external expenses consist primarily of payments to third parties in connection with outside laboratory and consulting fees. Our internal expenses primarily include salaries and benefits, and other costs such as depreciation on purchased equipment and amortization of patent costs.
- *Phase I Products and Internal Costs*—These expenses reflect both our direct external expenses and our internal expenses relating to the development of phase I product candidates and reflect other unallocated research and development expenses. Our direct external expenses primarily reflect payments to third parties for the active drug and proof-of-principle biostudies conducted for our phase I products. Our internal expenses include expenses such as salaries and benefits and laboratory facility costs.

Total research and product development expenses increased in 2003 primarily due to increased costs relating to the development of PW2101, as well as increased costs relating to the development of phase I product candidates and new drug delivery technologies, partially offset by decreased costs relating to the development of oxymorphone ER. Total research and product development expenses increased in 2002 due to increased costs relating to the development of oxymorphone ER, PW2101 and new drug delivery technologies, partially offset by decreased costs related to the development of phase I product candidates.

Oxymorphone ER, which we are developing with Endo, is the most advanced of our product candidates. Endo, which is responsible for conducting the clinical trials and seeking regulatory approval of the product, completed the clinical trials for this product in 2002, and the FDA accepted for filing the NDA for oxymorphone ER in February 2003. In October 2003, the FDA issued to Endo an approvable letter for oxymorphone ER. In the letter, the FDA requested that Endo address certain

questions, provide additional clarification and information, and conduct some form of additional clinical trials to further confirm the safety and efficacy of oxymorphone ER, before the FDA would approve Endo's NDA for oxymorphone ER. Endo has stated it expects to meet with the FDA during the first quarter of 2004 to clarify the issues raised in the letter and discuss its responses. We anticipate that Endo will receive information at that meeting about the final path to regulatory approval and whether any additional trials will be required by the FDA. Research and development expenses related to oxymorphone ER decreased in 2003, due to the discontinuation of our funding of the development of oxymorphone ER effective April 17, 2003. Research and development expenses related to oxymorphone ER increased in 2002 as a result of increased costs of clinical trials for oxymorphone ER. We have not incurred any research and development expenses related to oxymorphone ER since April 17, 2003, and we do not expect to incur any additional research and development expenses relating to oxymorphone ER unless we resume our participation in the funding of the expenses of oxymorphone ER.

Approximately 46% of the research and development spending in 2003 related to the direct costs associated with clinical development and manufacturing scale-up of PW2101. We have recently completed a pivotal trial of PW2101 for the treatment of hypertension and expect to release those results in the first quarter of 2004. In this trial we dosed 163 patients. The remainder of the development program includes additional work on a manufacturing site change, stability, and the compilation of the NDA. Assuming that the trials and the rest of the development work are successful, we expect that we would submit an NDA for this product in late 2004. Research and development expenses related to PW2101 increased in 2003 as a result of clinical trials and the scale-up and manufacturing of commercial batches, and increased in 2002 as a result of proof-of-principle biostudies and the manufacturing of clinical supplies. Although we have developed PW2101 on our own, we do not intend to market PW2101. As a result, we are currently seeking a marketing partner for this product.

There can be no assurance that any of our products will be successfully developed, will receive regulatory approval, or will be successfully commercialized. Completion of clinical trials and commercialization of these product candidates may take several years, and the length of time can vary substantially according to the type, complexity and novelty of a product candidate. Due to the variability in the length of time necessary to develop a product, the uncertainties related to the estimated cost of the development projects and ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the ultimate cost to bring our product candidates to market are not available.

Research and new technology development expenses increased in 2003 due primarily to our focus during the period on the expansion of the applications of our TIMERx technology and the intellectual property underlying our TIMERx technology. The increase in research and new technology development in 2002 was primarily due to our completion of the development of our SyncroDose technology.

Phase I products and internal costs increased in 2003 primarily as a result of an increase in the number of phase I product candidates in our pipeline, an increase in external costs incurred in connection with proof-of-principle biostudies for these phase I product candidates and an increase in the number of employees engaged in our research and development efforts and the costs associated with such employees.

Tax Rates

For continuing operations, the effective tax rates for 2003, 2002 and 2001 were essentially zero. The effective tax rates are higher than the federal statutory rate of a 34% benefit due primarily to valuation allowances recorded to offset net deferred tax assets relating to our net operating losses, and foreign income taxes.

Liquidity and Capital Resources

Sources of Liquidity

Subsequent to August 31, 1998, the date we became an independent, publicly-owned company, we have funded our operations and capital expenditures from the proceeds from the sale and issuance of shares of common stock, the sale of our excipient business, the sale of excipients, sales of formulated bulk TIMERx, royalties and milestone payments from Mylan and other collaborators, and advances under credit facilities.

We are a party to an agreement with Endo with respect to the development of oxymorphone ER. On April 17, 2003, we discontinued our participation in the funding of the development and marketing of oxymorphone ER. Accordingly, our research and development, and selling, general and administrative expenses with respect to oxymorphone ER decreased significantly in the second, third and fourth quarters of 2003 compared to the corresponding periods in 2002. We do not expect any expenses relating to oxymorphone ER in 2004 unless we resume our participation in the funding of the development and marketing of oxymorphone ER. We estimate that through December 31, 2003, the unfunded development costs under our agreement with Endo approximated \$6.7 million.

On February 27, 2003, we completed the sale of our excipient business to Rettenmaier. As a result of the sale of our excipient business, we had approximately \$35 million of net cash proceeds available after the closing. However, as a result of the sale of our excipient business, we no longer derive cash flow from the sale of excipients. A portion of the proceeds from the sale of our excipient business was used to repay the \$3.3 million of outstanding borrowings under our line of credit, which was terminated on February 27, 2003. In addition, we used the proceeds from the sale of our excipient business to repay in full a \$2.25 million note payable to AstraZeneca AB, incurred in connection with our acquisition of specified intellectual property related to the excipient business.

On August 5 and August 6, 2003, we completed the sale of a total of 2,507,762 shares of common stock through a private placement to selected institutional investors, resulting in net proceeds to us, after fees and expenses, of approximately \$49.3 million. As part of this transaction, we granted the institutional investors additional rights to purchase up to an additional 501,552 shares of common stock at a price of \$26.00 per share. These additional investment rights became exercisable on September 12, 2003, and expired on December 9, 2003. None of these additional investment rights were exercised.

Cash Flows

As of December 31, 2003, we had cash, cash equivalents, and short-term investments of \$63.9 million. We have no committed sources of capital other than Rettenmaier's commitment to repay us \$1.25 million in May 2004, pursuant to a promissory note in connection with the sale of the excipient business.

We had negative cash flow from operations for 2003 of \$22.2 million, primarily due to the loss from continuing operations of \$26.0 million in the period, partially offset by net cash provided by discontinued operations operating activities of \$874,000 for the period prior to the sale of our excipient business on February 27, 2003, and net increases in payables and accrued expenses of \$2.1 million. We had negative cash flow from operations for 2002 of \$14.8 million, primarily due to the loss from continuing operations of \$19.0 million in the period, partially offset by net cash provided by discontinued operations operating activities of \$2.2 million, and net increases in payables and accrued expenses of \$1.6 million. Our cash flow in 2003 has differed from our cash flow during 2002 primarily because we no longer derive revenues from sales of our excipient products and do not incur expenses in connection with our excipient business, except for the related revenues and expenses during the period from January 1, 2003 through February 26, 2003.

Net cash used in investing activities totaled \$2.7 million for 2003, primarily reflecting our receipt of cash proceeds from the sale of our excipient business of \$36.9 million, net of transaction costs paid of \$1.4 million, and our net investment in marketable securities of \$36.7 million. In addition, investing activities also reflected \$1.8 million in capital expenditures for the acquisitions of fixed assets primarily related to the second phase of an implementation project relating to our information system and laboratory equipment for drug development activities. Funds expended for intangible assets totaled \$1.0 million and include costs to secure patents on technology developed by us.

Financing activities provided \$48.5 million in cash, primarily due to the cash received from the private placement of our common stock in August 2003, as well as \$2.2 million in cash provided by discontinued operations, which was offset by the net repayment of approximately \$5.7 million in loans, primarily in connection with the sale of our excipient business.

Funding Requirements

We anticipate that, excluding any revenues from oxymorphone ER, our existing capital resources and anticipated internally generated funds from the sale of formulated bulk TIMERx, royalties from Mylan and other payments from collaborators, will be sufficient to fund our operations on an ongoing basis without requiring us to seek external financings through at least 2005. We expect to continue to invest in capital expenditures in 2004 at levels similar to 2003 capital spending, primarily for laboratory equipment for our drug development activities and for patents on technology and products developed by us.

Our requirements for capital in our business are substantial and will depend on many factors, including:

- whether oxymorphone ER is approved on a timely basis, or at all;
- whether we resume our participation in the funding of the development and marketing of oxymorphone ER;
- the timing and amount of payments received under existing and possible future collaborative agreements, in particular oxymorphone ER;
- the structure of any future collaborative or development agreements;
- the progress of our collaborative and independent development projects, funding obligations with respect to the projects, and the related costs to us of clinical studies for our products;
- the costs and timing of adding drug development capabilities;
- royalties received from Mylan; and
- the prosecution, defense and enforcement of potential patent claims and other intellectual property rights.

If our existing resources are insufficient to satisfy our need for capital due to a delay in the approval for oxymorphone ER, lower than expected revenues from oxymorphone ER or otherwise, or if we acquire additional product candidates or technologies, we may need to sell additional equity or debt securities or seek additional financing through other arrangements. If we determine to seek additional funding, we may do so through collaborative agreements or research and development arrangements and public or private financings. Additional financing may not be available to us on acceptable terms, if at all.

If we raise additional funds by issuing equity or debt securities, further dilution to our then existing shareholders may result. In addition, the terms of the financing may adversely affect the holdings or the rights of such shareholders. We cannot be certain that additional public or private financing will be

available in amounts or on terms acceptable to us, if at all. If we are unable to obtain this additional financing, we may be required to delay, reduce the scope of, or eliminate one or more of our planned research, development and commercialization activities, which could harm our financial condition and operating results.

Contractual Obligations

Our outstanding contractual cash obligations relate to our operating leases, primarily for facilities, and purchase obligations relating to capital expenditures and clinical development. Below is a table summarizing our contractual cash obligations under our operating leases having initial lease terms of more than one year and our purchase obligations, as of December 31, 2003:

	<u>Total</u>	<u>Less than One Year</u>	<u>1-3 Years</u>	<u>4-5 Years</u>	<u>After 5 Years</u>
	(in thousands)				
Operating Leases	\$ 615	\$296	\$319	\$ —	\$ —
Purchase Obligations	699	699	—	—	—
Total	<u>\$1,314</u>	<u>\$995</u>	<u>\$319</u>	<u>\$ —</u>	<u>\$ —</u>

Net Operating Loss Carryforwards

At December 31, 2003, we had federal net operating loss, or NOL, carryforwards of approximately \$63.8 million for income tax purposes, of which approximately \$6.2 million, \$8.4 million, \$9.1 million, \$17.7 million, \$19.3 million and \$3.1 million expire in 2018, 2019, 2020, 2021, 2022, and 2023, respectively. In addition, we had research and development tax credit carryforwards of approximately \$2.2 million of which \$299,000, \$306,000, \$777,000, and \$828,000 expire in 2019, 2020, 2021, and 2022 respectively. The use of the NOL carryforwards and research and development tax credit carryforwards are limited to our future taxable earnings. For financial reporting purposes, at December 31, 2003 a valuation allowance of \$26.5 million has been recognized to offset net deferred tax assets, primarily attributable to the NOL carryforwards. Utilization of the operating losses are subject to a limitation due to the ownership change provisions of the Internal Revenue Code.

Market Risk and Risk Management Policies

Market risk is the risk of loss to future earnings, to fair values or to future cash flows that may result from changes in the price of a financial instrument. The value of a financial instrument may change as a result of changes in interest rates, foreign currency exchange rates and other market changes. Market risk is attributed to all market sensitive financial instruments, including debt instruments. Our operations are exposed to financial market risks, primarily changes in interest rates. Our interest rate risk primarily relates to our investments in marketable securities.

The primary objectives for our investment portfolio are liquidity and safety of principal. Investments are made to achieve the highest rate of return to us, consistent with these two objectives. Our investment policy limits investments to specific types of instruments issued by institutions with investment grade credit ratings and places restrictions on maturities and concentration by issuer.

At December 31, 2003, marketable securities consisted primarily of corporate debt, U.S. Government-agency backed discounted notes and certificates of deposit, and approximated \$38.6 million. These securities have contractual maturity dates of up to twenty-three months. Due to the relatively short-term maturities of these securities, management believes there is no significant market risk. At December 31, 2003, market values approximated carrying values. At December 31, 2003 we had approximately \$63.9 million in cash, cash equivalents and investments in marketable securities,

and accordingly, a sustained decrease in the rate of interest earned of 1% would have caused a decrease in the annual amount of interest earned of up to approximately \$639,000.

At December 31, 2002, marketable securities consisted of corporate debt and approximated \$2.1 million. These securities had contractual maturity dates of up to eleven months. At December 31, 2002, market values approximated carrying values. At December 31, 2002, the Company had approximately \$6.5 million in cash, cash equivalents and investments in marketable securities, and accordingly, a sustained decrease in the rate of interest earned of 1% would cause a decrease in the annual amount of interest earned of up to approximately \$65,000.

Recent Accounting Pronouncements

In November 2002, the Emerging Issues Task Force, or EITF, finalized its tentative consensus on EITF Issue 00-21, "Revenue Arrangements with Multiple Deliverables," which provides guidance on the timing and method of revenue recognition for arrangements that include the delivery of more than one product or service. EITF 00-21 is effective prospectively for arrangements entered into in fiscal periods beginning after June 15, 2003. The adoption of EITF 00-21 did not have an effect on our financial position or results of operations.

In June 2002, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards, or SFAS, No. 146, "Accounting for Costs Associated with Exit or Disposal Activities." The statement addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies EITF Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)." SFAS No. 146 states that a liability for a cost associated with an exit or disposal activity shall be recognized and measured initially at its fair value in the period in which the liability is incurred, except for a liability for one-time termination benefits that are incurred over a period of time. The statement is effective for exit or disposal activities initiated after December 31, 2002. The adoption of SFAS 146 did not have an effect on our financial position or results of operations.

In December 2003, the FASB issued SFAS No. 132 (revised 2003) "Employers' Disclosures about Pensions and Other Postretirement Benefits an amendment of FASB Statements No. 87, 88, and 106." This Statement revises employers' disclosures about pension plans and other postretirement benefit plans. It does not change the measurement or recognition of those plans required by FASB Statements No. 87, Employers' Accounting for Pensions, No. 88, Employers' Accounting for Settlements and Curtailments of Defined Benefit Pension Plans and for Termination Benefits, and No. 106, Employers' Accounting for Postretirement Benefits Other Than Pensions. This Statement retains the disclosure requirements contained in FASB Statement No. 132, "Employers' Disclosures about Pensions and Other Postretirement Benefits," which it replaces. It requires additional disclosures to those in the original Statement No. 132 about the assets, obligations, cash flows, and net periodic benefit cost of defined benefit pension plans and other defined benefit postretirement plans. The adoption of SFAS No. 132 (revised 2003) had no impact on the Company's financial position or results of operations.

Other pronouncements issued by the FASB or other authoritative accounting standards groups with future effective dates are either not applicable or not significant to our financial statements.

Forward Looking Statements

This annual report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. All statements, other than statements of historical facts, included or incorporated in this report regarding our strategy, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words "believes," "anticipates," "estimates," "plans," "expects," "intends," "may," "projects," "will," and "would" and similar expressions are intended to

identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. In addition, any forward-looking statements represent our estimates only as of the date this annual report is filed with the SEC and should not be relied upon as representing our estimates as of any subsequent date. We do not assume any obligation to update any forward-looking statements.

Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below in addition to the other information included or incorporated by reference in this prospectus before purchasing our common stock. If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer. In that case, the trading price of our common stock could fall, and you may lose all or part of the money you paid to buy our common stock.

We have not been profitable and expect to continue to incur substantial losses

We have incurred net losses since 1994, including net losses of \$15.9 million, \$17.1 million and \$16.0 million, during 2003, 2002, and 2001, respectively. We had a loss from continuing operations of \$26.0 million, \$19.0 million, and \$16.8 million in 2003, 2002, and 2001, respectively. As of December 31, 2003, our accumulated deficit was approximately \$94.4 million.

We expect net losses to continue until substantial sales of products commercialized utilizing TIMERx technology occur. If we are unable to successfully develop and commercialize these products, or generate substantial sales from these products, we may never achieve profitability.

A substantial portion of our revenues since 1994 has been generated from the sales of our pharmaceutical excipients. Our net losses in 2003, 2002 and 2001 were reduced as a result of the operating results of our excipient business. Since February 27, 2003, we have not generated any revenues from the sales of excipient products and our business depends exclusively on our drug delivery and drug development business.

Our future profitability will depend on several factors, including:

- the successful commercialization of TIMERx controlled release products, including in particular oxymorphone ER, a narcotic analgesic for the treatment of moderate to severe pain, being developed with Endo;
- royalties from Mylan's sales of Pfizer's 30 mg generic version of Procardia XL; and
- the level of investment in research and development activities.

Our strategy includes a significant commitment to spending on research and development targeted at identifying and developing modified release products that can be formulated using our TIMERx and other drug delivery technologies. We also expect to expend significant resources on the development of new drug delivery technologies, both internally and through in-licenses or acquisition. Our spending in the area of new technology, however, is discretionary and is subject to the availability of appropriate opportunities and funding.

We are dependent on collaborators to conduct clinical trials, obtain regulatory approvals for, and manufacture, market, and sell our TIMERx controlled release products

Many of our TIMERx controlled release products have been or are being developed and commercialized in collaboration with pharmaceutical companies. Under these collaborations, depending on the structure of the collaboration, we are dependent on our collaborators to fund some portion of

development, to conduct clinical trials, obtain regulatory approvals for, and manufacture, market and sell products utilizing our TIMERx controlled release technology. For instance, we are dependent on Endo to obtain the regulatory approvals required to market oxymorphone ER and will be dependent on Endo to manufacture and market oxymorphone ER in the United States. In addition, we are dependent on Mylan with respect to the marketing and sale of the 30 mg strength of Pfizer's generic version of Procardia XL.

Our collaborators may not devote the resources necessary or may otherwise be unable to complete development and commercialization of these potential products. Our existing collaborations are subject to termination on short notice under certain circumstances including, for example, if the collaborator determines that the product in development is not likely to be successfully developed or not likely to receive regulatory approval, if we breach the agreement or upon a bankruptcy event.

If we cannot maintain our existing collaborations or establish new collaborations, we would be required to terminate the commercialization of products or undertake commercialization activities at our own expense. Moreover, we have limited experience in conducting full-scale clinical trials, preparing and submitting regulatory applications and manufacturing, marketing and selling the pharmaceutical products. We may not be successful in performing these activities.

Our existing collaborations and any future collaborations with third parties may not be scientifically or commercially successful.

Factors that may affect the success of our collaborations include the following:

- our collaborators may be pursuing alternative technologies or developing alternative products, either on their own or in collaboration with others, that may be competitive with the product as to which they are collaborating with us, which could affect our collaborator's commitment to the collaboration with us;
- reductions in marketing or sales efforts, or a discontinuation of marketing or sales of our products by our collaborators would reduce our revenues, which may be based on a percentage of net sales by the collaborator;
- our collaborators may terminate their collaborations with us, which could make it difficult for us to attract new collaborators or adversely affect perception of us in the business and financial communities; and
- our collaborators may pursue higher priority programs or change the focus of their development programs, which could affect the collaborator's commitment to us.

We face significant competition, which may result in others discovering, developing or commercializing products before or more successfully than we do

The pharmaceutical industry is highly competitive and is affected by new technologies, governmental regulations, health care legislation, availability of financing, litigation and other factors. Many of our competitors have longer operating histories and greater financial, marketing, legal and other resources than we have and than some of our collaborators have.

We face competition from numerous public and private companies and their extended release technologies, including Johnson & Johnson's oral osmotic pump (OROS) technology, multiparticulate systems marketed by Elan Corporation plc, Biovail Corporation and K-V Pharmaceutical Company, traditional matrix systems marketed by SkyePharma, plc and other controlled release technologies marketed or under development by Andrx Corporation, among others.

Our TIMERx products in development will face competition from products with the same indication as the TIMERx products we are developing. For instance, we expect extended release

oxymorphone ER will face competition from MS Contin, Purdue Pharma's OxyContin and Duragesic marketed by Johnson & Johnson.

In addition to developing controlled release versions of immediate and other controlled release products, we also selectively develop generic versions of branded controlled release products. In development, we utilize our TIMERx technology and generic active ingredients to formulate product candidates. The success of these product candidates will depend, in large part, on the intensity of competition from the branded controlled release product, other generic versions of the branded controlled release product, and other drugs and technologies that compete with the branded controlled release product, as well as the timing of product approval.

The generic drug industry is characterized by frequent litigation between generic drug companies and branded drug companies. Those companies with significant financial resources will be better able to bring and defend any such litigation.

If our clinical trials are not successful or take longer to complete than we expect, we may not be able to develop and commercialize our products

In order to obtain regulatory approvals for the commercial sale of our potential products, including controlled release versions of immediate release products and branded generic products, we or our collaborators will be required to complete clinical trials in humans to demonstrate the safety and efficacy of the products. We or our collaborators may not be able to obtain authority from the FDA or other regulatory agencies to commence or complete these clinical trials.

The results from preclinical testing of a product that is under development may not be predictive of results that will be obtained in human clinical trials. In addition, the results of early human clinical trials may not be predictive of results that will be obtained in larger scale advanced stage clinical trials. Furthermore, we, our collaborators or the FDA may suspend clinical trials at any time if the subjects or patients participating in such trials are being exposed to unacceptable health risks, or for other reasons.

The rate of completion of clinical trials is dependent in part upon the rate of enrollment of patients. Patient accrual is a function of many factors including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study and the existence of competitive clinical trials. Delays in planned patient enrollment may result in increased costs and program delays.

We and our collaborators may not be able to successfully complete any clinical trial of a potential product within any specified time period. In some cases, we may not be able to complete the trial at all. Moreover, clinical trials may not show any potential product to be safe or efficacious. Thus, the FDA and other regulatory authorities may not approve any of our potential products for any indication.

Our business, financial condition, or results of operations could be materially adversely affected if:

- we or our collaborators are unable to complete a clinical trial of one of our potential products;
- the results of any clinical trial are unfavorable; or
- the time or cost of completing the trial exceeds our expectations.

We may not obtain regulatory approval; the approval process can be time-consuming and expensive

We are not able to market any of our products in the United States, Europe or in any other jurisdiction without marketing approval from the FDA, the European Agency for the Evaluation of Medicinal Products, or an equivalent foreign regulatory agency. The regulatory process to obtain market approval for a new drug takes many years and requires the expenditure of substantial resources. We have had only limited experience in preparing applications and obtaining regulatory approvals.

We also have a number of TIMERx products in our development pipeline. The most advanced of these is oxymorphone ER, which we are developing with Endo. In February 2003, the FDA accepted for filing an NDA for oxymorphone ER. In October 2003, the FDA issued to Endo an approvable letter for oxymorphone ER. In the letter, the FDA requested that Endo address certain questions, provide additional clarification and information, and conduct some form of additional clinical trials to further confirm the safety and efficacy of oxymorphone ER, before the FDA would approve Endo's NDA for oxymorphone ER. Endo intends to communicate with the FDA throughout the final approval process in order to address the issues raised in the approvable letter and determine the appropriate course of action. If the NDA for oxymorphone ER is not approved on a timely basis or at all, it would have a material adverse effect on our business, financial condition and results of operations.

We may encounter delays or rejections during any stage of the regulatory approval process based upon the failure of clinical data to demonstrate compliance with, or upon the failure of the product to meet, the FDA's requirements for safety, efficacy and quality; and those requirements may become more stringent due to changes in regulatory agency policy or the adoption of new regulations. After submission of a marketing application, in the form of an NDA or an abbreviated new drug application, or ANDA, the FDA may deny the application, may require additional testing or data and/or may require post marketing testing and surveillance to monitor the safety or efficacy of a product. While the U.S. Food, Drug and Cosmetic Act, or FDCA, provides for a 180-day review period, the FDA commonly takes one to two years to grant final approval to a marketing application.

Further, the terms of approval of any marketing application, including the labeling content, may be more restrictive than we desire and could affect the marketability of products incorporating our controlled release technology.

Certain products containing our TIMERx controlled release technology require the filing of an NDA. A full NDA must include complete reports of preclinical, clinical and other studies to prove adequately that the product is safe and effective, which involves, among other things, full clinical testing, and as a result requires the expenditure of substantial resources. In certain cases involving controlled release versions of FDA-approved immediate release drugs, we may be able to rely on existing publicly available safety and efficacy data to support an NDA for controlled release products under Section 505(b)(2) of the FDCA when such data exists for an approved immediate release version of the same chemical entity. However, we can provide no assurance that the FDA will accept such section 505(b)(2) NDA, or that we will be able to obtain publicly available data that is useful. The section 505(b)(2) NDA process is a highly uncertain avenue to approval because the FDA's policies on section 505(b)(2) NDAs have not yet been fully developed. There can be no assurance that the FDA will approve an application submitted under section 505(b)(2) in a timely manner or at all.

The FDA also has the authority to revoke or suspend approvals of previously approved products for cause, to debar companies and individuals from participating in the drug-approval process, to request recalls of allegedly volatile products, to seize allegedly volatile products, to obtain injunctions to close manufacturing plants allegedly not operating in conformity with current Good Manufacturing Practices and to stop shipments of allegedly volatile products. The FDA may seek to impose pre-clearance requirements on products currently being marketed without FDA approval, and there can be no assurance that we or our third-party manufacturers or collaborators will be able to obtain approval for such products within the time period specified by the FDA.

Even if we obtain marketing approval, our products will be subject to ongoing regulatory review

If regulatory approval of a product is granted, such approval may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for costly post-marketing follow-up studies. As to products for which marketing approval is obtained, the manufacturer of the product and the manufacturing facilities will be subject to continual review and

periodic inspections by the FDA and other regulatory authorities. The subsequent discovery of previously unknown problems with the product, manufacturer or facility may result in restrictions on the product or manufacturer, including withdrawal of the product from the market.

If we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

We may require additional funding, which may be difficult to obtain

As of December 31, 2003, we had cash, cash equivalents, and short-term investments of \$63.9 million. We have no committed sources of capital other than Rettenmaier Holding GmbH & Co. KG's commitment to repay us \$1.25 million due in May 2004, in connection with the sale of the excipient business.

We anticipate that, excluding any revenues from oxymorphone ER, our existing capital resources and anticipated internally generated funds from the sale of formulated bulk TIMERx, royalties from Mylan and other payments from collaborators will be sufficient to fund our operations on an ongoing basis without requiring us to seek external financings through at least 2005.

We have had negative cash flows and net losses since 1994. See "We have not been profitable and expect to continue to incur substantial losses" for a discussion of our risk of continued losses. We expect negative cash flows from operations to continue until substantial sales of products commercialized utilizing TIMERx technology occur, particularly because we expect our operating expenses to continue to increase in the future, including our research and development expenses, as our product development efforts accelerate.

The proceeds from the sale of our excipient business provided us with significant funding, but we have lost the positive cash flows generated by our excipient business.

Our requirements for additional capital are substantial and will depend on many factors, including:

- whether oxymorphone ER is approved on a timely basis, or at all;
- whether we resume our participation in the funding of the development and marketing of oxymorphone ER;
- the timing and amount of payments received under existing and possible future collaborative agreements, in particular oxymorphone ER;
- the structure of any future collaborative or development agreements;
- the progress of our collaborative and independent development projects, funding obligations with respect to the projects, and the related costs to us of clinical studies for our products;
- the costs and timing of adding drug development capabilities;
- royalties received from Mylan; and
- the prosecution, defense and enforcement of potential patent claims and other intellectual property rights.

If our existing resources are insufficient to satisfy our need for capital due to a delay in the approval for oxymorphone ER, lower than expected revenues from oxymorphone ER or otherwise, or if we acquire additional product candidates or technologies, we may need to sell additional equity or debt securities or seek additional financing through other arrangements. If we determine to seek additional funding, we may do so through collaborative agreements or research and development arrangements and public or private financings. Additional financing may not be available to us on acceptable terms, if at all.

If we raise additional funds by issuing equity securities, further dilution to our then existing shareholders may result. In addition, the terms of the financing may adversely affect the holdings or the rights of such shareholders. Any sale of additional equity or debt securities may result in additional dilution to our shareholders, and we cannot be certain that additional public or private financing will be available in amounts or on terms acceptable to us, if at all. If we are unable to obtain this additional financing, we may be required to delay, reduce the scope of, or eliminate one or more of our planned research, development and commercialization activities, which could harm our financial condition and operating results.

Our controlled release products that are generic versions of branded controlled release products that are covered by one or more patents may be subject to litigation

We expect to file or have our collaborators file ANDAs or NDAs for our controlled release products under development that are covered by one or more patents of the branded product. It is likely that the owners of the patents covering the brand name product or the sponsors of the NDA with respect to the branded product will sue or undertake regulatory initiatives to preserve marketing exclusivity, as Pfizer did with respect to our generic version of Procardia XL that was developed with Mylan. Any significant delay in obtaining FDA approval to market our product candidates as a result of litigation, as well as the expense of such litigation, whether or not we or our collaborators are successful, could have a material adverse effect on our business, financial condition and results of operations.

The market may not be receptive to products incorporating our drug delivery technologies

The commercial success of products incorporating our extended release technology that are approved for marketing by the FDA and other regulatory authorities will depend upon their acceptance by the medical community and third party payors as clinically useful, cost-effective and safe. No product based on our TIMERx or other extended release technology is marketed in the United States, so there can be no assurance as to market acceptance.

Other factors that we believe could materially affect market acceptance of these products include:

- the timing of the receipt of marketing approvals and the countries in which such approvals are obtained;
- the safety and efficacy of the product as compared to competitive products; and
- the cost-effectiveness of the product and the ability to receive third party reimbursement.

Our success depends on our protecting our patents and patented rights

Our success depends in significant part on our ability to develop patentable products, to obtain patent protection for our products, both in the United States and in other countries, and to enforce these patents. The patent positions of pharmaceutical firms, including us, are generally uncertain and involve complex legal and factual questions. As a result, patents may not issue from any patent applications that we own or license. If patents are issued, the claims allowed may not be sufficiently broad to protect our technology. In addition, issued patents that we own or license may be challenged, invalidated or circumvented. Our patents also may not afford us protection against competitors with similar technology.

Our success also depends on our not infringing patents issued to competitors or others. We are aware of patents and patent applications belonging to competitors and others that may require us to alter our products or processes, pay licensing fees or cease certain activities.

We may not be able to obtain a license to any technology owned by a third party that we require to manufacture or market one or more products. Even if we can obtain a license, the financial and other terms may be disadvantageous.

Our success also depends on our maintaining the confidentiality of our trade secrets and patented know-how. We seek to protect such information by entering into confidentiality agreements with employees, consultants, licensees and pharmaceutical companies. These agreements may be breached by such parties. We may not be able to obtain an adequate, or perhaps any, remedy to such a breach. In addition, our trade secrets may otherwise become known or be independently developed by our competitors.

We may become involved in patent litigation or other intellectual property proceedings relating to our products or processes which could result in liability for damage or stop our development and commercialization efforts

The pharmaceutical industry has been characterized by significant litigation, interference and other proceedings regarding patents, patent applications and other intellectual property rights. The types of situations in which we may become parties to such litigation or proceedings include:

- We or our collaborators may initiate litigation or other proceedings against third parties to enforce our patent rights.
- We or our collaborators may initiate litigation or other proceedings against third parties to seek to invalidate the patents held by such third parties or to obtain a judgment that our products or processes do not infringe such third parties' patents.
- If our competitors file patent applications that claim technology also claimed by us, we or our collaborators may participate in interference or opposition proceedings to determine the priority of invention.
- If third parties initiate litigation claiming that our processes or products infringe their patent or other intellectual property rights, we and our collaborators will need to defend against such proceedings.

An adverse outcome in any litigation or other proceeding could subject us to significant liabilities to third parties and require us to cease using the technology that is at issue or to license the technology from third parties. We may not be able to obtain any required licenses on commercially acceptable terms or at all.

The cost of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Although the legal costs of defending litigation relating to a patent infringement claim are generally the contractual responsibility of our collaborators (unless such claim relates to TIMERx in which case such costs are our responsibility), we could nonetheless incur significant unreimbursed costs in participating and assisting in the litigation. Some of our competitors may be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

We have only limited manufacturing capabilities and will be dependent on third party manufacturers

We lack commercial scale facilities to manufacture our TIMERx material or any products we may develop in accordance with cGMP requirements prescribed by the FDA. We currently rely on Draxis Pharma, Inc. for the bulk manufacture of our TIMERx material for delivery to our collaborators under a contract that expires in September 2004. The agreement shall be automatically renewed for successive

one year periods, unless either party gives notice of its intent not to renew the contract, at least six months prior to the end of the then-current term.

We believe that there are a limited number of manufacturers that operate under cGMP regulations capable of manufacturing our TIMERx materials. Although we have qualified alternate suppliers with respect to the xanthan and locust bean gums used to manufacture our TIMERx material, if Draxis is unable to manufacture the TIMERx material in the required quantities, on a timely basis or at all, we may be unable to obtain alternative contract manufacturing, or obtain such manufacturing on commercially reasonable terms. There can be no assurance that Draxis or any other third parties upon which we rely for supply of our TIMERx material will perform, and any failures by third parties may delay development or the submission of products for regulatory approval, impair our collaborators' ability to commercialize products as planned and deliver products on a timely basis, or otherwise impair our competitive position, which could have a material adverse effect on our business, financial condition and results of operations.

If our third party manufacturers fail to perform their obligations, we may be adversely affected in a number of ways, including:

- our collaborators may not be able to meet commercial demands for our products on a timely basis;
- our collaborators may not be able to initiate or continue clinical trials of products that are under development; and
- our collaborators may be delayed in submitting applications for regulatory approvals of our products.

We have limited experience in manufacturing TIMERx material on a commercial scale and no facilities or equipment to do so. If we determine to develop our own manufacturing capabilities, we will need to recruit qualified personnel and build or lease the requisite facilities and equipment. We may not be able to successfully develop our own manufacturing capabilities. Moreover, it may be very costly and time consuming for us to develop such capabilities.

The manufacture of any of our products is subject to regulation by the FDA and comparable agencies in foreign countries. Any delay in complying or failure to comply with such manufacturing requirements could materially adversely affect the marketing of our products and our business, financial condition and results of operations.

We are dependent upon a limited number of suppliers for the gums used in our TIMERx material

Our drug delivery systems are based a hydrophilic matrix combining a heterodispersed mixture primarily composed of two polysaccharides, xanthan and locust bean gums, in the presence of dextrose. These gums are also used in our Geminex and SyncroDose drug delivery systems. We purchase these gums from a primary supplier. We have qualified alternate suppliers with respect to such materials, but we can provide no assurance that interruptions in supplies will not occur in the future or that we will not have to obtain substitute suppliers. Any interruption in these supplies could have a material adverse effect on our ability to manufacture bulk TIMERx for delivery to our collaborators.

If we or our collaborators fail to obtain an adequate level of reimbursement by third party payors for our controlled release products, they may not be able to successfully commercialize controlled release products

The availability of reimbursement by governmental and other third party payors affects the market for any pharmaceutical product. These third party payors continually attempt to contain or reduce the costs of health care by challenging the prices charged for medical products and services. In specific

foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control.

The generic versions of controlled release products being developed may be assigned an AB rating if the FDA considers the product to be therapeutically equivalent to the branded controlled release drug. Failure to obtain an AB rating from the FDA would indicate that for certain purposes the drug would not be deemed to be therapeutically equivalent, would not be fully substitutable for the branded controlled release drug and would not be relied upon by Medicaid and Medicare formularies for reimbursement.

In both the U.S. and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system. Further proposals are likely. The potential for adoption of these proposals may affect our ability to raise capital, obtain additional collaborative partners and market our products.

If we or our collaborators obtain marketing approvals for our products, we expect to experience pricing pressure due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals. We may not be able to sell our products profitably if reimbursement is unavailable or limited in scope or amount.

We will be exposed to product liability claims and may not be able to obtain adequate product liability insurance

Our business exposes us to potential product liability risks which are inherent in the testing, manufacturing, marketing and sale of pharmaceutical products. Product liability claims might be made by consumers, health care providers, pharmaceutical companies, or others that sell our products. These claims may be made even with respect to those products that are manufactured in licensed and regulated facilities or that otherwise possess regulatory approval for commercial sale.

We are currently covered by primary product liability insurance in the minimum amounts of \$1 million per occurrence and \$2.0 million annually in the aggregate on a claims-made basis and by umbrella liability insurance in excess of \$25.0 million which can also be used for product liability insurance. This coverage may not be adequate to cover any product liability claims. Product liability coverage is expensive. In the future, we may not be able to maintain or obtain such product liability insurance at a reasonable cost or in sufficient amounts to protect us against losses due to liability claims. Any claims that are not covered by product liability insurance could have a material adverse effect on our business, financial condition and results of operations.

The market price of our common stock may be volatile

The market price of our common stock, like the market prices for securities of pharmaceutical, biopharmaceutical and biotechnology companies, have historically been highly volatile. The market from time to time experiences significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Factors such as fluctuations in our operating results, future sales of our common stock, announcements of technological innovations or new therapeutic products by us or our competitors, announcements regarding collaborative agreements, clinical trial results, government regulation, developments in patent or other proprietary rights, public concern as to the safety of drugs developed by us or others, changes in reimbursement policies, comments made by securities analysts and general market conditions may have a significant effect on the market price of the common stock.

Specific provisions of our Shareholder Rights Plan, Certificate of Incorporation and Bylaws and of Washington law make a takeover of Penwest or a change in control or management of Penwest more difficult

We have adopted a shareholder rights plan, often referred to as a poison pill. The rights issued under the plan will cause substantial dilution to a person or group that attempts to acquire us on terms that are not approved by our board of directors, unless the board first determines to redeem the rights. Various provisions of our Certificate of Incorporation, our Bylaws and Washington law may also have the effect of deterring hostile takeovers or delaying or preventing changes in control or management of our company, including transactions in which our shareholders might otherwise receive a premium for their shares over then current market prices. In addition, these provisions may limit the ability of shareholders to approve transactions that they may deem to be in their best interest.

ITEM 7A: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Reference is made to the disclosure under the caption "Market Risk and Risk Management Policies" in "Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations."

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

All financial statements required to be filed hereunder are filed as Appendix A hereto and are listed under Item 15(a) included herein.

ITEM 9: CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures. Our management, with the participation of our Chief Executive Officer, or CEO, and Chief Financial Officer, or CFO, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act) as of December 31, 2003. Based on this evaluation, our CEO and CFO concluded that, as of December 31, 2003, our disclosure controls and procedures were (1) designed to ensure that material information relating to us, is made known to our CEO and CFO by others within our company, particularly during the period in which this report was being prepared and (2) effective, in that they provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms.

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

PART III

ITEM 10: DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information set forth under "Election of Directors," "Committees of the Board," "Code of Ethics" and "Section 16(a) Beneficial Ownership Reporting Compliance" in our definitive Proxy Statement for the 2004 Annual Meeting of Shareholders is incorporated herein by reference.

Information regarding our executive officers is set forth in Part I, under the caption "Executive Officers of the Registrant."

ITEM 11: EXECUTIVE COMPENSATION

The information set forth under "Executive Compensation," "Director Compensation" and "Compensation Committee Interlocks and Insider Participation" in our definitive Proxy Statement for the 2004 Annual Meeting of Shareholders is incorporated herein by reference.

ITEM 12: SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information set forth under "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance Under the Equity Compensation Plans" in our definitive Proxy Statement for the 2004 Annual Meeting of Shareholders is incorporated herein by reference.

ITEM 13: CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information relating to certain relationships and related transactions set forth under "Certain Relationships and Related Transactions" in our definitive Proxy Statement for the 2004 Annual Meeting of Shareholders is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information set forth under "Independent Auditor Fees and Other Matters" in our definitive Proxy Statement for the 2004 Annual Meeting of Shareholders is incorporated herein by reference.

PART IV

ITEM 15: EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

(a)(1) Financial Statements and Financial Statement Schedule

The following documents are filed as Appendix A hereto and are included as part of this Annual Report on Form 10-K.

The consolidated balance sheets as of December 31, 2003 and 2002 and the related statements of operations, cash flows and shareholders' equity for each of the three years in the period ended December 31, 2003.

Schedule II—Valuation and Qualifying Accounts

All other schedules for which provision is made in the applicable accounting regulations of the Securities and Exchange Commission are omitted because they are not applicable or because the information is presented in the financial statements or notes thereto.

(2) Exhibits

The list of Exhibits filed as part of this Annual Report on Form 10-K are set forth on the Exhibit Index immediately preceding such exhibits, and is incorporated herein by reference. This list includes a subset containing each management contract, compensatory plan, or arrangement required to be filed as an exhibit to this report.

(b) Reports on Form 8-K.

On October 20, 2003, we filed a report on Form 8-K announcing that the United States Food and Drug Administration had issued to Endo Pharmaceuticals Inc. an approvable letter for oxymorphone ER.

On October 30, 2003, we filed a report on Form 8-K announcing our results for the third quarter ended September 30, 2003.

On November 21, 2003, we filed a report on Form 8-K announcing that in its Quarterly Report on Form 10-Q for the quarter ended September 20, 2003, Endo addressed the status of the FDA approval process for oxymorphone ER and stated that it no longer believed that the launch date of the product would be the first quarter of 2004.

On December 22, 2003, we filed a report on Form 8-K announcing that in a press release issued on December 18, 2003, Endo stated that it expected to meet with the FDA prior to the end of the first quarter of 2004 to discuss the approvable letter it received for oxymorphone ER and that it anticipated having further clarity as to the path required to obtain final approval from the FDA subsequent to such meeting.

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.

PENWEST PHARMACEUTICALS CO.

Date: March 9, 2004

/s/ TOD R. HAMACHEK

Tod R. Hamachek,
*Chairman of the Board
and Chief Executive Officer
(Principal Executive Officer)*

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Date: March 9, 2004

/s/ TOD R. HAMACHEK

Tod R. Hamachek,
Chairman of the Board, Chief Executive Officer
and Director
(Principal Executive Officer)

Date: March 9, 2004

/s/ JENNIFER L. GOOD

Jennifer L. Good,
Sr. Vice President, Finance and Chief Financial
Officer
(Principal Financial and Accounting Officer)

Date: March 9, 2004

/s/ PAUL E. FREIMAN

Paul E. Freiman,
Director

Date: March 9, 2004

/s/ JERE E. GOYAN

Jere E. Goyan, Ph.D.,
Director

Date: March 9, 2004

/s/ ROLF H. HENEL

Rolf H. Henel,
Director

Date: March 9, 2004

/s/ ROBERT J. HENNESSEY

Robert J. Hennessey,
Director

Date: March 9, 2004

/s/ JOHN N. STANIFORTH

John N. Staniforth, Ph.D.,
Director

Date: March 9, 2004

/s/ ANNE M. VANLENT

Anne M. VanLent,
Director

APPENDIX A
PENWEST PHARMACEUTICALS CO.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS AND
FINANCIAL STATEMENT SCHEDULE

	<u>Page</u>
Consolidated Financial Statements	
Report of Independent Auditors	F-2
Consolidated Balance Sheets	F-3
Consolidated Statements of Operations	F-4
Consolidated Statements of Shareholders' Equity	F-5
Consolidated Statements of Cash Flows	F-6
Notes to Consolidated Financial Statements	F-7
Schedule II—Valuation and Qualifying Accounts	S-1

REPORT OF INDEPENDENT AUDITORS

To the Board of Directors and Shareholders
Penwest Pharmaceuticals Co.

We have audited the accompanying consolidated balance sheets of Penwest Pharmaceuticals Co. as of December 31, 2003 and 2002, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2003. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the 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 financial statements referred to above present fairly, in all material respects, the consolidated financial position of Penwest Pharmaceuticals Co. at December 31, 2003 and 2002, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

/s/ ERNST & YOUNG LLP

Stamford, Connecticut
February 6, 2004

PENWEST PHARMACEUTICALS CO.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share amounts)

	DECEMBER 31,	
	2003	2002
	(see Note 2—Basis of Presentation)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 25,307	\$ 1,629
Marketable securities	38,586	2,057
Trade accounts receivable	1,153	1,078
Inventories	656	461
Prepaid expenses and other current assets	1,364	1,902
Deferred transaction costs	—	1,741
Note receivable	1,250	—
Assets held for sale	—	33,143
Total current assets	68,316	42,011
Fixed assets, net	3,533	2,406
Patents, net	3,689	2,947
Cash surrender value of life insurance policy	2,965	2,856
Total assets	\$ 78,503	\$ 50,220
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,804	\$ 880
Accrued expenses	2,133	2,886
Accrued development costs	2,682	2,785
Taxes payable	—	258
Loans and notes payable	—	5,693
Deferred revenue	—	150
Liabilities held for sale	—	3,004
Total current liabilities	7,619	15,656
Deferred income taxes	—	118
Deferred revenue	84	134
Deferred compensation	3,104	2,889
Total liabilities	10,807	18,797
Shareholders' equity:		
Preferred stock, par value \$.001, authorized 1,000,000 shares, none outstanding	—	—
Common stock, par value \$.001, authorized 29,640,000 shares, issued and outstanding 18,362,523 shares at December 31, 2003 and 15,506,259 shares at December 31, 2002	18	16
Additional paid in capital	162,068	110,000
Accumulated deficit	(94,433)	(78,025)
Accumulated other comprehensive income (loss)	43	(568)
Total shareholders' equity	67,696	31,423
Total liabilities and shareholders' equity	\$ 78,503	\$ 50,220

See accompanying notes

PENWEST PHARMACEUTICALS CO.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	<u>YEAR ENDED DECEMBER 31,</u>		
	<u>2003</u>	<u>2002</u>	<u>2001</u>
	(see Note 2—Basis of Presentation)		
Revenues			
Product sales	\$ 455	\$ 619	\$ 814
Royalties and licensing fees	4,223	4,918	4,982
Total revenues	<u>4,678</u>	<u>5,537</u>	<u>5,796</u>
Cost of revenues	169	170	243
Gross profit	<u>4,509</u>	<u>5,367</u>	<u>5,553</u>
Operating expenses			
Selling, general and administrative	10,361	7,568	6,358
Research and product development	20,590	16,955	16,190
Total operating expenses	<u>30,951</u>	<u>24,523</u>	<u>22,548</u>
Operating loss from continuing operations	(26,442)	(19,156)	(16,995)
Investment income	476	379	477
Interest expense	34	243	290
Loss from continuing operations before income tax expense	(26,000)	(19,020)	(16,808)
Income tax expense	6	8	6
Loss from continuing operations	<u>(26,006)</u>	<u>(19,028)</u>	<u>(16,814)</u>
Earnings from discontinued operations, net of income tax expense of \$26, \$369 and \$467	177	1,929	833
Gain on sale of discontinued operations	9,894	—	—
Total discontinued operations	<u>10,071</u>	<u>1,929</u>	<u>833</u>
Net loss	<u><u>\$(15,935)</u></u>	<u><u>\$(17,099)</u></u>	<u><u>\$(15,981)</u></u>
Basic and diluted (loss) earnings per common share:			
Continuing operations	\$ (1.56)	\$ (1.23)	\$ (1.21)
Discontinued operations	0.60	0.12	0.06
Net loss	<u><u>\$ (0.96)</u></u>	<u><u>\$ (1.11)</u></u>	<u><u>\$ (1.15)</u></u>
Weighted average shares of common stock outstanding	<u>16,678</u>	<u>15,462</u>	<u>13,905</u>

See accompanying notes

PENWEST PHARMACEUTICALS CO.
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(in thousands)

	COMMON STOCK SHARES	AMOUNT	ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)	TOTAL
Balances, December 31, 2000	12,670	\$13	\$ 77,276	\$(44,945)	\$(1,327)	\$ 31,017
Net loss				(15,981)		(15,981)
Translation adjustments					(244)	(244)
Unrealized gain on marketable securities					52	52
Comprehensive loss						(16,173)
Issuance of common stock— private placement	2,447	2	29,669			29,671
Issuance of common stock pursuant to stock compensation plans	149	—	985			985
Issuance of common stock pursuant to Stock Purchase Plan	11	—	124			124
Balances, December 31, 2001	15,277	15	108,054	(60,926)	(1,519)	45,624
Net loss				(17,099)		(17,099)
Translation adjustments					988	988
Changes in unrealized gain on marketable securities					(37)	(37)
Comprehensive loss						(16,148)
Issuance of common stock pursuant to stock compensation plans	217	1	1,799			1,800
Issuance of common stock pursuant to Stock Purchase Plan	12	—	147			147
Balances, December 31, 2002	15,506	16	110,000	(78,025)	(568)	31,423
Net loss				(15,935)		(15,935)
Translation adjustments					110	110
Accumulated foreign currency translation adjustments of discontinued operations sold				(473)	473	—
Changes in unrealized gain on marketable securities					28	28
Comprehensive loss						(15,797)
Issuance of common stock— private placement	2,508	2	49,302			49,304
Issuance of common stock pursuant to stock compensation plans	340	—	2,662			2,662
Issuance of common stock pursuant to Stock Purchase Plan	9	—	104			104
Balances, December 31, 2003	<u>18,363</u>	<u>\$18</u>	<u>\$162,068</u>	<u>\$(94,433)</u>	<u>\$ 43</u>	<u>\$ 67,696</u>

See accompanying notes

PENWEST PHARMACEUTICALS CO.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	YEAR ENDED DECEMBER 31,		
	2003	2002	2001
	(see Note 2—Basis of Presentation)		
Operating activities:			
Net loss	\$(15,935)	\$(17,099)	\$(15,981)
Less earnings from discontinued operations, net of tax expense	(177)	(1,929)	(833)
Less gain on sale of discontinued operations	(9,894)	—	—
Loss from continuing operations	(26,006)	(19,028)	(16,814)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	679	222	264
Amortization	219	166	154
Deferred income taxes	(118)	—	—
Deferred revenue	(53)	(84)	(10)
Deferred compensation	215	178	187
Stock compensation	110	105	119
Changes in operating assets and liabilities:			
Trade accounts receivable	(35)	115	1,866
Inventories	(195)	(270)	275
Accounts payable, accrued expenses and other	2,117	1,609	(48)
Net cash used in continuing operations operating activities	(23,067)	(16,987)	(14,007)
Net cash provided by discontinued operations operating activities	874	2,230	2,494
Net cash used in operating activities	(22,193)	(14,757)	(11,513)
Investing activities:			
Proceeds from sale of discontinued operations, net of transaction costs paid of \$1,351	36,900	—	—
Acquisitions of fixed assets, net	(1,810)	(1,359)	(544)
Intangible asset costs	(965)	(650)	(813)
Transaction costs	—	(1,741)	—
Purchases of marketable securities	(44,004)	—	(11,511)
Proceeds from maturities of marketable securities	7,299	7,255	2,000
Net cash (used in) provided by continuing operations investing activities	(2,580)	3,505	(10,868)
Net cash used in discontinued operations investing activities	(97)	(3,822)	(676)
Net cash used in investing activities	(2,677)	(317)	(11,544)
Financing activities:			
Proceeds from loans and notes payable	1,354	28,983	29,616
Repayments of loans and notes payable	(7,047)	(25,958)	(26,947)
Issuance of common stock, net	51,960	1,841	30,661
Net cash provided by discontinued operations financing activities	2,249	—	—
Net cash provided by financing activities	48,516	4,866	33,330
Effect of exchange rate changes on cash and cash equivalents of discontinued operations	32	308	(35)
Net increase (decrease) in cash and cash equivalents	23,678	(9,900)	10,238
Cash and cash equivalents at beginning of year	1,629	11,529	1,291
Cash and cash equivalents at end of year	<u>\$ 25,307</u>	<u>\$ 1,629</u>	<u>\$ 11,529</u>

See accompanying notes

PENWEST PHARMACEUTICALS CO.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. BUSINESS

Penwest develops pharmaceutical products based on innovative oral drug delivery technologies. The foundation of Penwest's technology platform is TIMERx®, an extended release delivery system that is adaptable to soluble and insoluble drugs and that is flexible for a variety of controlled release profiles. The Company has also developed two additional oral drug delivery systems, Geminex® and SyncroDose™. Geminex is a dual drug delivery system that is designed to provide independent release of different active ingredients contained in a drug. SyncroDose is a drug delivery system that is designed to release the active ingredient of a drug at the desired site and time in the digestive tract.

Prior to February 27, 2003, Penwest also developed, manufactured and distributed branded pharmaceutical excipients, which are the inactive ingredients in tablets and capsules, primarily consisting of binders, disintegrants and lubricants. On February 27, 2003, Penwest sold substantially all of the assets used in the Company's excipient business to subsidiaries and affiliates of Josef Rettenmaier Holding GmbH & Co. KG (the "Asset Sale"). The Company received \$39.5 million in cash and a promissory note for \$2.25 million in consideration for the excipient business. The Company received \$1.0 million of the \$2.25 million promissory note in April 2003 with the balance due in May 2004. The Company used approximately \$5.5 million of proceeds of the sale of its excipient business to repay debt (see note 8). As a result of the Asset Sale, the accompanying consolidated financial statements present Penwest's excipient business as a discontinued operation for all periods presented.

The Company has incurred net losses since 1994. As of December 31, 2003, the Company's accumulated deficit was approximately \$94.4 million. The Company expects operating losses and negative cash flows to continue until substantial sales of products commercialized utilizing TIMERx technology occur. A substantial portion of the Company's revenues through February 27, 2003 were generated from sales of the Company's pharmaceutical excipient product line. During 2001, 2002, and 2003 through the Asset Sale date, sales of its excipient products generated positive cash flows from operations although the Company as a whole had negative cash flows from operations. Effective February 27, 2003, the Company will not derive any revenues from the excipient business. Accordingly, the Company's revenues for 2003 were generated primarily from Mylan royalties and shipments of bulk TIMERx. The Company's future profitability will depend on several factors, including the successful commercialization of TIMERx controlled release products, including in particular oxymorphone ER, and royalties from Mylan's sales of Pfizer's 30 mg generic version of Procardia ER, and the level of our research and development activities.

The Company is subject to the risks and uncertainties associated with a drug delivery company actively engaged in research and development. These risks and uncertainties include, but are not limited to, a history of net losses, technological changes, dependence on collaborators and key personnel, the successful completion of development efforts and of obtaining regulatory approval, the successful commercialization of TIMERx controlled release products, compliance with government regulations, patent infringement litigation and competition from current and potential competitors, some with greater resources than the Company, and a requirement for additional funding.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying consolidated financial statements include the accounts of Penwest and its wholly owned subsidiaries. Material intercompany balances and transactions have been eliminated. As a result

PENWEST PHARMACEUTICALS CO.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

of the Asset Sale, the accompanying consolidated financial statements present Penwest's excipient business as a discontinued operation, for all periods presented. All wholly owned subsidiaries were included in the Asset Sale (see note 13).

The preparation of 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 financial statements and accompanying notes. Actual results could differ from those estimates.

Cash and Cash Equivalents

All highly liquid investments with maturities of three months or less when purchased are considered cash equivalents.

Marketable Securities

The Company accounts for marketable securities in accordance with Statement of Financial Accounting Standards No. 115 ("SFAS No. 115"), "Accounting for Certain Investments in Debt and Equity Securities." The Company classifies its marketable securities as available-for-sale securities. Such securities are stated at fair value and primarily consist of corporate bonds, commercial paper, discounted notes backed by U.S. government agencies and certificates of deposit. Unrealized holding gains or losses are included in shareholders' equity as a separate component of accumulated other comprehensive income (loss). The specific identification method is used to compute the realized gains and losses, if any, on marketable securities.

Credit Risk and Fair Value of Financial Instruments

The Company performs ongoing credit evaluations of its customers and generally does not require collateral. Revenues from product sales and licensing fees are primarily derived from major pharmaceutical companies that have significant cash resources. The Company maintains an allowance for doubtful accounts which management believes is sufficient to cover potential credit losses. Allowances for doubtful accounts receivable are maintained based on historical payment patterns, aging of accounts receivable and actual write-off history. One customer of the Company accounted for approximately 88%, 87% and 82% of total revenues in 2003, 2002 and 2001, respectively. Another customer of the Company accounted for approximately 11% and 16% of total revenues for 2003 and 2001, respectively.

The primary objectives for the Company's investment portfolio are liquidity and safety of principal. Investments are made to achieve the highest rate of return to the Company, consistent with these two objectives. The Company's investment policy limits investments to certain types of instruments issued by institutions with investment grade credit ratings and places restrictions on maturities, and concentration by issuer.

The carrying value of financial instruments, which includes cash, cash equivalents, marketable securities, receivables, obligations under the Company's loans and notes payable, and accounts payable, approximates fair value due to the short term nature of these instruments.

PENWEST PHARMACEUTICALS CO.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Long-Lived Assets

Fixed assets are recorded at cost and depreciated using the straight-line method over their estimated useful lives or over the lease term for leasehold improvements. Estimated useful lives by class of assets are substantially as follows:

Machinery and equipment	5-10 years
Office furniture, equipment and software	3-10 years
Leasehold improvements	3-4 years

Effective January 1, 2002, the Company adopted Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS No. 144"). SFAS No. 144 supercedes Statement of Financial Accounting Standards No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of," and the accounting and reporting provisions of Accounting Principles Boards No. 30, "Reporting the Results of Operations—Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions." SFAS No 144 provides updated guidance concerning the recognition and measurement of an impairment loss for certain types of long-lived assets and expands the scope of a discontinued operation to include a component of an entity. The adoption of SFAS No. 144 did not impact the Company's financial position or results of operations.

The Company reviews the recoverability of its long-lived assets, including definite-lived intangible assets whenever facts and circumstances indicate that the carrying amount may not be fully recoverable. For purposes of recognizing and measuring impairment, the Company evaluates long-lived assets based upon the lowest level of independent cash flows ascertainable to evaluate impairment. If the sum of the undiscounted future cash flows expected over the remaining asset life is less than the carrying value of the assets, the Company may recognize an impairment loss. The impairment related to long-lived assets is measured as the amount by which the carrying amount of the assets exceeds the fair value of the asset. When fair values are not readily available, the Company estimates fair values using expected discounted future cash flows.

Foreign Currencies

The assets and liabilities, and operating results of the Company's foreign operations are reported as discontinued operations as a result of the Asset Sale. Assets and liabilities of the Company's foreign operations were translated into U.S. dollars at year-end exchange rates and revenue and expenses were translated at average exchange rates. For each of the foreign operations, the functional currency was the local currency. Accumulated other comprehensive income (loss) includes the cumulative translation adjustments, which is a component of other comprehensive loss included in the Company's financial statements. Realized gains and losses from foreign currency transactions are reflected in the consolidated statements of operations. Foreign currency transaction gains and losses were not significant in each year in the three year period ended December 31, 2003.

Accumulated Other Comprehensive Income (Loss)

Accumulated other comprehensive income (loss) at December 31, 2003, 2002 and 2001 consists of the Company's foreign currency translation adjustment and a net unrealized gain on marketable securities (see Note 17).

PENWEST PHARMACEUTICALS CO.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Income Taxes

The liability method, prescribed by SFAS No. 109, "Accounting for Income Taxes," is used in accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities. The Company recorded no income tax benefits relating to the net operating losses generated during 2003, 2002, and 2001, as such losses were offset by valuation allowances. Valuation allowances are established against the recorded deferred income tax assets to the extent that management believes it is more likely than not that a portion of the deferred income tax assets are not realizable.

Revenue Recognition

Revenues from product sales are recognized when title transfers and customer acceptance provisions have lapsed, provided collections of the related accounts receivable are probable. Shipping and handling costs are included in cost of revenues. Revenues received from non-refundable upfront licensing fees are recognized ratably over the development period of the collaboration agreement, when this period involves development risk associated with the incomplete stage of a product's development or over the estimated or contractual licensing and supply term when there exists an obligation to supply inventory for manufacture. Non-refundable milestone fees received for the development funding of a product are partially recognized upon receipt based on the Company's proportionate development efforts achieved to date relative to the total expected development efforts and the remainder is generally recognized ratably over the remaining expected development period. The proportionate development efforts achieved are measured by estimating the percentage of work completed that is required of the Company in the development effort for the product. This estimate is primarily derived from the underlying project plans and timelines, developed by qualified personnel who work closely on such projects. In particular, the Company reviews output measures such as job specifications and tasks completed, compared to all such job specifications and tasks outlined for a particular project. Job specifications vary with each project and primarily include development activities regarding initial formulation work, manufacturing scale-up, proof-of-principle biostudies, clinical development and regulatory matters. Other contractual fees received in connection with a collaborator's launch of a product are also recognized ratably over the estimated or contractual licensing and supply term. Product royalty fees are recognized when earned.

Research and Development

Research and development expenses consist of costs associated with products being developed internally as well as products being developed under collaboration agreements and include related salaries, benefits and other personnel related expenses, clinical trial costs, and contract and other outside service fees. Research and development costs are expensed as incurred. Certain reimbursements of costs, generally related to drug formulation on feasibility studies, are netted against research and development expense. A significant portion of the Company's development activities are outsourced to third parties including contract research organizations, and contract manufacturers in connection with the production of clinical materials, or may be performed by the Company's collaborators. These arrangements may require estimates be made of related service fees or the Company's share of development costs, in which actual results could materially differ from the estimates and affect the reported amounts in the Company's financial statements.

PENWEST PHARMACEUTICALS CO.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Per Share Data

Loss per common share is computed based on the weighted average number of common shares outstanding during the period. For all years reported, diluted loss per share was the equivalent of basic loss per share due to the respective net losses. No dilution for common share equivalents is included in 2003, 2002, and 2001 as the effects would be antidilutive.

Stock Based Compensation

The Company adopted the disclosure provisions of Statement of Financial Accounting Standards (“SFAS”) No. 148, “Accounting for Stock-Based Compensation—Transition and Disclosure,” which amends SFAS No. 123, “Accounting for Stock-Based Compensation,” in 2002. SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation, which was originally provided under SFAS No. 123. The Statement also improves the timeliness of disclosures by requiring the information to be included in interim as well as annual financial statements. The adoption of these disclosure provisions had no impact on the Company’s 2003 consolidated results of operations, financial position or cash flows.

At December 31, 2003, the Company maintained two stock-based employee compensation plans (see Note 9). The Company accounts for these employee stock compensation plans in accordance with the intrinsic value-based method prescribed by Accounting Principles Board Opinion No. 25, “Accounting for Stock Issued to Employees.” During the year ended December 31, 2003, the Company recorded \$106,000 in compensation expense in connection with the acceleration of the vesting date of certain stock options. In addition, in connection with board of directors’ retainer and meeting fees in 2003, the Company recorded \$68,000 of expense associated with the issuance of discounted stock options and \$132,000 of expense associated with restricted stock grants. No other stock-based employee compensation expense is reflected in net loss as all other options granted under these plans had an exercise price equal to the fair market value of the underlying common stock on the date of grant.

The following table reflects pro forma net loss and loss per share had the Company elected to adopt the fair value approach of SFAS No. 123:

	<u>YEAR ENDED DECEMBER 31,</u>		
	<u>2003</u>	<u>2002</u>	<u>2001</u>
	<u>(IN THOUSANDS, EXCEPT PER SHARE DATA)</u>		
Net loss—as reported	\$(15,935)	\$(17,099)	\$(15,981)
Stock options’ fair value effect	<u>(3,350)</u>	<u>(2,804)</u>	<u>(1,621)</u>
Net loss—pro forma after stock options’ fair value effect	<u>\$(19,285)</u>	<u>\$(19,903)</u>	<u>\$(17,602)</u>
Net loss per share, basic and diluted—as reported	\$ (0.96)	\$ (1.11)	\$ (1.15)
Net loss per share, basic and diluted—pro forma after stock options’ fair value effect	\$ (1.16)	\$ (1.29)	\$ (1.27)

3. RECENT ACCOUNTING PRONOUNCEMENTS

In November 2002, the Emerging Issues Task Force (“EITF”) finalized its tentative consensus on EITF Issue 00-21, “Revenue Arrangements with Multiple Deliverables,” which provides guidance on the timing and method of revenue recognition for arrangements that include the delivery of more than

PENWEST PHARMACEUTICALS CO.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3. RECENT ACCOUNTING PRONOUNCEMENTS (Continued)

one product or service. EITF 00-21 is effective prospectively for arrangements entered into in fiscal periods beginning after June 15, 2003. The adoption of EITF 00-21 did not have an effect on the Company's financial position or results of operations.

In June 2002, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 146, "Accounting for Costs Associated with Exit or Disposal Activities." The statement addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies EITF Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)." SFAS No. 146 states that a liability for a cost associated with an exit or disposal activity shall be recognized and measured initially at its fair value in the period in which the liability is incurred, except for a liability for one-time termination benefits that are incurred over a period of time. The statement is effective for exit or disposal activities initiated after December 31, 2002. The adoption of SFAS 146 did not have an effect on the Company's financial position or results of operations.

In December 2003, the FASB issued SFAS No. 132 (revised 2003) "Employers' Disclosures about Pensions and Other Postretirement Benefits an amendment of FASB Statements No. 87, 88, and 106." This Statement revises employers' disclosures about pension plans and other postretirement benefit plans. It does not change the measurement or recognition of those plans required by FASB Statements No. 87, Employers' Accounting for Pensions, No. 88, Employers' Accounting for Settlements and Curtailments of Defined Benefit Pension Plans and for Termination Benefits, and No. 106, Employers' Accounting for Postretirement Benefits Other Than Pensions. This Statement retains the disclosure requirements contained in FASB Statement No. 132, "Employers' Disclosures about Pensions and Other Postretirement Benefits", which it replaces. It requires additional disclosures to those in the original Statement No. 132 about the assets, obligations, cash flows, and net periodic benefit cost of defined benefit pension plans and other defined benefit postretirement plans. The adoption of SFAS No. 132 (revised 2003) had no impact on the Company's financial position or results of operations (see Note 12).

Other pronouncements issued by the FASB or other authoritative accounting standards groups with future effective dates are either not applicable or not significant to the financial statements of the Company.

PENWEST PHARMACEUTICALS CO.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

4. MARKETABLE SECURITIES

The amortized costs and estimated fair values of marketable securities are as follows:

	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Value</u>
	(IN THOUSANDS)			
December 31, 2003				
Corporate debt securities	\$23,522	\$27	\$ 6	\$23,543
U.S. government agency-backed discounted notes	14,044	25	—	14,069
Certificates of deposit	<u>977</u>	<u>—</u>	<u>3</u>	<u>974</u>
Total marketable securities	<u>\$38,543</u>	<u>\$52</u>	<u>\$ 9</u>	<u>\$38,586</u>
December 31, 2002				
Corporate debt securities	<u>\$ 2,042</u>	<u>\$15</u>	<u>\$—</u>	<u>\$ 2,057</u>

Maturities of marketable securities at fair value as of December 31, 2003, are as follows (in thousands):

Contractual maturity:

Maturing in one year or less	\$14,167
Maturing after one year through two years	<u>24,419</u>
Total marketable securities	<u>\$38,586</u>

The primary objectives for the Company's investment portfolio are liquidity and safety of principal. Investments are made to achieve the highest rate of return to the Company, consistent with these two objectives. The Company's investment policy limits investments to certain types of instruments issued by institutions with investment grade credit ratings and places restrictions on maturities, and concentration by issuer (see Note 2, "Credit Risk and Fair Value of Financial Instruments").

5. INVENTORIES

Inventories, which consist of raw materials and manufactured bulk TIMERx, are stated at the lower of cost (first-in, first-out) or market.

Inventories are summarized as follows:

	<u>DECEMBER 31,</u>	
	<u>2003</u>	<u>2002</u>
	(IN THOUSANDS)	
Raw materials	\$196	\$149
Finished products	<u>460</u>	<u>312</u>
Total inventories	<u>\$656</u>	<u>\$461</u>

The Company periodically reviews and quality tests its inventory to identify obsolete, slow moving or otherwise unsaleable inventories. Inventories at December 31, 2003 and 2002 are net of allowances of \$82,000 and \$16,000, respectively.

PENWEST PHARMACEUTICALS CO.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. INVENTORIES (Continued)

In September 1999, the Company entered into a five-year contract (plus automatic renewals of one year each) for the manufacturing of TIMERx material with another third party pharmaceutical company. There are a limited number of third party manufacturers capable of producing the TIMERx material. There can be no assurance that third parties upon which the Company relies for supply of its TIMERx material will perform, and any failures by third parties may delay development or the submission of products for regulatory approval, impair the Company's collaborators' ability to commercialize products as planned and deliver products on a timely basis, or otherwise impair the Company's competitive position, which could have a material adverse effect on the Company's business, financial condition, cash flows and results of operations.

The Company's TIMERx technology is based on a hydrophilic matrix combining a heterodispersed mixture primarily composed of two polysaccharides, xanthan and locust bean gums, in the presence of dextrose. The Company purchases these gums from a primary supplier. Although the Company has qualified alternate suppliers with respect to these gums and to date has not experienced difficulty acquiring these materials, there can be no assurance that interruptions in supplies will not occur in the future or that the Company will not have to obtain substitute suppliers. Any of these events could have a material adverse effect on the Company's ability to manufacture bulk TIMERx for delivery to its collaborators, which could have a material adverse effect on the Company's business, financial condition, cash flows and results of operations.

6. FIXED ASSETS

Fixed assets, at cost, summarized by major categories, consist of the following:

	DECEMBER 31,	
	2003	2002
	(IN THOUSANDS)	
Equipment and leasehold improvements	\$4,602	\$3,615
Software	1,540	—
Projects in progress	—	831
	6,142	4,446
Less: accumulated depreciation	2,609	2,040
	\$3,533	\$2,406

The Company capitalizes certain costs associated with developing or obtaining internal-use software. These costs include external direct costs of materials and services used in developing or obtaining the software, and payroll and payroll-related costs for employees directly associated with the software development project. For the years ended December 31, 2003 and 2002, the Company capitalized \$923,000 and \$606,000, respectively, of software development costs that are primarily related to the development of the Company's enterprise-wide software systems. The Company includes these costs within equipment and software, and generally depreciates the software development costs over a period of five years, once the systems are placed in service.

PENWEST PHARMACEUTICALS CO.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. PATENTS

Patents, net of accumulated amortization, consist of the following:

	DECEMBER 31,	
	2003	2002
	(IN THOUSANDS)	
Patents, net of accumulated amortization of \$904 and \$690	\$3,689	\$2,947

Patents include costs to secure patents on technology developed by the Company. Patents are amortized on a straight-line basis over their estimated useful lives of 17 to 20 years. Amortization expense of \$219,000, \$166,000, and \$154,000 was recorded in the years ended December 31, 2003, 2002, and 2001, respectively. Estimated amortization expense on existing patent costs is approximately \$243,000 for each of the next five years.

Patents are evaluated for potential impairment whenever events or circumstances indicate that future undiscounted cash flows may not be sufficient to recover their carrying amounts. An impairment loss is recorded to the extent the asset's carrying value is in excess of the fair value of the asset. When fair values are not readily available, the Company estimates fair values using expected discounted future cash flows. During the fourth quarters of 2003, 2002, and 2001, for continuing operations, the Company recorded impairment losses of \$5,000, \$121,000, and \$108,000, respectively, net of accumulated amortization, relating to its patents. Such impairment losses are reflected in research and product development expense on the consolidated statements of operations.

8. LOANS AND NOTES PAYABLE

Amounts outstanding under loans and notes payable are summarized below:

	DECEMBER 31,	
	2003	2002
	(IN THOUSANDS)	
Revolving line of credit	\$—	\$2,807
Note payable to AstraZeneca AB	—	2,250
Business insurance premium financing	—	636
	\$—	\$5,693

Credit Facilities

On January 17, 2001, the Company completed arrangements for a revolving line of credit ("Revolver") with a financial institution. Under the terms of the Revolver, the Company could borrow up to \$10.0 million ("Line of Credit") as determined by a formula based on the Company's Eligible Accounts Receivable and Eligible Saleable Inventory, as defined in the agreement. Under the formula, generally 85% of the Company's U.S. and Canadian receivables, as well as generally 60% of the Company's U.S. saleable inventories, were included in the borrowing base. Amounts outstanding under the Revolver were collateralized by the Company's U.S. and Canadian accounts receivable, and its inventory and general intangibles. The Revolver had an initial term of three years, and provided for annual renewals thereafter. On February 27, 2003, the Company paid off the outstanding balance of

PENWEST PHARMACEUTICALS CO.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

8. LOANS AND NOTES PAYABLE (Continued)

\$3.3 million and terminated the Revolver in connection with the sale of its excipient business (see Note 13).

The Revolver bore interest at a specified bank's prime rate plus 1% per annum, on the greater of \$3.0 million or on the average outstanding balance. The Revolver also required fees be paid of 0.5% per annum on unused portions of the Line of Credit and provided for early termination fees of up to 0.75% upon termination of the Revolver prior to the end of the initial term. As of December 31, 2002, the interest rate on the Revolver was 5.25% and approximately \$2.8 million was outstanding.

The Revolver contained covenants, including the requirement that the Company maintain at all times, certain minimum levels of tangible net worth as defined, at varying specified amounts during the initial term of the agreement, and restrictions on the incurrence of additional indebtedness and the payment of dividends. The Revolver included a lockbox requirement under the control of the lender, whereby collections of certain trade receivables were used to immediately reduce the balance of the Revolver.

Note Payable to AstraZeneca AB

As part of the Company's agreement to acquire assets including trademarks and other intellectual property related to an excipient product, Pruv, for \$3 million on October 25, 2002, the Company issued a note to the seller, AstraZeneca AB, in the principal amount of \$2.25 million. Under the agreement, the note required the Company to pay all indebtedness outstanding under the note upon the closing of the Asset Sale, which included these assets, and which occurred in February 2003. As a result, this note was paid in full in February 2003 (see Note 13).

Business Insurance Premium Financing

On September 24, 2002, the Company entered into a Premium Finance Agreement (a "Finance Agreement") through which it financed approximated \$1.1 million of premiums payable in connection with the annual renewal of its general business insurance. Under the Finance Agreement, Penwest was required to repay the amount financed in equal monthly installments through June 2003, plus interest at a rate of 3.11% per annum. In addition, the Company assigned, as a security interest, any and all unearned premiums or other amounts which may become payable to the Company under the related insurance policies.

Approximately \$34,000, \$243,000, and \$214,000, of total interest was paid in 2003, 2002, and 2001, respectively.

9. SHAREHOLDERS' EQUITY

On August 5 and August 6, 2003, the Company completed the sale of a total of 2,507,762 shares of common stock through a private placement to selected institutional investors (the "Private Placement"), resulting in net proceeds to the Company, after fees and expenses, of approximately \$49.3 million. As part of the Private Placement, the Company granted the institutional investors additional rights to purchase up to an additional 501,552 shares of common stock at a price of \$26.00 per share. These additional investment rights became exercisable on September 12, 2003, and expired on December 9, 2003. None of these additional investment rights were exercised. The Company intends to use the net

PENWEST PHARMACEUTICALS CO.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

9. SHAREHOLDERS' EQUITY (Continued)

proceeds from the Private Placement to fund the research, development, marketing and commercialization of its products and technologies, and for general corporate purposes.

On July 11, 2001, the Company completed a private placement of 2,447,187 shares of common stock to selected institutional investors, resulting in proceeds of approximately \$30 million, after fees and expenses. The Company used the net proceeds of this offering primarily for the development of drug delivery products as well as to fund the research and development of new oral drug delivery technologies.

In 1997, the Company effected a 0.76-for-1 reverse split of its common stock. Prior to the effectiveness of the reverse stock split, the number of authorized shares of common stock equaled 39,000,000. The reverse split was effected by means of an amendment to the Company's Articles of Incorporation which left the number of authorized shares of common stock at 39,000,000. Consequently, following the effectiveness of the reverse stock split, the Company continued to report that it had 39,000,000 shares of common stock authorized for issuance. The Company understands that under an interpretation of the Washington Business Corporation Act, the number of shares of common stock authorized for issuance under the Company's Articles of Incorporation may have been required to be adjusted to reflect the reverse stock split. Based on this interpretation, the Company is reporting on the accompanying consolidated balance sheet 29,640,000 shares of common stock authorized for issuance ($0.76 \times 39,000,000$).

Penwest Stock Option Plans

As of December 31, 2003 the Company had two stock option plans: the 1997 Equity Incentive Plan (the "1997 Plan"), and the 1998 Spin-off Option Plan (the "Spin-off Plan"). The 1997 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock awards and other stock-based awards, including the grant of securities convertible into Common Stock and the grant of stock appreciation rights (collectively "Awards"). A total of 3,410,000 shares of Common Stock may be issued pursuant to Awards granted under the 1997 Plan. Awards may be granted at an exercise price which may be less than, equal to or greater than the fair market value of the Common Stock on the date of grant subject to certain limitations. Restricted stock awards entitle recipients to acquire shares of Common Stock, subject to the right of the Company to purchase all or part of such shares from the recipient in the event that the conditions specified in the applicable Award are not satisfied prior to the end of the applicable restriction period established for such Award. In 2003, a total of 60,000 restricted shares were granted. No such shares were granted in 2002 or 2001.

On August 31, 1998, Penford Corporation ("Penford") distributed to the shareholders of Penford common stock, all of the outstanding shares of the Company's common stock (the "Distribution"). In connection with such transaction, the Company's 1998 Spin-off Option Plan was adopted in June 1998 to provide for the grant of stock options to employees of Penwest and non-employee directors of Penford who held options to purchase Penford Common Stock as of the Distribution date and who ceased to be employees of Penford under the terms of Penford's stock option plans. As of the Distribution date, options to purchase 1,000,722 shares of Common Stock were granted to the Company's employees and non-employee directors of Penford under the Spin-off Plan. The exercise price and number of options was calculated so as to preserve the Penford options' approximate value as of the Distribution date. The Board may not grant any additional options under the Spin-off Plan. If

PENWEST PHARMACEUTICALS CO.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

9. SHAREHOLDERS' EQUITY (Continued)

any option expires or is terminated, surrendered, canceled or forfeited, the unused Common Stock covered by such option will cease to be available for grant under the Spin-off Plan.

The following table presents a summary of the Company's stock option activity and related information for the years ended December 31:

	<u>SHARES</u>	<u>OPTION PRICE RANGE</u>	<u>WTD. AVERAGE EXERCISE PRICE</u>
BALANCE, DECEMBER 31, 2000	2,263,356	\$ 3.70-14.38	\$ 7.77
2001			
Granted	382,501	\$ 8.58-18.18	\$12.65
Exercised	(135,842)	\$ 3.70- 8.88	\$ 6.38
Cancelled	(230,000)	\$ 6.38-11.81	\$11.72
BALANCE, DECEMBER 31, 2001	<u>2,280,015</u>	\$ 3.70-18.18	\$ 8.26
Options Exercisable	<u>1,381,264</u>	\$ 3.70-14.38	\$ 7.28
2002			
Granted	291,087	\$ 6.15-19.76	\$15.89
Exercised	(163,113)	\$ 4.06-11.81	\$ 8.51
Cancelled	(8,875)	\$15.47-19.76	\$18.85
BALANCE, DECEMBER 31, 2002	<u>2,399,114</u>	\$ 3.70-19.76	\$ 9.37
Options Exercisable	<u>1,566,988</u>	\$ 3.70-18.18	\$ 7.66
2003			
Granted	539,511	\$ 7.43-21.24	\$11.32
Exercised	(334,914)	\$ 4.06-12.75	\$ 7.30
Cancelled	(166,911)	\$ 3.70-19.13	\$ 9.65
BALANCE, DECEMBER 31, 2003	<u>2,436,800</u>	\$ 3.70-21.24	\$10.06
Options Exercisable	<u>1,464,472</u>	\$ 3.70-19.76	\$ 9.16

The weighted average fair value of options granted during the years ended December 31, 2003, 2002, and 2001, was \$6.34, \$11.51, and \$8.03, respectively. The weighted average remaining contractual life of options outstanding at December 31, 2003 is 6.0 years. The weighted effect of applying SFAS No. 123 for providing pro forma disclosures for the years ended December 31, 2003, 2002, 2001, is not likely to be representative of the effects in future years because the amounts above reflect only the options granted before 1995 that vest over four to five years. No additional Penford shares were granted to the Company employees subsequent to December 31, 1997.

PENWEST PHARMACEUTICALS CO.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

9. SHAREHOLDERS' EQUITY (Continued)

The fair value of each option grant was estimated using the Black-Scholes option-pricing model with the following weighted average assumptions:

	<u>2003</u>	<u>2002</u>	<u>2001</u>
Expected dividend yield	None	None	None
Risk free interest rate	3.8%	4.9%	5.5%
Expected volatility	78%	69%	52%
Expected life of options	7.5 years	7.5 years	7.5 years

Employee Stock Purchase Plan

The Employee Stock Purchase Plan was approved in October 1997 and enables all employees to subscribe "during specified offering periods" to purchase shares of common stock at the lower of 85% of the fair market value of the shares on the first or last day of such offering period. A maximum of 228,000 shares are authorized for issuance under the Plan. There were 8,967 shares, 12,282 shares, and 10,696 shares issued under the Plan during 2003, 2002, and 2001, respectively.

Rights Agreement

On June 25, 1998, the Company's Board of Directors declared a dividend of one right for each outstanding share of the Company's Common Stock (the "Right") to shareholders of record at the close of business on July 28, 1998. Each Right entitles the registered holder to purchase from the Company one one-thousandth of a share of the Series A Preferred Stock, at a purchase price of \$60 in cash, subject to adjustment.

The Rights are not currently exercisable and will not be exercisable until the earlier of (i) 10 business days (or such later date as may be determined by the Board) following the later of (a) a public announcement that a person or group of affiliated or associated persons (a "Rights Acquiring Person") has acquired, or obtained the right to acquire, beneficial ownership of 15% or more of the outstanding shares of Common Stock or (b) the first date on which an executive officer of the Company has actual knowledge that a Rights Acquiring Person has become such, or (ii) 10 business days (or such later date as may be determined by the Board) following the commencement of a tender offer or exchange offer that would result in a person or group beneficially owning 15% or more of such outstanding shares of Common Stock. The Rights will expire upon the close of business on July 27, 2008 unless earlier redeemed or exchanged.

10. COMMITMENTS

Leases

Under a lease agreement signed with Rettenmaier on February 27, 2003, the Company has the right to occupy approximately 14,000 square feet of office and research and development space in the Patterson, New York facility until February 2008, initially on a rent-free basis (plus operating expenses) for two years and then pursuant to three successive one-year options at monthly rent payments approximating \$14,000, plus operating expenses. In addition, in February 2003, the Company signed a lease agreement for approximately 11,000 square feet of office space in Danbury, Connecticut. This lease has an initial term expiring January 31, 2006, with renewal options through December 30, 2006,

PENWEST PHARMACEUTICALS CO.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

10. COMMITMENTS (Continued)

and requires that monthly base rents be paid, including escalation clauses, in amounts ranging from approximately \$20,000 to \$22,000 through the initial lease term. The Company moved its corporate offices to Danbury, Connecticut on March 31, 2003 (see Note 13).

As of December 31, 2003, certain of the Company's property and equipment is leased under operating leases ranging from one to four years. Rental expense under operating leases was \$551,000, \$91,000, and \$63,000, for the years ended December 31, 2003, 2002, and 2001, respectively. Of such amounts, approximately \$88,000 in 2003 related to contingent rents including allocated operating expenses of the Company's leased facility in Patterson, New York.

Future minimum lease payments as of December 31, 2003 for noncancellable operating leases having initial lease terms of more than one year are as follows:

	OPERATING LEASES
	(IN THOUSANDS)
2004	\$296
2005	290
2006	29
2007	—
2008	—
Thereafter	—
Total minimum lease payments	<u>\$615</u>

11. INCOME TAXES

The provision for income taxes consists of the following:

	2003	2002	2001
	(IN THOUSANDS)		
Federal:			
Current	\$ —	\$ —	\$ —
Deferred	—	—	—
Foreign:			
Current	6	8	6
Deferred	—	—	—
State:			
Current	—	—	—
Deferred	—	—	—
	<u>\$ 6</u>	<u>\$ 8</u>	<u>\$ 6</u>

PENWEST PHARMACEUTICALS CO.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

11. INCOME TAXES (Continued)

The reconciliation between the statutory tax rate and those reflected in the Company's income tax provision is as follows:

	<u>2003</u>	<u>2002</u>	<u>2001</u>
Statutory tax rate	(34)%	(34)%	(34)%
Valuation allowance	34	34	34
Foreign taxes	—	—	—
	<u>—%</u>	<u>—%</u>	<u>—%</u>

The components of deferred income tax (assets) and liabilities at December 31 are as follows:

	<u>2003</u>	<u>2002</u>
	(IN THOUSANDS)	
Trade accounts receivable allowance	\$ —	\$ (68)
Inventory allowance and basis differences	(161)	(274)
Deferred compensation and SERP liability	(1,199)	(1,115)
Deferred revenue	(32)	(110)
Tax credit carryforward	(2,218)	(1,396)
Net operating loss carryforwards	(24,657)	(23,393)
Other	(191)	(151)
Total deferred tax assets	<u>(28,458)</u>	<u>(26,507)</u>
Depreciation and amortization	1,683	2,856
Other	269	477
Total deferred tax liabilities	<u>1,952</u>	<u>3,333</u>
Net deferred tax asset before valuation allowance	(26,506)	(23,174)
Valuation allowance	26,506	23,292
Net deferred tax liability	<u>\$ —</u>	<u>\$ 118</u>

For continuing operations, the Company's income tax payments, consisting solely of foreign income taxes, approximated \$6,000, \$8,000, and \$6,000, for the years ended December 31, 2003, 2002, and 2001, respectively.

At December 31, 2003, the Company had federal net operating loss ("NOL") carryforwards of approximately \$63.8 million for income tax purposes, of which approximately \$6.2 million, \$8.4 million, \$9.1 million, \$17.7 million, \$19.3 million and \$3.1 million expire in 2018, 2019, 2020, 2021, 2022, and 2023, respectively. In addition, the Company had research and development tax credit carryforwards of approximately \$2.2 million of which \$299,000, \$306,000, \$777,000, and \$828,000 expire in 2019, 2020, 2021, and 2022, respectively. The use of the NOLs, and research and development tax credit carryforwards are limited to future taxable earnings of the Company. For financial reporting purposes, at December 31, 2003 a valuation allowance of \$26.5 million has been recognized to offset net deferred tax assets, primarily attributable to the NOL carry-forward. Utilization of the operating losses are subject to a limitation due to the ownership change provisions of the Internal Revenue Code.

PENWEST PHARMACEUTICALS CO.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

11. INCOME TAXES (Continued)

During the fourth quarter of 2003, the Company reversed \$346,000 of income tax accruals to reflect the decreased foreign tax risk that was associated with its former excipient business. In addition, the Company reduced its tax provision on the gain on the sale of its excipient business by \$51,000 (see Note 13). The effect of these adjustments is included in the gain on sale of discontinued operations.

12. RETIREMENT PLANS AND OTHER EMPLOYEE BENEFITS

Savings Plan

Company employees participate in the Penwest Pharmaceuticals Co. Savings Plan, a defined contribution plan generally covering all of its U.S. employees. Under the Plan, the Company may make quarterly employer matching contributions as defined in the Plan agreement, in an amount equal to a percentage of each participant's pre-tax contributions to the Plan up to 6% of earnings. Participants are immediately vested in their contributions, as well as any earnings thereon. Vesting in the employer contribution portion of their accounts, as well as any earnings thereon is based on years of credited service and vest over a four-year period. For continuing operations, the Company's expense under the Plan was \$228,000, \$148,000, and \$111,000 for 2003, 2002 and 2001, respectively.

The Plan also includes a discretionary annual profit-sharing component that is awarded by Penwest's Board of Directors generally based on achievement of predetermined corporate goals. This feature is available to all employees who meet the eligibility requirements of the Plan. There was no profit sharing expense in 2003, 2002, or 2001.

Supplemental Executive Retirement Plan

The Company has a Supplemental Executive Retirement Plan ("SERP"), a nonqualified plan, which covers the Chairman and Chief Executive Officer of Penwest. For 2003, 2002 and 2001, the net expense for the SERP was \$212,000, \$85,000 and \$100,000, respectively, for continuing operations, and \$5,000, \$21,000 and \$25,000, respectively, for discontinued operations. The Company does not fund this liability and no assets are held by the Plan. The Company uses a measurement date of December 31 for its SERP. The following disclosures summarize information relating to the Plan.

Change in benefit obligation:

	2003	2002
	(IN THOUSANDS)	
Benefit obligation at beginning of period	\$1,839	\$1,580
Service cost	(27)	(22)
Interest cost	122	113
Actuarial gains	114	168
Benefit obligation at December 31,	\$2,048	\$1,839

PENWEST PHARMACEUTICALS CO.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. RETIREMENT PLANS AND OTHER EMPLOYEE BENEFITS (Continued)

Funded status:

	<u>2003</u>	<u>2002</u>
	<u>(IN THOUSANDS)</u>	
Funded status (unfunded)	\$(2,048)	\$(1,839)
Unrecognized net transition obligation	40	100
Unrecognized prior service cost	17	31
Unrecognized net actuarial gain	<u>(177)</u>	<u>(318)</u>
Net amount recognized at December 31, (included in deferred compensation)	<u>\$(2,168)</u>	<u>\$(2,026)</u>

Amounts recognized in the statement of financial position consist of:

	<u>2003</u>	<u>2002</u>
	<u>(IN THOUSANDS)</u>	
Accrued benefit cost (minimum liability)	\$(2,168)	\$(2,026)
Net amount recognized at December 31,	<u>\$(2,168)</u>	<u>\$(2,026)</u>

Information for plans with an accumulated benefit obligation in excess of plan assets, December 31:

	<u>2003</u>	<u>2002</u>
	<u>(IN THOUSANDS)</u>	
Projected benefit obligation	\$2,048	\$1,839
Accumulated benefit obligation	\$1,515	\$1,363
Plan assets of fair value	\$ —	\$ —

Components of net periodic benefit cost:

	<u>2003</u>	<u>2002</u>
	<u>(IN THOUSANDS)</u>	
Service cost	\$(27)	\$(22)
Interest cost	122	113
Amortization of unrecognized transition obligation	60	60
Amortization of prior service cost	14	20
Amortization of gains	<u>(26)</u>	<u>(65)</u>
Net periodic benefit cost	<u>\$143</u>	<u>\$106</u>

The amortization of prior service cost is determined using straight-line amortization of the cost over the average remaining service period of the employee expected to receive benefits under the Plan:

Weighted-average assumptions used to determine benefit obligations as of December 31:

	<u>2003</u>	<u>2002</u>
Discount rate	6.25%	6.75%
Rate of compensation increase	4.0%	4.0%

PENWEST PHARMACEUTICALS CO.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. RETIREMENT PLANS AND OTHER EMPLOYEE BENEFITS (Continued)

Weighted-average assumptions used to determine net periodic benefit cost for years ended December 31:

	<u>2003</u>	<u>2002</u>
Discount rate	6.75%	7.25%
Rate of compensation increase	4.0%	4.0%

The Company expects to make no contributions to the Plan nor any benefit payments to the Plan participant in 2004.

Health Care and Life Insurance Benefits

The Company offers health care and life insurance benefits to most active employees. Costs incurred for these benefits for continuing operations were \$568,000, \$422,000 and \$327,000 in 2003, 2002 and 2001, respectively.

13. DISCONTINUED OPERATIONS

On February 27, 2003, Penwest sold substantially all of the assets (the "Assets") used in the Company's excipient business to subsidiaries and affiliates of Josef Rettenmaier Holding GmbH & Co. KG ("Rettenmaier") for \$41.75 million, plus the assumption of specified liabilities. The Assets of the excipient business were sold to Rettenmaier, either directly or through the sale of the outstanding capital stock of the three subsidiaries of Penwest that did business in the UK, Germany and Finland. The purchase price included \$39.5 million in cash and a non-interest bearing promissory note of \$2.25 million, with \$1.0 million paid in April 2003 and \$1.25 million due May 25, 2004.

In 2003, the Company recorded a gain on the Asset Sale of approximately \$9.9 million (no tax effect), and has reported the operating results of the excipient business as a discontinued operation in accordance with SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." The net carrying amount of the assets and liabilities on the date of the Asset Sale was approximately \$29.5 million. The approximate carrying values of the major classes were: property, plant and equipment of \$11.4 million; inventory of \$8.3 million; receivables of \$6.0 million; and intangible assets of \$4.3 million offset by other net liabilities. The Company has presented its December 31, 2002 balance sheet in the consolidated financial statements to reflect the assets and liabilities of the excipient business separately as assets held for sale and liabilities held for sale. The gain on the Asset Sale is net of transaction related costs totaling \$3.1 million, primarily consisting of professional and advisory fees. As of December 31, 2002, these costs approximated \$1.7 million and were reflected as deferred transaction costs on the consolidated balance sheet. Revenues and pretax profits for the excipient business approximated \$6.1 million and \$203,000, respectively, for the period January 1, 2003 through the Asset Sale date of February 27, 2003. Revenues and pretax profits for the excipient business approximated \$36.4 million and \$2.3 million, respectively, for 2002, and \$34.2 million and \$1.3 million, respectively, for 2001.

Prior to the sale of the excipient business, the Company owned its office, laboratory and warehouse facility in Patterson, New York, as well as a facility in Cedar Rapids, Iowa, where it manufactured pharmaceutical excipients. As part of the Asset Sale, the Company transferred these properties and assigned its lease of a pharmaceutical excipient manufacturing facility in Nastola,

PENWEST PHARMACEUTICALS CO.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. DISCONTINUED OPERATIONS (Continued)

Finland to Rettenmaier. Under a lease agreement signed with Rettenmaier on February 27, 2003, the Company has the right to occupy approximately 14,000 square feet of office and research and development space in the Patterson facility until February 2008, initially on a rent-free basis (plus operating expenses) for two years and then pursuant to three successive one-year options at monthly rent payments approximating \$14,000, plus operating expenses.

14. LICENSING AGREEMENTS

The Company enters into collaborative arrangements with pharmaceutical companies to develop, manufacture or market products formulated with its drug delivery technologies.

In September 1997, the Company entered into a strategic alliance agreement with Endo Pharmaceuticals, Inc. with respect to the development of oxymorphone ER, an extended release formulation of oxymorphone, a narcotic analgesic for the treatment of moderate to severe pain, based on the Company's TIMERx technology. This agreement was amended and restated in April 2002. Endo has a broad product line including established brands such as Percodan®, Percocet®, and Lidoderm®. Endo is registered with the U.S. Drug Enforcement Administration as a developer, manufacturer and marketer of controlled narcotic substances.

Under the strategic alliance agreement, the responsibilities of the Company and Endo with respect to the oxymorphone product are determined by a committee comprised of an equal number of members from each of the Company and Endo (the "Alliance Committee"). During the development of the product, the Company formulated oxymorphone ER, and Endo conducted all clinical studies and prepared and filed all regulatory applications. The Company has agreed to supply TIMERx material to Endo, and Endo has agreed to manufacture and market oxymorphone ER in the United States. The manufacture and marketing outside of the United States may be conducted by the Company, Endo or a third party, as determined by the Alliance Committee.

Prior to March 17, 2003, the Company and Endo shared the costs involved in the development of oxymorphone ER. On March 17, 2003, the Company notified Endo that it was discontinuing its participation in the funding of the development and marketing of oxymorphone ER effective April 17, 2003. As a result of this termination of funding, Endo has the right to complete the development of oxymorphone ER and recoup the portion of development costs incurred by Endo that otherwise would have been funded by Penwest ("Unfunded Development Costs"). Endo may recoup such development costs through a temporary adjustment in the royalty rate payable to Penwest that will return to its pre-adjustment level once Endo has recovered such costs. Endo may also allow the Company to reimburse Endo directly for the unfunded amounts. The Company estimates that through December 31, 2003 "Unfunded Development Costs" approximated \$6.7 million. The parties have agreed that the party marketing oxymorphone ER will pay the other party royalties initially equal to 50% of the net realization (as defined in the agreement) subject to adjustment for the Unfunded Development Costs. This percentage will decrease if the aggregate U.S. net realization exceeds pre-determined thresholds. In general, the royalty payable by the marketing party to the other party will not drop below 40%. However, the royalty will be reduced by one-third in limited circumstances, including termination of the agreement based on uncured material breaches of the agreement by the royalty receiving party and certain bankruptcy and insolvency events involving the royalty receiving party. Under the agreement, Endo will purchase formulated TIMERx material for use in oxymorphone

PENWEST PHARMACEUTICALS CO.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

14. LICENSING AGREEMENTS (Continued)

ER exclusively from the Company at specified prices, and include these purchases in cost of goods sold of the product prior to determining net realization.

On March 2, 2000, Mylan announced that it had signed a supply and distribution agreement with Pfizer to market a generic version of all three strengths (30 mg, 60 mg, 90 mg) of Pfizer's Procardia XL. In connection with that agreement, Mylan decided not to market Nifedipine XL, a product the Company had developed in collaboration with Mylan, and agreed to pay Penwest a royalty on all future net sales of the 30 mg strength of Pfizer's generic Procardia XL. The royalty percentage was comparable to the percentage called for in Penwest's original agreement with Mylan for Nifedipine XL. Mylan has retained the marketing rights to the 30 mg strength of Nifedipine XL. Mylan's sales in the United States in 2003 of the 30 mg dosage strength version of Pfizer's generic Procardia XL totaled approximately \$36.8 million. The term of this agreement continues until such time as Mylan permanently ceases to market generic Procardia XL.

15. CONTINGENCIES

Substantial patent litigation exists in the pharmaceutical industry. Patent litigation generally involves complex legal and factual questions, and the outcome frequently is difficult to predict. An unfavorable outcome in any patent litigation affecting the Company could cause the Company to pay substantial damages, alter its products or processes, obtain licenses and/or cease certain activities. Even if the outcome is favorable to the Company, the Company could incur substantial litigation costs. Although the legal costs of defending litigation relating to a patent infringement claim (unless such claim relates to TIMERx) are generally the contractual responsibility of the Company's collaborators, the Company could nonetheless incur significant unreimbursed costs in participating and assisting in the litigation.

16. SEGMENT INFORMATION

The Company is engaged in the research, development and commercialization of novel oral drug delivery products and technologies. The Company's product portfolio consists of technically advanced and patented excipients that may be licensed to customers or collaborators, and conducts its business primarily in North America and Europe. Prior to the Asset Sale (see Note 13) the Company had European operations consisting of a manufacturing facility in Nastola, Finland and sales offices in Reigate, England, and Bodenheim, Germany.

17. ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)

Accumulated other comprehensive income (loss) consisted of the following at December 31:

	<u>2003</u>	<u>2002</u>
	(IN THOUSANDS)	
Cumulative translation adjustment	\$ 473	\$(583)
Cumulative translation adjustment of discontinued operations sold	(473)	—
Unrealized gain on marketable securities	<u>43</u>	<u>15</u>
Accumulated other comprehensive income (loss)	<u>\$ 43</u>	<u>\$(568)</u>

PENWEST PHARMACEUTICALS CO.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

18. QUARTERLY FINANCIAL DATA (UNAUDITED)

Summarized quarterly financial data for the years ended December 31, 2003 and 2002 is as follows:

	QUARTER ENDED			
	MAR. 31, 2003 (UNAUDITED)	JUNE 30, 2003 (UNAUDITED)	SEPT. 30, 2003 (UNAUDITED)	DEC. 31, 2003 (UNAUDITED) (a)
(IN THOUSANDS, EXCEPT PER SHARE DATA)				
Total revenues	\$ 1,172	\$ 1,249	\$ 1,016	\$ 1,241
Gross profit	1,091	1,186	1,005	1,227
Loss from continuing operations	(4,787)	(7,522)	(5,537)	(8,160)
Earnings (loss) from discontinued operations	9,757	(83)	—	397
Net income (loss)	<u>\$ 4,970</u>	<u>\$(7,605)</u>	<u>\$(5,537)</u>	<u>\$(7,763)</u>
Loss from continuing operations per share	\$ (0.31)	\$ (0.48)	\$ (0.32)	\$ (0.44)
Earnings (loss) from discontinued operations per share	0.63	(0.01)	—	0.02
Net income (loss) per share	<u>\$ 0.32</u>	<u>\$(0.49)</u>	<u>\$(0.32)</u>	<u>\$(0.42)</u>

	QUARTER ENDED			
	MAR. 31, 2002 (UNAUDITED)	JUNE 30, 2002 (UNAUDITED)	SEPT. 30, 2002 (UNAUDITED)	DEC. 31, 2002 (UNAUDITED) (b)
(IN THOUSANDS, EXCEPT PER SHARE DATA)				
Total revenues	\$ 1,115	\$ 1,268	\$ 1,681	\$ 1,473
Gross profit	1,089	1,233	1,622	1,423
Loss from continuing operations	(4,819)	(6,024)	(4,943)	(3,242)
Earnings from discontinued operations	501	706	467	255
Net loss	<u>\$(4,318)</u>	<u>\$(5,318)</u>	<u>\$(4,476)</u>	<u>\$(2,987)</u>
Loss from continuing operations per share	\$ (0.31)	\$ (0.39)	\$ (0.32)	\$ (0.21)
Earnings from discontinued operations per share	0.03	0.05	0.03	0.02
Net loss per share	<u>\$ (0.28)</u>	<u>\$(0.34)</u>	<u>\$(0.29)</u>	<u>\$(0.19)</u>

(a) During the fourth quarter of 2003, the following adjustments were recorded:

- i) The Company reversed \$346,000 of income tax accruals to reflect the decreased foreign tax risk that was associated with its former excipient business. In addition, the Company reduced its tax provision on the gain on sale of its excipient business by \$51,000. The effect of these adjustments is included in the gain on sale of discontinued operations.

(b) During the fourth quarter of 2002, the following adjustments were recorded:

- i) The Company recorded the reimbursement of approximately \$780,000 of costs from one of its collaborators, a reduction of research and product development expense.

PENWEST PHARMACEUTICALS CO.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

18. QUARTERLY FINANCIAL DATA (UNAUDITED) (Continued)

- ii) The Company recorded an adjustment of approximately \$317,000 to reduce the accrual for 2002 bonuses.
- iii) The Company recorded an impairment loss of approximately \$121,000, net of accumulated amortization, relating to its patents.

PENWEST PHARMACEUTICALS CO.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

SCHEDULE II—VALUATION AND QUALIFYING ACCOUNTS

PENWEST PHARMACEUTICALS CO.
DECEMBER 31, 2003

(IN THOUSANDS)

	<u>Balance at Beginning of Period</u>	<u>Charged to Costs and Expenses</u>	<u>Charged to Other Accounts- Describe</u>	<u>Deductions- Describe</u>	<u>Balance at End of Period</u>
Year ended December 31, 2003					
Allowance for Doubtful Accounts	\$—	\$ —	\$—	\$ —	\$—
Inventory Allowances	\$16	\$113	\$—	\$47(a)	\$82
Year ended December 31, 2002					
Allowance for Doubtful Accounts	\$50	\$(50)	\$—	\$ —	\$—
Inventory Allowances	\$ 6	\$ 12	\$—	\$ 2(a)	\$16
Year ended December 31, 2001					
Allowance for Doubtful Accounts	\$52	\$ (2)	\$—	\$ —	\$50
Inventory Allowances	\$—	\$ 6	\$—	\$ —	\$ 6

(a) Disposals of unrecoverable inventory costs.

CORPORATE DIRECTORY AND SHAREHOLDER INFORMATION

OFFICERS

TOD R. HAMACHEK
Chairman of the Board
and Chief Executive Officer

ANAND R. BAICHWAL, Ph.D.
Chief Scientific Officer and
Senior Vice President, Research
& New Technology Development

FERDINAND BANTI
Vice President, Corporate Development

JENNIFER L. GOOD
Senior Vice President, Finance
and Chief Financial Officer

THOMAS R. SCIASCIA, M.D.
Vice President, Clinical Operations
and Chief Medical Officer

BOARD COMMITTEES

EXECUTIVE COMMITTEE

Tod R. Hamachek
Paul E. Freiman
Robert J. Hennessey

AUDIT COMMITTEE

Anne M. VanLent, Chair
Paul E. Freiman
Rolf H. Henel

COMPENSATION AND BENEFITS COMMITTEE

Robert J. Hennessey, Chair
Paul E. Freiman

NOMINATING AND GOVERNANCE COMMITTEE

Paul E. Freiman, Chair
Robert J. Hennessey
Anne M. VanLent

SCIENTIFIC ADVISORY BOARD

Jere E. Goyan, Ph.D., Chair
John N. Staniforth, Ph.D.
Darrell R. Abernethy, M.D., Ph.D.
Kenneth Cartwright, M.B., Ch.B.,
M.F.C.M., D.P.M., M.R.C.P.
Marvin E. Jaffe, M.D.
Marvin Meyer, Ph.D.
Stephen E. Rudolph, Ph.D.
Joseph R. Robinson, M.D., Ph.D.

PENWEST HEADQUARTERS

39 Old Ridgebury Road
Suite 11
Danbury, CT 06810-5120
(203) 796-3700
(877) PENWEST
Fax: (203) 794-1573

TECHNICAL OPERATIONS

2981 Route 22
Patterson, NY 12563-2335
(845) 878-8400

WEBSITE

www.penwest.com

SHAREHOLDER INFORMATION

Market Price of and Dividends on the
Registrant's Common Stock and Related
Shareholder Matters

Our common stock, \$.001 par value, is listed
with and trades on the Nasdaq National
Market under the symbol "PPCO." The high
and low sale prices of our common stock
during 2003 and 2002 are set forth below.
These prices reflect inter-dealer prices,
without retail mark-up, mark-down or
commission and may not necessarily represent
actual transactions.

Period 2003	High	Low
Quarter Ended March 31	\$17.05	\$ 8.60
Quarter Ended June 30	\$24.66	\$15.35
Quarter Ended September 30	\$25.02	\$19.19
Quarter Ended December 31	\$24.03	\$13.69

Period 2002	High	Low
Quarter Ended March 31	\$19.75	\$17.20
Quarter Ended June 30	\$20.99	\$17.00
Quarter Ended September 30	\$17.25	\$ 7.89
Quarter Ended December 31	\$10.98	\$ 7.01

On February 29, 2004 there were 787
shareholders of record.

We have never paid cash dividends on our
common stock. We presently intend to
retain earnings, if any, for use in the operation
of our business, and therefore do not
anticipate paying any cash dividends in the
foreseeable future.

ANNUAL MEETING

11:00 a.m., June 2, 2004

LEGAL COUNSEL

Hale and Dorr LLP
60 State Street
Boston, MA 02109

AUDITORS

Ernst & Young LLP
1111 Summer Street
Stamford, CT 06905

INVESTOR RELATIONS

Kekst and Company, Inc.
437 Madison Avenue
New York, NY 10022

TRANSFER AGENT & REGISTRAR

Mellon Investor Services LLC
111 Founders Plaza
Eleventh Floor
East Hartford, CT 06108

SHAREHOLDER INFORMATION

Mellon Investor Services LLC
(800) 288-9541

FORWARD-LOOKING STATEMENTS

This Annual Report contains certain forward-
looking statements within the meaning of
Section 27A of the Securities Act of 1933
and Section 21E of the Securities Exchange
Act of 1934. For this purpose, any state-
ments contained herein that are not
statements of historical fact may be deemed
to be forward-looking statements. Without
limiting the foregoing, the words "believes,"
"anticipates," "plans," "expects," "intends,"
"may," and other similar expressions are
intended to identify forward-looking state-
ments. There are a number of important
factors that could cause our actual results to
differ materially from those indicated by
forward-looking statements contained in
this report and presented elsewhere by
management from time to time. These
factors include the factors discussed under
the caption "Risk Factors" in Penwest's
Annual Report on Form 10-K for the year
ended December 31, 2003.

Penwest

55 Old Ridgebury Road

Suite 11

Danbury, CT 06810-5120

953-796-3700

77 PENWEST

www.penwest.com