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PENWEST

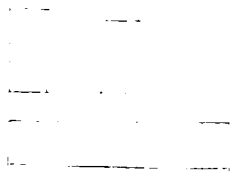
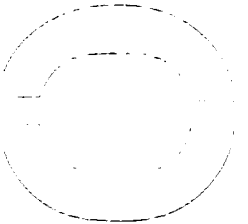
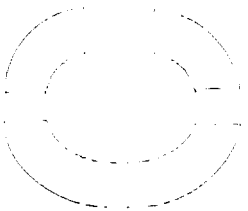
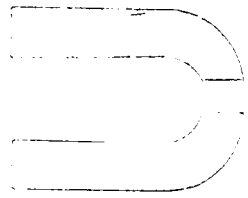
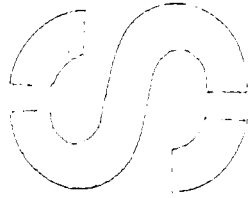
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PENWEST | Penwest develops pharmaceutical products based on innovative oral drug delivery technologies. The foundation of Penwest's technology platform is TIMERx[®], an extended release delivery system that is adaptable to soluble and insoluble drugs, and 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 pharmaceutical product, and SyncroDose is a chronotherapeutic drug delivery system that is designed to release the drug at the desired site and time in the body.



DEAR FELLOW SHAREHOLDERS

2002 was a transforming year for Penwest — one in which we solidified the strategic focus of the Company and generated the positive momentum that we believe will yield increasing benefits in the years ahead. I am pleased with the progress we have made and look forward to carrying this momentum into 2003 and beyond.

STRATEGIC FOCUS | Over the past two years, Penwest's strategy has focused on increasing the Company's participation in the drug development process.

By controlling the product development process, Penwest expects to be better able to manage the product selection and subsequent development timelines, strengthen its patent position, and participate more fully in the revenue stream from future product sales by assuming an equal or full share of the development costs. Through these efforts, we expect to more effectively facilitate and support the regulatory process and help our products enter the market faster. In addition, as we make a greater financial commitment to the development of products, we expect to be better able to capture a greater portion of the potential economic value of a product — up to 50% of the net profit versus the 5%-15% of net sales a company typically receives for the early stage licensing of a product. This strategy, we believe, better positions Penwest to enhance future revenue and profitability opportunities, and thereby grow Penwest's long-term shareholder value.

By concentrating the Company's considerable talent and experience on enhancing and expanding our product portfolio through internal development and third party collaborations, we are now beginning to realize our goal of leveraging Penwest's proprietary oral drug delivery technologies into pharmaceutical products that provide better medicines for patients.

ORAL DRUG DELIVERY MARKET | The U.S. oral drug delivery segment of the pharmaceutical market is large and growing. In 2002, the US drug delivery market was valued at approximately \$15.5 billion, with oral controlled release products accounting for about 52% of that market. We believe that the potentially large number of oral drug delivery opportunities combined with our proven proprietary drug delivery technology platform will continue to provide Penwest with excellent long-term growth opportunities.

TIMERx[®], our proprietary oral controlled release technology platform, is the foundation of our drug delivery efforts. Our twelve to twenty-four hour extended release technology is adaptable to soluble and insoluble drugs, flexible to a variety of release profiles, and provides easy scale-up and technology transfer to more rapidly formulate and advance products into clinical trials. Based on the TIMERx[®] platform, we have developed two additional and distinct oral delivery systems: Geminex[™], which releases drugs at two different rates, and the chronotherapeutic delivery system SyncroDose[™], which releases the drug at the desired site and time in the body to better treat the intended disease and/or symptom.

PRODUCT PIPELINE | Currently, Penwest's product portfolio includes four approved products with key development collaborators, including Mylan

Pharmaceuticals, Sanofi-Synthelabo, Merck S.A., and Leiras. Three of these drugs are indicated for hypertension and/or angina, the fourth is used to treat urinary incontinence.

In addition, we have nine products currently under development in our pipeline. These products are currently in formulation, Phase I proof-of-principle studies, and/or about to enter Phase II. They are in multiple therapeutic categories such as pain, hypertension, and chemo-induced emesis. This growing drug delivery pipeline demonstrates the flexibility and broad applicability of our technology platform and our commitment to building our own drug development pipeline.

MILESTONES ACHIEVED Two key milestones were achieved in 2002 that will help to lay the foundation for the growth of Penwest's drug delivery business.

The first was the sale of our excipient business to privately held Josef Rettenmaier Holding GmbH & Co. KG ("Rettenmaier") in November for \$41.75 million. This transaction closed in the first quarter of 2003. Rettenmaier is a global leader in cellulosic and organic fiber products and manufacturing with a well-established excipients business.

As part of the transaction, Rettenmaier has retained all of Penwest's employees who worked for our excipient business, including Stephen J. Berté, Jr., who continues to serve as General Manager of the business. I would like to thank all of our former excipient employees who have worked so diligently and who now have joined Rettenmaier.



Tod Hamachek Chairman and CEO

“ We are focused on developing a strong product pipeline to support Penwest’s long-term growth. ”

The second major milestone achieved in 2002 was the acceptance by the FDA of the NDA filing by Endo Pharmaceuticals, Inc. of our lead product, oxymorphone ER, a product that was jointly developed by Penwest and Endo. We are very pleased with the FDA filing and look forward to Endo bringing this important new pain product to the market. We believe, that if approved, oxymorphone ER will offer physicians and their patients an important new option for managing moderate to severe chronic pain, and will contribute significantly to the approximately \$3 billion market for long-acting opioids.

FINANCIAL POSITION | With the sale of our excipient business complete, 2002 will be the last year we include excipients revenue in our results as a continuing operation. Going forward, Penwest’s results will emphasize income from Penwest’s royalties, TIMERx bulk sales, investment in research and development, and progress in our product pipeline.

For the year ended December 31, 2002, Penwest reported total revenues of \$42.0 million and a net loss of \$17.1 million, or a \$1.11 loss per share. For the year ended December 31, 2001, the Company reported total revenues of \$40.0 million and a net loss of \$16.0 million, or a \$1.15 loss per share. The increase in revenues was primarily driven by growth in the sales of our excipient products. Gross profit also increased in 2002 due to an improvement in the mix of excipient products sold during the period.

The Company continued to invest heavily in research and development. R&D spending for the full year was \$17.6 million compared to \$17.0 million in 2001. The biggest percentage of the R&D spend was used for completing the clinical trials of oxymorphone ER. The remainder of the R&D spend was on formulation work for several new product concepts as well as research for new oral drug delivery technologies. Because we believe that the development cycle for the drugs we develop takes three to five years from identification to a filing with the FDA, or other regulatory agency, our efforts are aimed at generating attractive growth opportunities beyond the 2004 introduction of oxymorphone ER.

Spending for selling, general and administrative was also up significantly for 2002 at a level of \$15.8 million compared to \$13.9 million in 2001. This increase includes prelaunch marketing costs related to oxymorphone ER, higher costs of business insurance, and the costs for professional fees involved in the planning for and implementation of the sale of the excipient business.

We feel the investments we made in the business in 2002 are important for the Company’s long-term growth.

N. STEWART ROGERS, FOUNDING DIRECTOR

Honesty and integrity must be at the heart of all corporate endeavors. Unfortunately these values that serve as the pillars for shareholders' trust in corporate boards and management have been seriously abused by a number of well publicized U.S. corporations. Since its inception, Penwest has been fortunate to have had a director who has been a vigorous advocate for the shareholder and the practice of good corporate governance.

Having reached the age of 74, N. Stewart Rogers chose to retire from the Penwest Board of Directors in September 2002. What he has left behind is a legacy and role model of directors' stewardship that is exemplary by any measure. Stewart's great sense of curiosity and inquisitive mind never manifested itself in arrogance and always with civility. This curiosity and his ever present self-effacing sense of humor led him to ask questions that many others would have been reluctant to ask. Stewart recognized that knowledge and wisdom are built upon seeking answers that would enable him to enhance his understanding. Substance always meant more to Stewart than appearance. He abhorred arrogance and promoted and applauded modesty.

Stewart held a fundamental belief that directors and management serve at the behest and for the benefit of the shareholders. The Board and I share Stewart's beliefs in the necessity of strong board oversight and good board governances. We will greatly

miss Stewart's wisdom and counsel. On behalf of our shareholders, the Board and management, I thank Stewart for his immense contributions to Penwest.

FORWARD MOMENTUM While we have had several important accomplishments in 2002, we have a great deal of hard work ahead of us to execute our drug development strategy. With the NDA for oxymorphone ER filed at the FDA, we are focused on developing a strong product pipeline to support Penwest's long-term growth.

I am confident in the caliber and capability of our people to build upon the accomplishments over the past year. We have a proven and expanding drug delivery technology portfolio and a growing product pipeline with which Penwest can execute its drug development strategy and provide good long-term value to our shareholders.



Tod R. Hamachek
Chairman and CEO
Penwest Pharmaceuticals Co.



TECHNOLOGY



Our technologies serve as strategic tools which can extend a product's life cycle and boost a drug's position in the marketplace.

With the overall aim of enhancing the therapeutic value of drugs, Penwest utilizes its drug delivery technologies to develop and enhance pharmaceutical products. Our drug delivery technologies serve as strategic tools which can extend a product's life cycle, boost a drug's position in the marketplace, and provide superior medicines for patients.

Penwest's dedication to innovation in oral drug delivery is evidenced by its research and development spending targeted at identifying and developing new extended release systems. Drug products can be formulated with any one of our technologies which include **TIMERx**[®] for extended release, **Geminex**[™] for dual delivery, and our newest technology for chronotherapeutic delivery — **SyncroDose**[™]. These technologies can be applied to a wide range of drugs with different physical and chemical properties.

TIMERx[®] | The **TIMERx** controlled release delivery technology is where “it all began” and has served as the foundation of Penwest's drug delivery technology platform. **TIMERx** is adaptable to both soluble and insoluble drugs, flexible to meet a variety of controlled release profiles, and provides easy scale-up and technology transfer. We believe these attributes enable Penwest to solve difficult delivery and drug development challenges and potentially provide collaborative partners with a “speed-to-market advantage.”

TIMERx technology offers multiple controlled release delivery profiles to optimize the therapeutic benefits of drugs. They include:

- TIMERx 1st Order — releases drug at a decreasing amount over time.
- TIMERx Z Order — releases drug at a constant amount over time.
- TIMERx Burst CR — releases drug at two distinct intervals--an immediate release burst followed by a controlled release.

TIMERx allows for the controlled release development of drugs that can provide a therapeutic benefit to patients by delivering medicines that are more efficacious, have decreased side effects, and provide greater patient compliance. With these principles we are building the foundation upon which our drug delivery technologies emerge.

GEMINEX™ Geminex is a dual drug delivery technology that can deliver one or more drugs at different times. The Geminex technology controls the release rate of the two drugs to maximize their individual therapeutic effect and minimize side effects. The benefit of Geminex to the pharmaceutical industry, and ultimately to patients, is that two different actives or the same active can be delivered at differing rates in a single tablet.

Penwest is actively applying its Geminex technology to the following therapeutic areas: cardiovascular disorders, diabetes, cancer, and disorders of the central nervous system.

The Geminex technology is yet another innovative technology that resulted from our commitment to enhancing the therapeutic value of a drug.

SYNCRODOSE™ A significant advancement to the TIMERx technology platform was the introduction of SyncroDose, a chronotherapeutic delivery technology. SyncroDose works with the body's biological clock to customize time and site of drug release while reducing dose and improving efficacy of the drug.



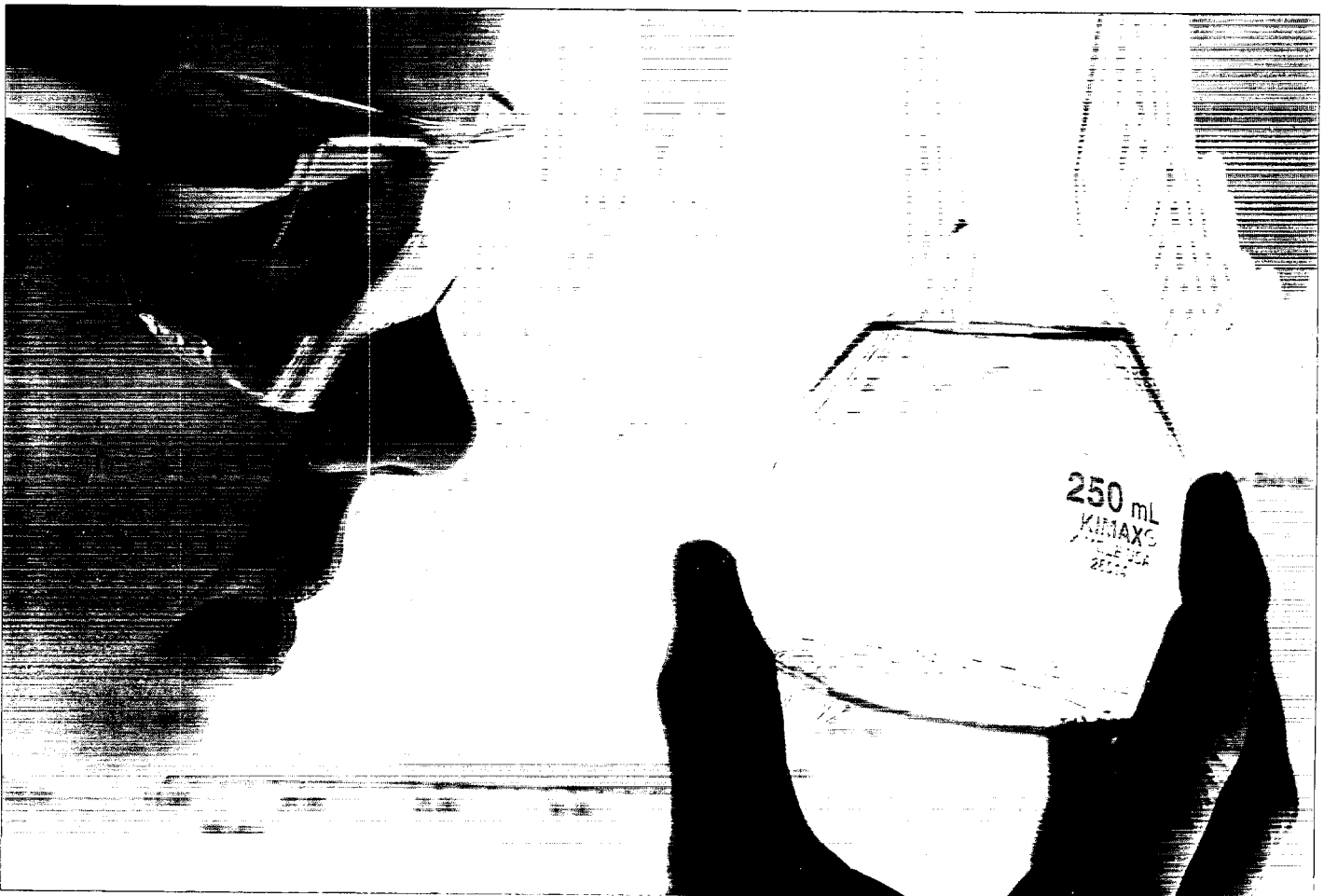
☞ ☞ SyncroDose works with the body's
biological clock to customize time and site
of drug release. ☞ ☞

SyncroDose works to maximize the effectiveness of the drug by coordinating the drug delivery times with the individual's biological or circadian rhythms.

Based on research done in chronotherapeutic therapies, we believe that SyncroDose can be effective for disease states such as arthritis, asthma, cardiovascular disorders, neurological disorders, and cancer.

Penwest's experience and dedication in developing new ways to solve oral drug delivery problems and formulate more efficacious medications is evidenced through the creation of the SyncroDose technology.

OUR STRATEGY | As the market for oral extended release drugs has been evolving, Penwest has been expanding its role in drug delivery. In 2002 we continued to grow our drug delivery platforms and we continued to develop our own drug product portfolio — now in various stages of clinical development. We have active development programs in therapeutic categories such as pain management, rheumatoid arthritis, and hypertension. We intend to expand our core offerings by developing, licensing, or acquiring those technologies that complement our current product development pipeline. We intend to leverage the core capabilities of our partners in order to bring products to market faster and more efficiently. With the strength and ability of Penwest's people to build upon the success of our technologies and expand our product portfolio, Penwest believes it can deliver long-term value to its shareholders.





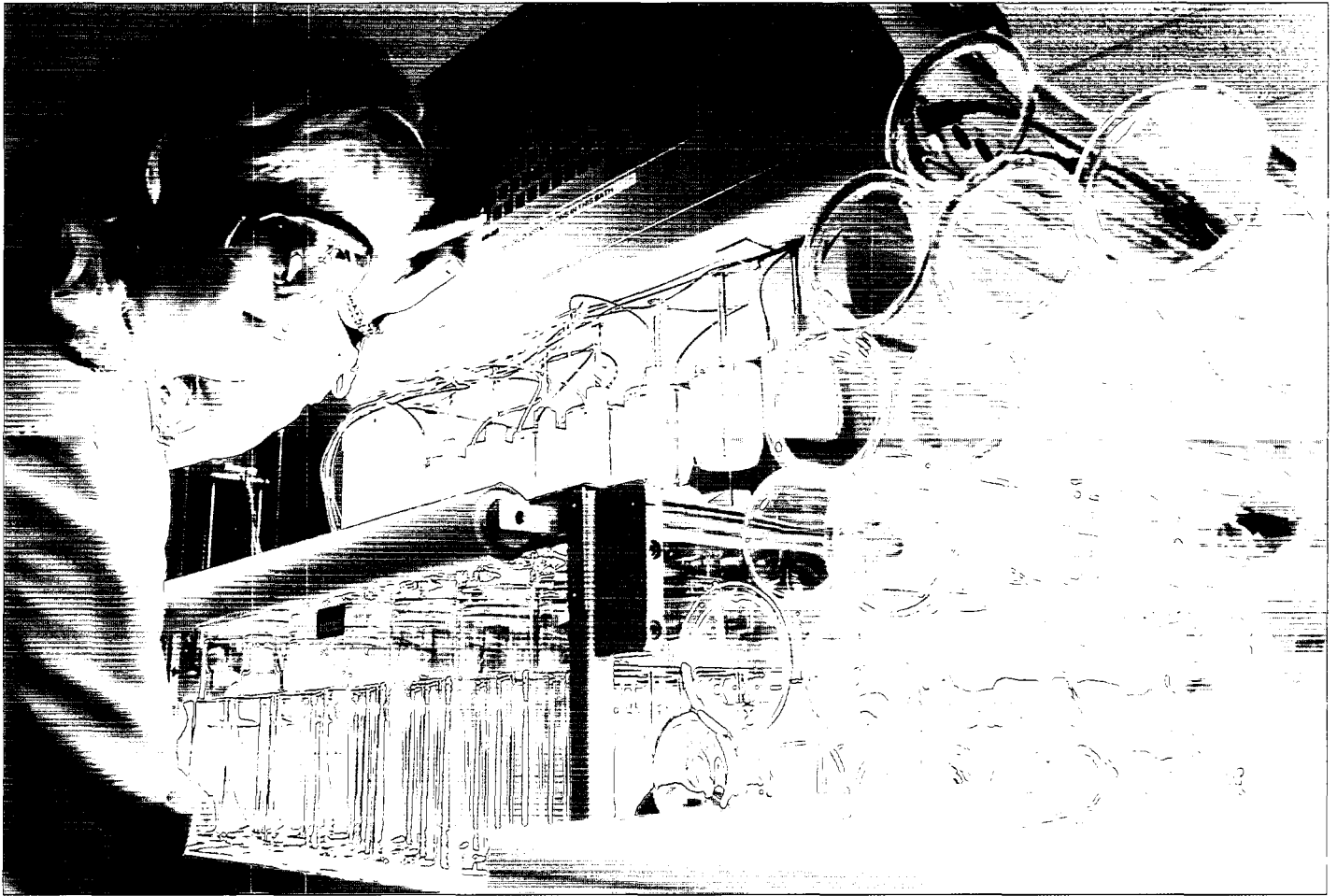
PRODUCT PORTFOLIO

Product selection and portfolio management are critical components of the Company's success. Penwest is developing a diverse pipeline of pharmaceutical products enhanced with our drug delivery technologies. Our product strategy is to reformulate drugs that are already on the market that can benefit from our proprietary oral drug delivery technologies — TIMERx, Geminex, and SyncroDose. During 2002, we continued to invest in the development of our own products, which has further enabled Penwest to have more control over product selection and subsequent development timelines, increase its patent position, and participate more fully in the revenue stream from future product sales by assuming more of the clinical development costs and risk.

Penwest's product portfolio is continually evolving to include development opportunities to improve medications over a broad range of therapeutic categories. Because of the flexibility of our drug delivery technologies, we believe our technologies can be applied to a broad range of therapeutic categories. The current pipeline products will be used to treat patients suffering from:



Penwest is developing a diverse pipeline of drug delivery enhanced products that will improve medications over a broad range of therapeutic categories.



- *Asthma.* Asthma is one of the nation's most common and costly diseases. It affects approximately 15 million Americans, including almost 5 million children. A New Drug Application (NDA) was filed with the FDA by one of our collaborative partners in November 2002 for PW3101. This compound was formulated with TIMERx and is expected to be dosed twice daily for the relief of bronchospasm in patients with reversible obstructive airway disease.
- *Diabetes.* Type 2 diabetes results from insulin resistance (a condition in which the body fails to properly use insulin), combined with relative insulin deficiency. Approximately 90 to 95% of the 17 million diabetics have type 2 diabetes. Penwest's Metformin ER was formulated with the TIMERx delivery system. The product successfully completed bio-equivalence studies in 2002 comparing it to Glucophage® XR.
- *Emesis (chemotherapy-induced).* Approximately one million new cases of cancer are diagnosed each year in the United States. Half of these patients undergo chemotherapy and two thirds of the more than 30 anticancer agents used in chemotherapy can cause moderate to severe nausea and vomiting. PW1101 is a combination drug product formulated with the Geminex dual delivery system that delivers two different actives for the prevention of both acute and delayed emesis.

PRODUCT PIPELINE

| PRODUCT | INDICATION | DEVELOPMENT STATUS | COLLABORATIVE PARTNER |
|-----------------------|-----------------------------------|------------------------|-------------------------------|
| OXYMORPHONE ER | Moderately Severe/ Severe Pain | Filed | Endo Pharmaceuticals |
| PW3101 | Asthma | Filed | Ivax |
| METFORMIN ER | Type II Diabetes | Bioequivalence results | Internal Development |
| OXYBUTYNIN ER | Urinary Incontinence | Bioequivalence studies | Internal Development |
| PW1101 | Chemo-induced Emesis | Pre-clinical | Internal Development |
| PW2101 | Hypertension | Phase I | Internal Development |
| PW2102 | Hypertension | Pre-clinical | Internal Development |
| PW4102 | Neuropathic Pain | Pre-clinical | Internal Development |
| PW4103 | Menstrual Migraine Prophylaxis | Phase I | Internal Development |
| PW4146 | Migraine Prophylaxis | Phase II | First Horizon Pharmaceuticals |
| PW9101 (AD121) | Rheumatoid Arthritis | Phase I/II | Arakis, Ltd. |

- *Hypertension.* In the United States there are 30 million individuals actively being treated for high blood pressure. The hypertension population is growing at a rate of 5% per year. Penwest is currently developing two products for the treatment of hypertension: PW2101 — a once-daily medication for treating hypertension formulated with TIMERx and PW2102 — a once-daily combination drug product formulated with Geminex.
- *Migraine Prophylaxis.* Migraine is a neurological disorder characterized by recurrent headache attacks. Migraine affects approximately 24 million Americans. PW4146 is being developed with First Horizon, a collaborative partner, to be a daily prophylactic medication for migraine sufferers, while PW4103 is being developed to be a prophylactic medication for women who consistently have attacks between two days prior to menses and the last day of menses. Menstrual migraines are longer in duration, more likely to recur, and more resistant to treatment than other migraines. It has been reported that 14.4 million women are migraine sufferers and about 60% of these women have an increased number of headaches in association with their menstrual period. In 10% to 14% of these women, the migraine occurs around the time of the period and at no other time.
- *Pain.* Pain management is complex and has few efficacious treatment options. The market for pain management drugs remains a substantial growth opportunity due to an increasing elderly population



Product selection and portfolio management are critical components to the Company's success.

- and unmet medical needs. We are developing PW4102 to help improve the quality of life for the nearly 10 million Americans who suffer from neuropathic pain, a condition that results in sharp, stinging, or stabbing pain.
- *Rheumatoid Arthritis (RA)*. RA currently afflicts 1 to 2% of the US population. It is an autoimmune disease that appears to have a genetic component and an external trigger. We are developing AD121 with a collaborative partner for the treatment of rheumatoid arthritis. AD121 utilizes SyncroDose to release the drug to coincide with the body's IL-6 cascade. AD121 is a once daily chronotherapeutic formulation that would be taken at night to relieve morning pain and stiffness associated with arthritis.
 - *Urinary Incontinence*. It is estimated that more than 12 million Americans have urinary incontinence. Incontinence affects all ages, both sexes, and people of every social and economic level. We are developing an oxybutynin ER formulation to be a generic equivalent formulation to Ditropan® XL. As the first controlled release urinary incontinence drug available in the US market, Ditropan XL commanded approximately \$300 million in sales in 2002 (IMS reported data).

Product selection and portfolio management are critical components of the Company's success. Our product selection is not limited by therapeutic category. Penwest's flexible strategy for building a product portfolio — through collaboration, independent product development, or product improvement and licensing — balances opportunity and risk to create long-term financial value and strengthen our position in the marketplace.



PARTNERSHIPS

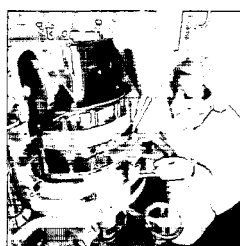
Dr. Robin Bannister, Research and Development Director of Arakis, and Dr. Anand Baichwal of Penwest, review product opportunities in the area of pain management.

Collaborations are a critical component of Penwest's overall growth. We are fully committed to forming beneficial collaborations, leveraging our scientific, technological and formulation expertise with a partner's clinical development, marketing, and manufacturing knowledge to produce enhanced pharmaceutical products. Our goal is to jointly develop products that address unmet medical needs, advance patient care, and achieve long-term business success.

Through teamwork and commitment, we form synergistic alliances that promote expeditious product development. Our collaborations are built on mutual trust, common goals, and the ability to fully exploit each partner's expertise. Each collaboration has clear clinical and commercial strategies, intellectual property protection, and a development plan. Alliance teams, comprising scientific and senior business representatives from both companies, manage the collaboration and meet regularly for project planning and budgeting.

FLEXIBLE DEAL STRUCTURE Penwest is open to a variety of collaborative arrangements. Current business relationships include two basic types:

- Technology and product licensing agreements with built-in milestones and a royalty stream on sales. These products can be out-licensed at various stages of clinical development.
- Financial arrangements, in which partners share equally in the risks and rewards.



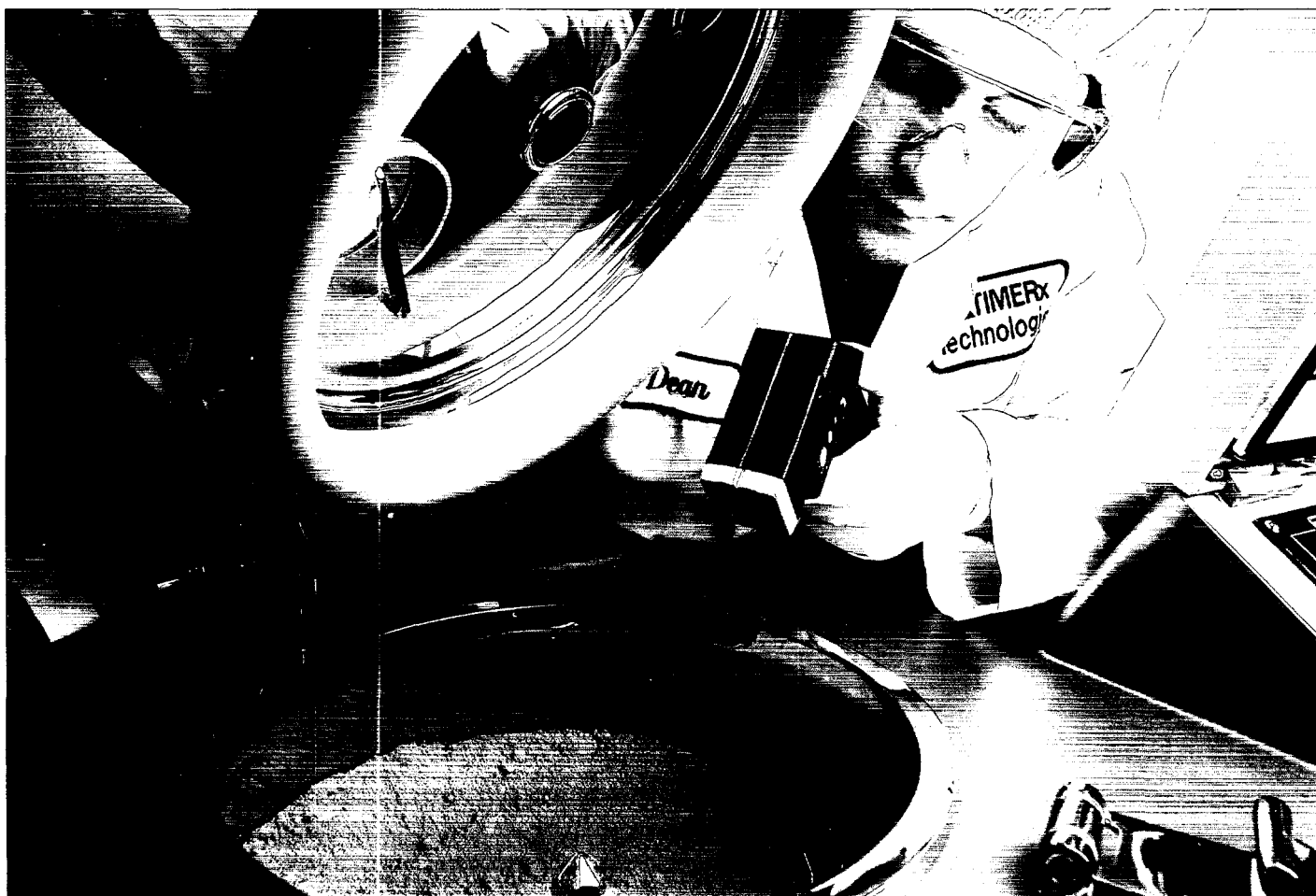
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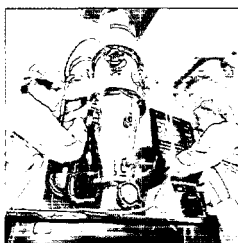
Through collaborations, we seek to maximize the value of our technologies, drug formulation expertise, and product pipeline, while providing intellectual property and pipeline opportunities to our partners. Penwest collaborations include:

- Endo Pharmaceuticals
- Arakis Ltd.
- E. Merck
- Mylan Pharmaceuticals
- Ranbaxy Laboratories, Ltd.
- Sanofi-Synthelabo

ENDO ALLIANCE | In 1997, Penwest and Endo Pharmaceuticals entered into a strategic alliance to develop a **TIMERx** oral extended release tablet formulation of Endo's oxymorphone product. Oxymorphone ER is a narcotic analgesic that will be used in the treatment of chronic moderate-to-severe pain.

Oxymorphone ER, being developed for twice-a-day dosing, would represent the first oral extended release version of oxymorphone, and would directly compete in the moderate-to-severe analgesic market with OxyContin[®], the market leader for moderate-to-severe pain, and MS Contin[®], Duragesic[®], and Avinza[®]. The market was approximately \$3 billion in 2002.





☞ ☞ FDA approval of oxymorphone ER
would give physicians and patients a new option
for managing chronic pain. ☞ ☞

Under the agreement terms, Penwest and Endo equally share development, manufacturing, and marketing costs, and initially agreed to split net profits. However, on March 17, 2003, Penwest gave Endo notice that it is discontinuing its participation in the funding of the development and marketing of Oxymorphone. Therefore, this split will be adjusted by any amounts unfunded by Penwest at the time of market launch. Penwest was responsible for formulating the drug and will supply bulk TIMERx materials. Endo is responsible for conducting the clinical studies, preparing and submitting the regulatory filings, and marketing and manufacturing the finished product. The collaboration is managed by an alliance committee that includes the senior management from both companies.

Development Progress Oxymorphone posed challenges in formulation, particularly with respect to its high first pass metabolism. Endo needed a delivery system that could deliver and sustain meaningful levels of drug in the blood, which would in turn generate meaningful efficacy.

An extensive clinical development program was executed over a four year period in which oxymorphone ER was tested in over 1,000 patients. Clinical studies were done in several pain models including osteoarthritis, low back pain, cancer, and post surgical pain. The drug was tested in several pain models in order to be able to obtain broad class labeling.

Regulatory An NDA for the oxymorphone ER tablets, submitted on December 19, 2002, was accepted for filing by the U.S. Food and Drug Administration on February 19, 2003. FDA approval would



give physicians and patients a new option for managing chronic pain, and should enable Penwest and Endo to successfully compete in the growing approximately \$3 billion market for long-acting opioids.

This alliance with Endo demonstrates how the value of leveraging complementary expertise and understanding the partner's needs can provide a win-win relationship.

ARAKIS PAIN ALLIANCE Penwest entered into collaboration with Arakis Limited in November 2000 to jointly develop AD 121, a chronotherapeutic product for the treatment of rheumatoid arthritis. In November 2001, we expanded the collaboration, entering a three-year strategic alliance to develop enhanced medicines for pain management, a vast market of unmet medical needs. These medicines will be jointly developed by combining Penwest's drug delivery technologies and formulation expertise with Arakis' ability to use new scientific information to enhance the performance of pharmacological agents. From conception to formulation, both companies share equally in the development process, risks and rewards. Two pain projects are now in preclinical feasibility studies to gain insight into the formulation options for future clinical trials. AD121 for rheumatoid arthritis is in Phase I clinical studies.

BOARD OF DIRECTORS

PAUL E. FREIMAN

Mr. Freiman is the Chief Executive Officer and President of Neurobiological Technologies Inc. and the former Chairman and Chief Executive Officer of Syntex Corporation. He is Chairman of the Board of Digital Gene Technologies and also serves on the boards of Calypte Biomedical Corporation, PHYTOS Inc., and Otsuka America Pharmaceuticals, Inc. He has been Chairman of the Pharmaceutical Manufacturers Association of America (PhRMA) and has also chaired a number of key committees. Mr. Freiman holds a B.S. degree in Pharmacy 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 Board of Emisphere Technology, Sili Pharmaceuticals, VasoGenix and Institute for World Health. 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 having served 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. Dr. Goyan 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 healthcare industry and is a Partner at Naimark & Associates, a health care consulting firm. He is a director and member of the Audit Committee of both SciClone Pharmaceuticals and Draxis Health Inc., a Canadian company, where he is also on the Corporate Governance Committee. Additionally, he is a director and the treasurer of Community Blood Services of Paramus, New Jersey and of its foundation. Mr. Henel also serves as President of the Northern New Jersey Chapter of the American Association of Individual Investors. He is the retired President of Cyanamid International Lederle Division. He holds an M.B.A. from New York University and a B.A. from Yale.

ROBERT J. HENNESSEY

Mr. Hennessey is the former President and CEO of Genome Therapeutics Corporation and currently serves as a Board member. In addition, he worked as 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.

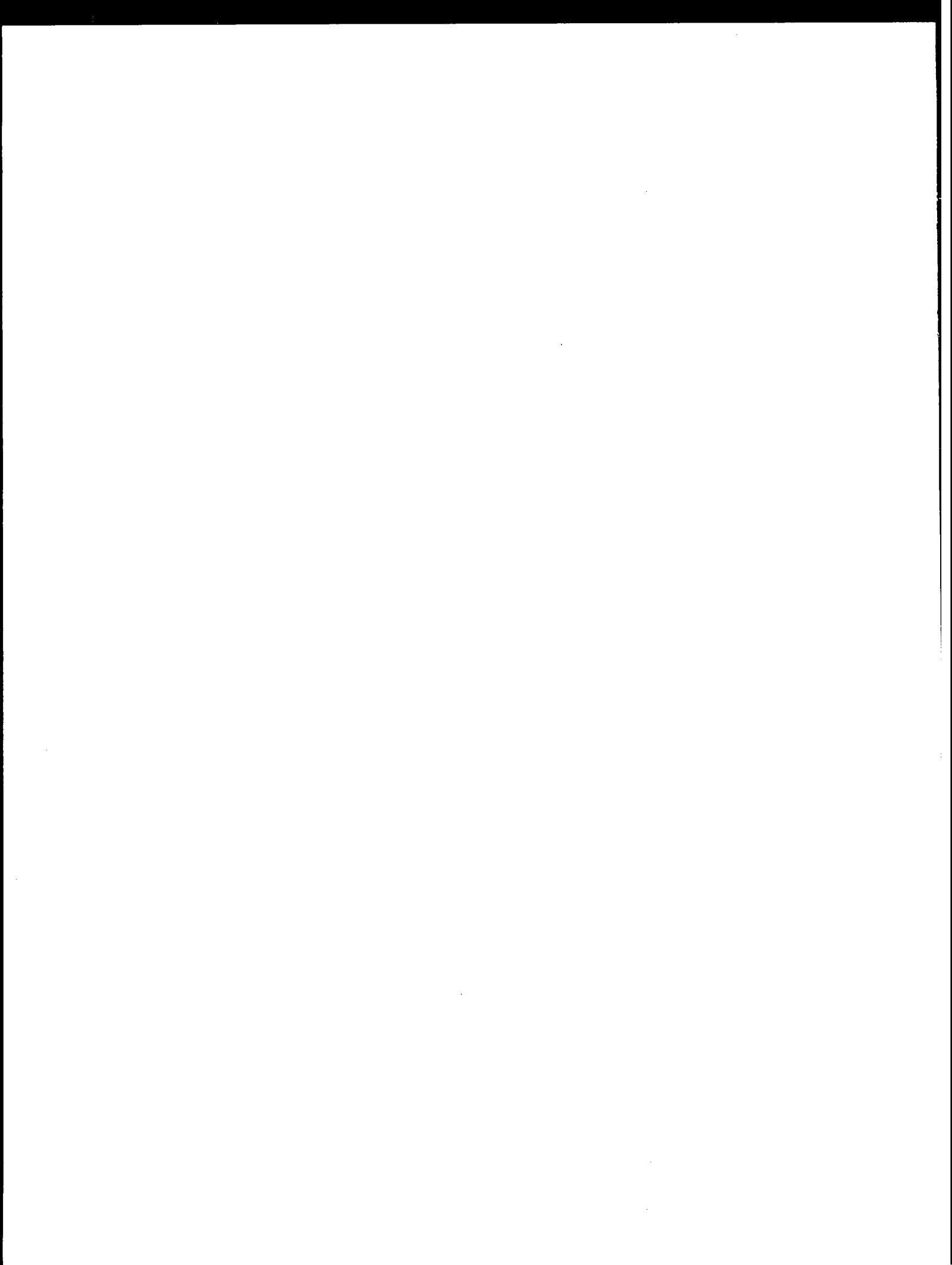
JOHN N. STANIFORTH, PH.D.

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 been affiliated with a number of universities in the United States as well as Monash University in Australia. His research in the field of powder technology has been widely published and has received 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 Executive Vice President and Chief Financial Officer of 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. Her last position with Sarnoff 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 on the Board of Directors of i-STAT Corporation, a public company engaged in the development and commercialization of point of care diagnostics and 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, 2002

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 28, 2002 was approximately \$302 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 March 20, 2003 was 15,510,880.

DOCUMENTS INCORPORATED BY REFERENCE

The Registrant's definitive Proxy Statement relating to the 2003 Annual Meeting of Shareholders to be held on June 4, 2003 is incorporated by reference into portions of Part III of this Form 10-K.

PENWEST PHARMACEUTICALS CO.

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PART I

ITEM 1: BUSINESS

Overview

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, and SyncroDose is a chronotherapeutic drug delivery system that is designed to release the active ingredient of a drug at the desired site and time in the body.

Penwest's product portfolio includes four products utilizing its proprietary controlled release drug delivery technology, that were developed with collaborators and have been approved in various countries. In addition, the Company has a number of product candidates in its drug development pipeline. The most advanced of these is oxymorphone ER, an extended release formulation of oxymorphone incorporating TIMERx technology. The Company is developing oxymorphone ER with Endo Pharmaceuticals Inc. The FDA accepted for filing a new drug application, or NDA, submitted by Endo for oxymorphone ER in February 2003.

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 Company received \$39.5 million in cash and a promissory note for \$2.25 million in consideration for the excipient business.

Penwest Strategy

Penwest's strategy is to develop pharmaceutical products utilizing the Company's innovative extended release oral drug delivery technologies.

- *Leverage its drug delivery technologies into a portfolio of product candidates for development.* The Company believes that it has significant expertise in drug formulation and in oral drug delivery technologies. The Company's 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, the Company can formulate drugs with precise release profiles. In selecting product candidates for development, the Company focuses on opportunities in which its drug delivery technologies can provide benefits to patients and result in branded, proprietary products. The Company does not limit the products it develops by therapeutic area.
- *Expand the product development pipeline to include drugs in various stages of development.* The Company intends to aggressively add product candidates into its development pipeline and control more of the clinical development process. Historically, the Company has formulated product candidates and then relied upon third party collaborators to complete the remainder of the clinical development program and market the drugs. Although the Company will still have a portion of its product portfolio it intends to out-license early on, the Company intends to develop more products on its own or jointly in collaboration with third parties. The Company has identified several product candidates that are in the formulation stage or in clinical trials for which the Company intends to complete the clinical trials through at least Phase II. The

Company believes that by controlling development through at least Phase II, it will be better able to control the development timelines of its portfolio of product candidates. The Company expects to continue to seek to license at an early stage in the development process generic product candidates, product candidates for which the Company believes that the development process is too expensive or too risky and product candidates that require early marketing input.

- *Increase participation in the funding of drug development to capture an increased share of the economic value of the product when and if it is marketed.* Developing pharmaceutical products is expensive. If the Company develops products on its own or jointly with third parties, it will need to devote significant resources to the products. However, the Company believes by assuming a larger role in the funding of a product's development, it will receive a greater share of the returns from the product.
- *Expand the core drug delivery technologies.* The Company's expertise is in oral drug delivery technologies and drug formulation. The Company intends to continue to develop its core technologies as well as to seek to develop, in-license or acquire new technologies that are synergistic with its product development pipeline.
- *Establish collaborations for development, manufacturing and marketing.* The Company does not anticipate establishing manufacturing or sales and marketing capabilities in the next few years. As a result, in addition to seeking to enter into collaborations to develop its products, the Company also expects to seek to enter into collaborations for the manufacturing and the selling and marketing of its products. The Company is a party to collaborative agreements with Endo, Leiras OY, Mylan Pharmaceuticals Inc., Sanofi-Synthelabo S.A., IVAX Pharmaceuticals, First Horizon, Ranbaxy Laboratories, Ltd. and E. Merck.

Drug Delivery Technologies and Products

TIMERx® Extended Release Delivery Systems

The Company developed its TIMERx delivery system to address the limitations of currently available oral extended release delivery systems. The Company believes that the TIMERx system has advantages over other oral drug delivery technology, 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 the Company is developing additional products in its 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. The gums are also used in Penwest's 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.

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 Leiras.

- Sildenafil XL, an extended release version of sildenafil for the treatment of angina, is being marketed in the United Kingdom and Italy by Sanofi.
- 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 the Company's 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, 90 mg) of Pfizer's Procardia XL. In connection with that agreement, Mylan agreed to pay Penwest a royalty on net sales of Pfizer's 30 mg strength of generic Procardia XL. The royalties are comparable to those 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.
- Cronodipin, an extended release version of nifedipine for the treatment of angina, is being marketed in Brazil by Merck S.A. Industries Quimicas.

Products in Pipeline

The Company also has a number of TIMERx products in its development pipeline. The most advanced of these is an extended release formulation of oxymorphone incorporating TIMERx technology, oxymorphone ER, which the Company is developing with Endo. Oxymorphone ER is a narcotic analgesic that is being developed for the treatment of 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 2002 of approximately \$150,000. 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 2002 of approximately \$2.5 billion. Oxymorphone ER is being developed for twice-a-day dosing in patients suffering moderate to severe pain. 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. The FDA accepted for filing the NDA submitted by Endo for oxymorphone ER in February 2003.

The table below summarizes the principal products in the Company's drug development pipeline, the therapeutic use, the development status of each product and the Company's collaborator, if any, on each product:

| <u>PRODUCT</u> | <u>INDICATION</u> | <u>DEVELOPMENT STATUS</u> | <u>COLLABORATOR</u> |
|----------------|-----------------------------------|----------------------------|----------------------------------|
| OXYMORPHONE ER | Moderately Severe/ Severe Pain | NDA Accepted for Filing | Endo Pharmaceuticals |
| PW3101 | Asthma | NDA Accepted for Filing | Ivax |
| METFORMIN ER | Type II Diabetes | Bioequivalence Studies | Internal Development |
| OXYBUTYNIN ER | Urinary Incontinence | Bioequivalence Studies | Internal Development |
| PW1101 | Chemo-induced Ermesis | Pre-clinical | Internal Development |
| PW2101 | Hypertension | Phase I | Internal Development |
| PW4102 | Neuropathic pain | Pre-clinical | Internal Development |
| PW4103 | Menstrual Migraine Prophylaxis | Phase I | Internal Development |
| PW4146 | Migraine Prophylaxis | Phase II | First Horizon Pharmaceuticals |
| PW9101(AD121) | Rheumatoid Arthritis | Phase I | Arakis, Ltd. |

Geminex™ Dual Release Technology

The Company developed its Geminex dual release technology to provide for the independent release of different active ingredients contained in one pharmaceutical product. 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. The Company is utilizing Geminex technology in several product candidates that are currently in the formulation stage.

SyncroDose™ Chronotherapeutic Drug Delivery

The Company developed its SyncroDose drug delivery system to deliver drugs chronotherapeutically in the body. The technology is timed with the body's biological clock to customize the delivery of a drug with the intent of reducing the dose and improving efficacy. SyncroDose is a technology based on the Company's underlying TIMERx platform. The Company believes that there are several disease states that can benefit from chronotherapeutic delivery including: arthritis, cardiovascular disorders, asthma and neurological disorders. The SyncroDose technology utilizes the TIMERx gum matrix in the coating combined with the active and various other excipients in the core. The Company is currently developing a product candidate for rheumatoid arthritis with Arakis utilizing the SyncroDose chronotherapeutic technology. This product candidate is in phase I clinical trials.

Collaborative Arrangements

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

The Company has two primary types of collaborative agreements. In the first type, research and development are funded by Penwest and its collaborator, and Penwest receives no up-front licensing fees or milestone payments. In these arrangements, the Company will share in a pre-determined percentage of the royalties. The second type of agreement involves the straight licensing of the Company's technology to the collaborator. The Company has no obligation to fund the ongoing clinical development or marketing costs of the product. Under these collaborative agreements, the Company receives up-front license fees and milestone payments. In addition, under all its current collaborative arrangements, the Company is entitled to receive royalties on the sale of the products covered by such collaborative arrangements and payments for the purchase of formulated TIMERx material. The Company's principal collaborative arrangements are described below.

Mylan Pharmaceuticals, Inc.

In August 1994, the Company entered into product development and supply agreements with Mylan with respect to the development of generic versions of Procardia XL (nifedipine) based on the Company's TIMERx technologies. Mylan is one of the leading generic pharmaceutical companies in the United States.

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 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 for the 30 mg strength of Nifedipine XL. Mylan's sales in the United States in 2002 of the 30 mg dosage strength version of Pfizer's generic Procardia XL totaled approximately \$34.9 million. The term of this agreement continues until such time as Mylan permanently ceases to market generic Procardia XL. In 2002, 2001 and 2000, royalties from Mylan accounted for approximately 11%, 12% and 19%, respectively, of the Company's total revenue, and 86%, 82% and 50% of the Company's total revenue that was not associated with the excipient business that the Company sold in February 2003.

Endo Pharmaceuticals, Inc.

In September 1997, the Company entered into a strategic alliance agreement with Endo with respect to the development of an extended release formulation of oxymorphone based on the Company's TIMERx technology, oxymorphone ER. 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 with 12 branded products, including established brands such as Percodan® and Percocet®. 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 oxymorphone ER 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 manufacture and 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 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 gave Endo notice that it is discontinuing its

participation in the funding of the development and marketing of oxymorphone ER. The Company believes that its current strategic focus should be on funding products in its development pipeline. As a result of this termination, 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. Endo may recoup such development costs solely through a temporary adjustment in the royalty rate payable to Penwest which shall return to its pre-adjustment level once Endo has recovered such costs. 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). 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 ER exclusively from the Company at specified prices. Such prices will be reflected in the determination of net profits.

Sanofi-Synthelabo S.A.

In February 1997, the Company entered into a product development and supply agreement with Sanofi with respect to the development of a generic version of Adalat LA, a drug that utilizes the same controlled release technology as Procardia XL. This generic version is based on the Company's TIMERx technology (the "Sanofi Product"). Sanofi is a research-based international pharmaceutical company, based in Paris, France, which has a European infrastructure from which to develop, register and market prescription pharmaceuticals.

Under the product development and supply agreement, the Company was responsible for conducting pilot bioequivalence studies of the Sanofi Product and is responsible for manufacturing and supplying TIMERx material to Sanofi. Sanofi was responsible for conducting all full scale bioequivalence and clinical studies, preparing all regulatory applications and submissions and is responsible for manufacturing and marketing the Sanofi Product in specified countries in Europe and in South Korea. The Sanofi Product was approved and Sanofi began marketing the Sanofi Product in the United Kingdom in November 1998. Sanofi also received regulatory approval in Italy in 2000 and is marketing the product.

The product development and supply agreement expires with respect to each specified country on the 10th, 13th, 16th or 19th anniversary of the date on which the Sanofi Product is approved by the relevant regulatory authority in such country for commercial sale if notice is provided by either party prior to any of such anniversary dates that the agreement will expire with respect to such country on such anniversary date. The agreement is also subject to earlier termination by either party under specified circumstances, including termination by the Company if Sanofi fails to meet minimum sales volume requirements and termination by either party upon a material breach of the agreement by the other party. If the Company does not satisfy its obligations under the agreement, the Company will be in breach of the agreement and Sanofi will be entitled to terminate the agreement.

The Company received milestone payments under the product development and supply agreement. The Company is receiving royalties upon the sale of the Sanofi Product. One-half of such payments will be paid to Mylan in accordance with a distribution agreement signed with Mylan. In addition, Sanofi has agreed that, during the term of the product development and supply agreement, it will purchase, and Sanofi is purchasing, formulated TIMERx material for use in the Sanofi Product exclusively from the Company at specified prices.

Leiras Oy

In July 1992, the Company entered into an agreement with Leiras with respect to the development and commercialization of Cystrin CR, a controlled release formulation of Cystrin based on the Company's TIMERx technology. In May 1995, the Company entered into a second agreement with Leiras clarifying certain matters with respect to the collaboration. In addition, during 2001, the Company reacquired the North American marketing rights to this product.

Under the agreements, the Company was responsible for the development and formulation of Cystrin CR and is now responsible for supplying TIMERx material to Leiras for use in the manufacture of Cystrin CR. Leiras is responsible for preparing all regulatory applications and submissions and manufacturing and marketing Cystrin CR on a worldwide basis, except for the marketing rights in North America which have been licensed back to Penwest. Leiras has the right to transfer its rights and responsibilities under the agreements and its related product rights for specified territories, subject in certain circumstances to the approval of the Company. Leiras transferred the European rights to Sanofi, which is currently not marketing the product. Leiras received marketing approval for Cystrin CR in Finland in October 1997 and began marketing the product in Finland in 1998.

The agreements terminate upon the expiration of the TIMERx patents licensed to Leiras (which will occur in 2014), subject to earlier termination by either party under specified circumstances, including upon a material breach of the agreement by a party or upon the bankruptcy of a party. If the Company does not satisfy its obligations under either of these agreements, the Company will be in breach of such agreement and Leiras will be entitled to terminate such agreement. Leiras has also agreed to pay the Company royalties on the sale of Cystrin CR and to purchase formulated TIMERx material exclusively from the Company at specified prices.

Other Collaborations

The Company is a party to the following additional collaborative agreements involving its TIMERx technology:

- *IVAX Pharmaceuticals*. The Company's agreement with IVAX relates to the development of a drug for the treatment of asthma.
- *First Horizon*. The Company's agreement with First Horizon relates to the development of a drug for the treatment of migraine prophylaxis.
- *Ranbaxy Laboratories Ltd.* The Company's agreement with Ranbaxy relates to an extended release version of nifedipine for the treatment of angina.
- *E. Merck*. The Company's agreement with E. Merck relates to an extended release version of nifedipine for the treatment of angina that is being marketed in Brazil by Merck S.A. Industries Quimicas.

Research and Development

The Company conducts research and development activities with respect to additional applications of TIMERx technology, advances in the TIMERx technology, additional drug delivery technologies, and prior to the sale of the excipient business additional novel excipients such as ProSolv. The Company's research and development expenses in 2002, 2001, and 2000 were \$17.6 million, \$17.0 million and \$12.8 million. The drug delivery business accounted for approximately 96%, 94% and 94%, respectively, of the Company's research and development expense for 2002, 2001 and 2000. These expenses do not include amounts incurred by the Company's collaborators in connection with the development of

products under the collaboration agreements such as expenses for full-scale bioequivalence studies or clinical trials performed by the collaborators.

Manufacturing

The Company has 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. The Company is also currently validating and finalizing an agreement with a second source. The Company believes that there are a limited number of manufacturers that operate under cGMP regulations capable of manufacturing the Company's products. There can be no assurance that Draxis or any other 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 and results of operations.

The Company's drug delivery systems are 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 sole source supplier. Although the Company has qualified alternate suppliers with respect to these gums and to date the Company 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 and results of operations.

As the Company develops products on its own, the Company has outsourced and will seek to outsource the clinical and commercial manufacture of such products to third parties. The Company believes there are many companies which are capable of manufacturing these products.

Marketing and Distribution

Pursuant to the Company's collaborative agreements, the Company's collaborators have, or are expected to have, responsibility for the marketing and distribution of any extended release pharmaceuticals developed based on the Company's drug delivery technologies. Because the Company does not currently market any such pharmaceuticals without a collaborator, the Company has not developed any sales force with respect to such products. As a result, the Company is substantially dependent on the efforts of its collaborators to market the products. In selecting a collaborator for a drug candidate, some of the factors the Company considers 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

The Company believes that patent and trade secret protection of its drug delivery technology is important to its business and that the Company's success will depend in part on its 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 March 20, 2003, the Company has been issued 30 U.S. and 147 foreign patents, relating to the Company's controlled release drug delivery technology. The U.S. patents issued to the Company principally cover the Company's 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 (and combination) 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.

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 the Company's patents or any future patents will prevent other companies from developing non-infringing similar or functionally equivalent products or from successfully challenging the validity of the Company's patents. Furthermore, there is no assurance that:

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

The inability of the Company to protect its patent rights or infringement by the Company of the patent or proprietary rights of others could have a material adverse effect on the Company's business, financial condition and results of operations.

The Company also relies on trade secrets and proprietary knowledge, which it generally seeks 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 the Company will have adequate remedies for any breach or that the Company's 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 the Company is developing with its 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 sooner. Should a patent owner commence a lawsuit with respect to alleged patent infringement by the Company or its collaborators, the uncertainties inherent in patent litigation make the outcome of such litigation difficult to predict. The Company's collaborators are responsible for all legal costs under Waxman-Hatch lawsuits. The Company evaluates the probability of patent infringement litigation with respect to its collaborators' ANDA submissions on a case by case basis. The delay in obtaining FDA approval to market the

Company's product candidates as a result of litigation, whether or not the Company is successful, could have a material adverse effect on the Company's business, financial condition and results of operations.

Trademarks. TIMERx is a registered trademark of the Company. Geminex and SyncroDose are also trademarks of the Company. Other tradenames and trademarks appearing in this annual report 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 (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 certain 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.

ANDAs may be submitted for generic versions of brand name drugs ("Listed Drugs") where the generic drug is the "same" as the Listed Drug with respect to active ingredient(s) and route of administration, dosage form, strength, and conditions of use recommended in the labeling. ANDAs may also be submitted for generic drugs that differ with regard to certain changes from a Listed Drug if the

FDA has approved a petition from a prospective applicant permitting the submission of an ANDA for the changed product.

Rather than safety and efficacy studies, the FDA requires data demonstrating that the ANDA drug formulation is bioequivalent to the Listed Drug. The FDA also requires labeling, chemistry and manufacturing information. FDA regulations define bioequivalence as the absence of a significant difference in the rate and the extent to which the active ingredient becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study. If the approved generic drug is both bioequivalent and pharmaceutically equivalent to the Listed Drug, the agency will assign a code to the product in an FDA publication entitled "Approved Drug Products With Therapeutic Equivalence Evaluation." These codes will indicate whether the FDA considers the product to be therapeutically equivalent to the Listed Drug. The codes will be considered by third parties in determining whether the generic drug is therapeutically equivalent and fully substitutable for the Listed Drug and are relied upon by Medicaid and Medicare formularies for reimbursement.

Although the FDA has approved the ANDA filed by the Company's collaborator Mylan for the 30 mg dosage strength of a generic version of Procardia XL, there can be no assurance that applications filed by the Company's collaborators with respect to other products will be suitable or available for such products, or that such products will receive FDA approval on a timely basis.

Certain ANDA procedures for generic versions of controlled release products are the subject of petitions filed by brand name drug manufacturers, which seek changes from the FDA in the approval process for generic drugs. These requested changes include, among other things, tighter standards for certain bioequivalence studies and disallowance of the use by a generic drug manufacturer in its ANDA of proprietary data submitted by the original manufacturer as part of an original new drug application. The Company is unable to predict at this time whether the FDA will make any changes to its ANDA procedures as a result of such petitions or any future petitions filed by brand name drug manufacturers or the effect that such changes may have on the Company. Any changes in FDA regulations which make ANDA approvals more difficult could have a material adverse effect on the Company's business, financial condition and results of operations.

Some products containing the Company's TIMERx formulation, such as controlled release formulations of approved immediate release drugs, 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, the Company 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 the Company 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.

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.

Under the Waxman-Hatch Act, an applicant who files the first ANDA with a certification of patent invalidity or non-infringement with respect to a product may be entitled to receive, if such ANDA is approved by the FDA, 180-day marketing exclusivity (a 180-day delay in approval of other ANDAs for the same drug) from the FDA. However, there can be no assurance that the FDA will not approve an ANDA filed by another applicant with respect to a different dosage strength prior to or during such 180-day marketing exclusivity period.

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 the ability of the Company and its collaborators to use the Company's 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.

Foreign Regulatory Approval

Whether or not FDA approval has been obtained, approval of a pharmaceutical product by comparable governmental regulatory authorities in foreign countries must be obtained prior to the commencement of clinical trials and subsequent marketing of such product in such countries. The approval procedure varies from country to country, and the time required may be longer or shorter than that required for FDA approval.

Under European Union ("EU") law, either of two approval procedures may apply to the Company's products: a centralized procedure, administered by the EMEA (the European Medicines Evaluation Agency); or a decentralized procedure, which requires approval by the medicines agency in each EU Member State where the Company's products will be marketed. The centralized procedure is mandatory for certain biotechnology products and available at the applicant's option for certain other products. Although the decentralized procedure requires approval by the medicines agency in each EU Member State where the products will be marketed, there is a mutual recognition procedure under which the holder of marketing approval from one EU Member State may submit an application to one or more other EU Member States, including a certification to the effect that the application is identical to the application which was originally approved or setting forth the differences between the two applications. Within 90 days of such application, each EU Member State will be required to determine whether to recognize the prior approval.

Whichever procedure is used, the safety, efficacy and quality of the Company's products must be demonstrated according to demanding criteria under EU law and extensive nonclinical tests and clinical trials are likely to be required. In addition to premarket approval requirements, national laws in EU Member States will govern clinical trials of the Company's products, adherence to good manufacturing practice, advertising and promotion and other matters. In certain EU Member States, pricing or reimbursement approval may be a legal or practical precondition to marketing.

A procedure for abridged applications for generic products also exists in the EU. The general effect of the abridged application procedure is to give scope for the emergence of generic competition once patent protection has expired and the original product has been on the market for at least six or ten years. Independent of any patent protection, under the abridged procedure, new products benefit in principle from a basic six or ten year period of protection (commencing with the date of first authorization in the EU) from abridged applications for a marketing authorization. The period of protection in respect of products derived from certain biotechnological processes or other high-technology medicinal products viewed by the competent authorities as representing a significant innovation is ten years. Further, each EU Member State has discretion to extend the basic six-year period of protection to a ten-year period to all products marketed in its territory. Certain EU Member States have exercised such discretion. The protection does not prevent another company from making a full application supported by all necessary pharmacological, toxicological and clinical data within the period of protection. Abridged applications can be made principally for medicinal products which are essentially similar to medicinal products which have been authorized for either six or ten years. Under the abridged application procedure, the applicant is not required to provide the results of pharmacological and toxicological tests or the results of clinical trials. For such abridged applications, all data concerning manufacturing quality and bioavailability are required. The applicant submitting the abridged application generally must provide evidence or information that the drug product subject to this application is essentially similar to that of the referenced product in that it has the same qualitative and quantitative composition with respect to the active ingredient and the same dosage form, and is similar in bioavailability as the referenced drug.

Other Regulations. The Company is 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 the Company is 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 the Company's competitors have longer operating histories and greater financial, marketing, legal and other resources than the Company and certain of its collaborators. The Company expects that it will be subject to competition from numerous other entities that currently operate or intend to operate in the pharmaceutical industry, including companies that engage in the development of controlled release technologies.

The Company faces competition from numerous public and private companies and their controlled release technologies, including Johnson & Johnson's Oros technology, multiparticulate systems marketed by Elan Corporation plc and Biovail, traditional matrix systems marketed by SkyePharma, plc and other extended release technologies marketed or under development by Andrx Corporation, among others.

Most of the Company's products under development are extended release versions of existing immediate release drugs. These drugs will face competition from products with the same indication as the product developed by Penwest. For instance, the Company expects that oxymorphone ER will face competition from Purdue Pharma's OxyContin® and Johnson & Johnson's Duragesic® patch.

A number of the products that the Company has developed and still will selectively develop are generic versions of branded controlled release pharmaceuticals. Typically, selling prices of immediate release drugs have declined and profit margins have narrowed after generic equivalents of such drugs are first introduced and the number of competitive products has increased. Similarly, the success of generic versions of controlled release products based on the Company's TIMERx technology will depend, in large part, on the intensity of competition from currently marketed drugs and technologies that compete with the branded pharmaceutical, as well as the timing of product approvals. However, the Company believes that generic versions of controlled release pharmaceuticals based on TIMERx technology are less likely to suffer the same degree of price erosion as other generic pharmaceuticals because of formulation, and the fact that analytical and manufacturing complexity of the generic versions may be difficult for other companies to replicate, which could limit competition. Competition may also arise from therapeutic products that are functionally equivalent but produced by other methods.

Employees

As of March 20, 2003, the Company employed approximately 66 people, of whom 46 were involved in research and development, and 20 were in selling, general and administrative. As of March 20, 2003, none of the Company's employees are covered by collective bargaining agreements. The Company considers its employee relations to be good.

Information Available on the Internet

Penwest's internet address is www.penwest.com. Penwest makes available free of charge through its web site Penwest's 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 Penwest electronically files such materials with the Securities and Exchange Commission.

ITEM 2: PROPERTIES

The Company's has research facilities, comprising approximately 14,000 square feet, in Patterson, New York. Prior to the sale of the excipient business, the Company owned the site of the space in Patterson, New York, as well as a facility in Cedar Rapids, Iowa, where it manufactured pharmaceutical excipients. As part of the sale of the excipient business, the Company transferred these properties and assigned a lease for a pharmaceutical excipient manufacturing facility in Nastola, Finland. However, under its agreement with Rettenmaier, the Company has the right to occupy approximately 14,000 square feet of office and research and development space in the Patterson building until February 2008, initially on a rent-free basis for two years and then pursuant to three successive one-year options at a rental rate of \$12 per square foot.

The Company has signed a lease agreement for approximately 11,000 square feet of office space in Danbury, Connecticut. This lease expires on January 31, 2006, with renewal options through December 30, 2006. Effective March 31, 2003, the Company relocated its executive and administrative offices to Danbury.

ITEM 3: LEGAL PROCEEDINGS

The Company is not a party to material legal proceedings.

ITEM 4: SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matter was submitted to a vote of shareholders during the fourth quarter of fiscal 2002.

ITEM 4a: 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 | 57 | Chairman of the Board and Chief Executive Officer | 1997—current |
| | | President and Chief Executive Officer—Penford Corp. | 1985—1997 |
| Anand R. Baichwal, Ph.D. | 48 | Senior Vice President, Research & New Technology Development and Chief Scientific Officer | 1997—current |
| | | Vice President, Technology | 1994—1997 |
| Jennifer L. Good | 38 | Senior Vice President, Finance and Chief Financial Officer | 1997—current |
| | | Corporate Controller—Penford Corp. | 1993—1997 |

PART II

ITEM 5: MARKET PRICE OF AND DIVIDENDS ON THE REGISTRANT'S COMMON STOCK AND RELATED STOCKHOLDER MATTERS

Penwest's common stock, \$.001 par value, is listed with and trades on the Nasdaq National Market under the symbol "PPCO." The high and low closing prices of the Company's common stock during 2002 and 2001 are set forth below.

| <u>PERIOD 2002</u> | <u>HIGH</u> | <u>LOW</u> |
|----------------------------------|-------------|------------|
| 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 |
| <u>PERIOD 2001</u> | <u>HIGH</u> | <u>LOW</u> |
| Quarter Ended March 31 | \$14.63 | \$ 9.81 |
| Quarter Ended June 30 | \$16.05 | \$11.06 |
| Quarter Ended September 30 | \$20.30 | \$14.20 |
| Quarter Ended December 31 | \$20.19 | \$15.00 |

On March 20, 2003 there were 823 shareholders of record.

The Company has never paid cash dividends on its common stock. The Company presently intends to retain earnings, if any, for use in the operation of its business, and therefore does not anticipate paying any cash dividends in the foreseeable future.

ITEM 6: SELECTED FINANCIAL DATA

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

| | YEAR ENDED DECEMBER 31,(a) | | | | |
|---|---|-------------------|------------------|------------------|------------------|
| | 2002 | 2001 | 2000 | 1999 | 1998 |
| | (IN THOUSANDS, EXCEPT FOR PER SHARE DATA) | | | | |
| STATEMENT OF OPERATIONS DATA: | | | | | |
| Revenues (b) | \$ 41,959 | \$ 40,003 | \$42,058 | \$37,307 | \$29,149 |
| Cost of product sales (b) | 25,407 | 24,810 | 25,303 | 25,889 | 21,183 |
| Gross profit | 16,552 | 15,193 | 16,755 | 11,418 | 7,966 |
| Selling, general and administrative | 15,820 | 13,855 | 12,054 | 11,425 | 11,354 |
| Research and product development | 17,567 | 17,003 | 12,820 | 7,371 | 6,054 |
| Asset write-off (c) | — | — | — | — | 1,341 |
| Loss before cumulative effect of change in accounting principle | (17,099) | (15,981) | (8,376) | (7,681) | (8,829) |
| Cumulative effect of change in accounting principle (d) | — | — | (410) | — | — |
| Net loss | <u>\$(17,099)</u> | <u>\$(15,981)</u> | <u>\$(8,786)</u> | <u>\$(7,681)</u> | <u>\$(8,829)</u> |
| Basic and diluted loss per share before cumulative effect of change in accounting principle | \$ (1.11) | \$ (1.15) | \$ (0.68) | \$ (0.69) | \$ (0.80) |
| Cumulative effect of change in accounting principle per share | — | — | (0.03) | — | — |
| Net loss per share | <u>\$ (1.11)</u> | <u>\$ (1.15)</u> | <u>\$ (0.71)</u> | <u>\$ (0.69)</u> | <u>\$ (0.80)</u> |
| Weighted average shares of common stock outstanding | <u>15,462</u> | <u>13,905</u> | <u>12,330</u> | <u>11,103</u> | <u>11,037</u> |

| | DECEMBER 31, | | | | |
|-------------------------------------|----------------|-----------|----------|----------|----------|
| | 2002 | 2001 | 2000 | 1999 | 1998(e) |
| | (IN THOUSANDS) | | | | |
| BALANCE SHEET DATA: | | | | | |
| Cash and cash equivalents | \$ 4,420 | \$ 12,903 | \$ 2,204 | \$ 739 | \$ 1,476 |
| Marketable securities | 2,057 | 9,609 | — | — | — |
| Working capital | 10,329 | 27,059 | 11,129 | 7,713 | 7,648 |
| Total assets | 50,220 | 59,613 | 42,294 | 38,120 | 41,082 |
| Long-term debt | — | — | — | 6,700 | — |
| Accumulated deficit | (78,025) | (60,926) | (44,945) | (36,159) | (28,478) |
| Shareholders' equity | 31,423 | 45,624 | 31,017 | 22,509 | 30,032 |

- (a) During the years ended December 31, 2002, 2001, 2000, 1999 and 1998, revenues from the sale of excipient products were 87%, 86%, 79%, 95% and 97%, respectively, of total revenues. Effective February 27, 2003, the Company will not derive any revenues from the excipient business. See Note 18 to the Company's consolidated financial statements.
- (b) Reclassification recorded of amounts prior to 2000 for the adoption of EITF No. 00-10 "Accounting for Shipping and Handling Fees and Costs."
- (c) Represents a one-time charge relating to the write-off of costs associated with the decision to outsource certain manufacturing as opposed to constructing a new facility.
- (d) Cumulative effect of adopting Staff Accounting Bulletin No. 101 ("SAB No. 101") in 2000.
- (e) In conjunction with the August 31, 1998 distribution, in which the Company's former parent, Penford Corporation, distributed to the shareholders of record of Penford common stock on August 10, 1998 all of the shares of the Company's common stock, Penford contributed to the Company's capital, all existing intercompany indebtedness.

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

Overview

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, and SyncroDose is a chronotherapeutic drug delivery system that is designed to release the active ingredient of a drug at the desired site and time in the body.

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 Company received \$39.5 million in cash and a promissory note of \$2.25 million in consideration for the excipient business. The Company intends to use the proceeds of the sale of its excipient business to expand its drug delivery business. In the first quarter of 2003, the Company will report the results of the excipient business as a discontinued operation.

The Company has incurred net losses and has had negative cash flows since 1994. As of December 31, 2002, the Company's accumulated deficit was approximately \$78.0 million. The Company expects operating losses and negative cash flows from operations to continue until substantial sales of products commercialized utilizing TIMERx technology occur. A substantial portion of the Company's revenues to date have been generated from the Company's pharmaceutical excipient business. During 2001 and 2002, the Company derived 86% and 87%, respectively, of its revenues from the sales of its excipient products, and sales of its excipient products generated substantial 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 expects that its revenues for the balance of 2003 will be generated primarily from Mylan royalties and payments under collaboration agreements. The Company's future profitability will depend on several factors, including:

- the successful commercialization of TIMERx controlled release products, including in particular oxymorphone ER;
- the Company's ability to use the net proceeds from the sale of its excipient business to expand its drug development and delivery business;
- royalties from Mylan's sales of Pfizer, Inc.'s 30 mg generic version of Procardia XL; and
- the level of the Company's investment in research and development activities.

The Company's strategy includes a significant commitment to spending on research and development targeted at identifying and developing extended release products that can be formulated using the Company's TIMERx and other drug delivery technologies. The Company also expects to expend significant resources on the development of new drug delivery technologies, both internally and through in-licenses or acquisition. The Company's spending in the area of new technology, however, is discretionary and is subject to the Company identifying appropriate opportunities, as well as the availability of funds from the Company's operations, cash resources, collaborative research and development arrangements and external financing. There can be no assurance when or if the Company will achieve profitability or if it will be able to sustain profitability on a quarterly basis, if at all.

The Company's collaborative agreements include licensing arrangements in which the Company is entitled to receive milestone payments, royalties on the sale of the products covered by such collaborative agreements and payments for the purchase of formulated TIMERx material, as well as licensing arrangements which include revenue and cost sharing components in which the Company shares in the costs and profitability at predetermined percentages, but does not generally receive milestone payments. There can be no assurance that the Company's controlled release product development efforts will be successfully completed, that required regulatory approvals will be obtained or that approved products will be successfully manufactured or marketed.

The Company's excipient products were sold internationally and its results of operations were affected by fluctuations in currency exchange rates, as well as by governmental controls and other risks associated with international sales (such as export licenses, collectibility of accounts receivable, trade restrictions, and changes in tariffs). The Company's international subsidiaries transacted a substantial portion of their sales and purchases in European currencies other than their functional currency, which can result in the Company having gains or losses from currency exchange rate fluctuations. The Company does not use derivatives to hedge the impact of fluctuations in foreign currencies. As part of the sale of the excipient business, the Company sold the stock of its foreign subsidiaries. Accordingly, the Company expects that in the future its results of operations will be less likely to be affected by currency fluctuations.

The Company's results of operations may fluctuate from quarter to quarter depending on the volume and timing of orders of formulated bulk TIMERx, royalties on Mylan's sales of Pfizer's 30 mg generic version of Procardia XL and variations in payments under the Company's collaborative agreements, including payments upon the achievement of specified milestones.

Critical Accounting Policies and Estimates

The Company's discussion and analysis of its financial condition and results of operations are based upon the Company's consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The Company's significant accounting policies are more fully described in the notes to the consolidated financial statements. These policies are important to the portrayal of the Company's financial condition and results of operations. The preparation of these financial statements requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities as of the date of the financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2002, and the reported amounts of revenues and expenses during the reporting periods. Areas where significant judgments are made include, but are not limited to, revenue recognition, allowance for doubtful accounts, inventory, deferred taxes-valuation allowance and impairment of intangible assets. Actual results could differ materially from these estimates.

The following accounting policies meet these characteristics and are considered most significant:

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. 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. 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.

Allowance for Doubtful Accounts

Allowances for doubtful accounts receivable are maintained based on historical payment patterns, aging of accounts receivable and actual write-off history. The Company expects that the allowance for doubtful accounts will not be considered a critical estimate in the near future, because most of the Company's accounts receivable and the related allowance were related to the Company's excipient business.

Inventory

The Company writes down its inventory to net realizable value. Product obsolescence may be caused by shelf-life expiration, replacement products in the marketplace or other competitive situations.

Deferred Taxes—Valuation Allowance

The Company records a valuation allowance to reduce its deferred tax assets to the amount that is more likely than not to be realized. While the Company 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 the Company were to determine that it would be able to realize its deferred tax assets in the future in excess of its net recorded amount, an adjustment to the deferred tax asset would increase income in the period such determination was made. At December 31, 2002, the Company had recorded full valuation allowances totaling approximately \$23.3 million against its net deferred tax assets.

Impairment of Long-Lived Assets

In assessing the recoverability of the Company's intangible assets, the Company must make assumptions regarding estimated future cash flows and other factors to determine the fair value of the respective assets. If these estimates or their related assumptions change in the future, the Company may be required to record impairment charges for these assets.

Results of Operations

Years Ended December 31, 2002 and 2001

Total revenues increased 4.9% for the year ended December 31, 2002 to \$42.0 million from \$40.0 million the year ended December 31, 2001. Product sales increased by 5.2% to \$36.6 million for the year ended December 31, 2002 compared to \$34.8 million for the year ended December 31, 2001. The increase in product sales was due to increased sales of excipient products, primarily in Europe, which the Company believes was partially due to the Company beginning to sell its products direct in certain countries, but was partially offset by lower revenues on sales of formulated bulk TIMERx primarily due to the timing of customer orders. During the third quarter of 2002, the Company was notified by a major customer of excipient products that a contract for purchasing microcrystalline cellulose will not be renewed beginning January 1, 2003. Sales approximated \$2 million to this customer of the excipient business for the year ended December 31, 2002. Royalties and licensing revenues increased slightly in 2002 to \$5.4 million from \$5.2 million in 2001.

Gross profit increased to \$16.6 million, or 39.4% of total revenues, for the year ended December 31, 2002 from \$15.2 million, or 38.0% of total revenues, for the year ended December 31, 2001. The increase in the gross profit percentage was primarily due to changes in the product mix of excipient products sold in 2002, primarily reflecting increased ProSolv and Pruv sales in 2002, as compared to 2001.

Selling, general and administrative expenses increased by 14.2% for the year ended December 31, 2002, to \$15.8 million as compared with \$13.9 million the year ended December 31, 2001. The increase was primarily due to marketing costs paid to Endo for the joint development of oxymorphone ER, increased compensation expense primarily due to hiring additional drug delivery personnel and increased business insurance costs.

Research and product development expenses increased by 3.3% for the year ended December 31, 2002 to \$17.6 million from \$17.0 million for the year ended December 31, 2001. This increase was primarily due to the Company's share of the increased costs of clinical trials for oxymorphone ER being developed with Endo and the Company's increased investment in the development of new products utilizing TIMERx technology and in research involving new drug delivery technologies.

The Company's most advanced product candidate is oxymorphone ER, which the Company is developing with Endo. Endo, which is responsible for conducting the clinical trials and seeking regulatory approval of the product, completed the clinical trials of the product in July 2002 and the FDA accepted for filing an NDA for oxymorphone ER in February 2003. The Company has incurred costs relating to the research and development of oxymorphone ER of approximately \$8.9 million and \$8.7 million for 2002 and 2001, respectively. These project costs reflect amounts paid to Endo and do not include any pre-launch marketing costs or significant allocated internal costs. On March 17, 2003, the Company gave Endo notice that it is discontinuing its participation in the funding of the development of oxymorphone ER. Accordingly, the Company anticipates the Company's research and development expenses with respect to oxymorphone ER will decrease significantly in 2003. The Company anticipates using the funds that otherwise would have been expended on oxymorphone ER to increase its investment in the development of additional products utilizing TIMERx technology and in research and development involving new drug delivery technologies.

As of December 31, 2002, the Company had several other product candidates utilizing TIMERx technology in various stages of clinical trials. The Company's costs of research and new technology development were approximately \$2.2 million and \$1.4 million for 2002 and 2001, respectively. In addition, the Company incurred research and development costs of approximately \$611,000 and \$813,000 for 2002 and 2001, respectively, relating to its excipient business.

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. Because these projects are in early stage of development and given the technological and regulatory hurdles likely to be encountered in the development and commercialization of these products, the future timing and costs of these various research and development programs are uncertain. There can be no assurance that any of the Company's products will be successfully developed, will receive regulatory approval, or will be successfully commercialized.

The effective tax rates for 2002 and 2001 were expenses of 2% and 3%, respectively. 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 the Company's net operating losses, and state and foreign income taxes.

Years Ended December 31, 2001 and 2000

Total revenues decreased 4.9% for the year ended December 31, 2001 to \$40.0 million from \$42.1 million for the year ended December 31, 2000. Product sales decreased to \$34.8 million for 2001 compared to \$37.1 million for 2000, representing a decrease of 6.4%. The decrease in product sales was due to lower revenues on sales of formulated bulk TIMERx during 2001, reflecting the formulated bulk TIMERx shipments to Mylan in 2000, totaling \$3.2 million, under the Company's arrangement with Mylan relating to Nifedipine XL, which did not recur in 2001. The lower revenues on sales of formulated bulk TIMERx was partially offset by a \$717,000 or 2.2% increase in excipient sales in 2001, primarily in Europe. Royalties and licensing revenues increased 6.4% from \$4.9 million in 2000 to \$5.2 million in 2001, primarily as a result of increased royalties earned on Mylan's sales of the 30 mg strength of generic Procardia XL, as Mylan captured greater market share in 2001. This royalty, however, did trend down in the second quarter of 2001 compared to the previous two quarters, due to the entrant of a competitor, and remained fairly flat through the remainder of 2001.

Gross profit decreased to \$15.2 million, or 38.0% of total revenues for 2001, from \$16.8 million, or 39.8% of total revenues for 2000. Gross profit percentage on product sales decreased to 28.7% for 2001, from 31.9% for 2000. These decreases reflect competitive pressure on prices of the Company's excipients during 2001, primarily in North America. Also contributing to the lower gross profit in 2001 as compared with 2000, were the bulk TIMERx shipments to Mylan in 2000, which did not recur in 2001.

Selling, general and administrative expenses increased by 14.9% for 2001, to \$13.9 million, from \$12.1 million for 2000. The increase is primarily due to increased expenses for market research, business insurance, professional fees, including those associated with the Company's evaluation and pursuit of financing alternatives, and increased information technology and hiring costs associated with the Company strengthening its information technology infrastructure to prepare for anticipated increasing drug development activities.

Research and product development expenses increased by 32.6% for 2001 to \$17.0 million from \$12.8 million for 2000. This increase was partly due to the Company's share of increased expenses associated with clinical trials being conducted for the development of oxymorphone ER under the Company's collaboration with Endo. In addition, the Company increased its investment on developing new products utilizing TIMERx technology for its drug development pipeline and on the research of new drug delivery technologies.

The effective tax rates for 2001 and 2000 were expenses of 3% and 4%, respectively. The effective tax rates are higher than the federal statutory rate of a 34% benefit, due primarily to valuation allowances recorded to offset deferred tax assets relating to the Company's net operating losses, and state and foreign income taxes.

Liquidity and Capital Resources

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

On February 27, 2003, the Company consummated the sale of its excipient business to Rettenmaier. As a result of the sale, the Company had approximately \$35 million of net cash proceeds available after the closing, which the Company plans to use to fund development of products in its pipeline as well as the rest of the Company's operations. However, as a result of the sale, the Company will no longer derive cash flow from the sale of excipients.

Prior to the sale of the excipient business, the Company had a revolving line of credit with a financial institution. As of December 31, 2002, there were approximately \$2.8 million of outstanding borrowings under the revolving line of credit. A portion of the net proceeds from the sale of the excipient business was used to pay all outstanding borrowings under the line of credit, which was terminated on February 27, 2003.

As of December 31, 2002, the Company had cash, cash equivalents, and short-term investments of \$6.5 million, which amount does not include the approximately \$35 million in net cash proceeds from the sale of the Company's excipient business available after closing. The Company has no committed sources of capital other than Rettenmaier's commitment to repay the Company pursuant to promissory notes, \$1.0 million in April 2003 and \$1.25 million in May 2004 in connection with the sale of the excipient business.

As part of the Company's agreement to acquire assets including trademarks and other intellectual property related to the excipient product, Pruv, for \$3.0 million, on October 25, 2002, the Company issued a note to the seller, AstraZeneca AB, in the principal amount of \$2.25 million. The indebtedness under the note did not bear interest. Under the agreement, the indebtedness outstanding under the note was repaid upon the closing of the sale of the excipient business.

The Company is a party to an agreement with Endo with respect to the development of oxymorphone ER. The Company paid Endo approximately \$9.4 million and \$8.7 million in 2002 and 2001, respectively, for costs primarily relating to the research and development and pre-launch marketing of oxymorphone ER. On March 17, 2003, the Company gave Endo notice that the Company is discontinuing its participation in the funding of the development and marketing of oxymorphone ER. Accordingly, the Company anticipates its research and development expenses with respect to oxymorphone ER will decrease significantly in 2003. The Company anticipates using the funds that otherwise would have been expended on oxymorphone ER to increase its investment in the development of additional products utilizing TIMERx technology and in research and development involving new drug delivery technologies.

The Company had negative cash flow from operations for the year ended December 31, 2002 of \$13.3 million, primarily due to the net loss in the period. The Company had negative cash flow from operations for the year ended December 31, 2001 of \$11.1 million, primarily due to the net loss in the period, partially offset by net reductions of accounts receivable. Funds expended in 2002 for the acquisition of fixed assets were primarily related to additions at the Company's manufacturing facilities in Iowa and Finland, laboratory equipment for drug development activities, the planned implementation of a new information system in anticipation of the sale of the excipient business, and information technology associated with the Company strengthening its technology infrastructure to prepare for increasing drug development activities. Funds expended in 2001 for the acquisition of fixed assets were primarily related to additions at the Company's manufacturing facilities in Iowa and Finland, and information technology as described above. Funds expended for intangible assets included costs to acquire trademarks and other intellectual property related to Pruv, from AstraZeneca AB for \$3.0 million, as well as to secure patents on technology developed by the Company.

The Company expects that its cash flow in 2003 will differ from its cash flow during 2002 and 2001 because the Company will no longer derive revenues from sales of its excipient products nor will it incur expenses in connection with its excipient business, except for the revenues and expenses during the period ended February 26, 2003.

The Company anticipates that its existing capital resources, including the proceeds from the sale of its excipient business, and anticipated internally generated funds from the sale of formulated bulk TIMERx, royalties from Mylan and other payments from collaborators, will enable the Company to fund its currently planned operations, including its planned increase in drug development and commercialization efforts, through late 2004.

The Company's requirements for capital in its business are substantial and will depend on many factors, including:

- the ongoing costs under the Company's collaboration agreements;
- the structure of any future collaborative or development agreements;
- the progress of the Company's collaborative and independent development projects and funding obligations with respect to the projects;
- the costs to the Company of clinical studies for its products;
- the costs and timing of adding drug development capabilities;
- royalties received from Mylan;
- royalties from sales of TIMERx products;
- the timing and amount of payments received under existing and possible future collaborative agreements; and
- the prosecution, defense and enforcement of potential patent claims and other intellectual property rights.

If the Company needs to raise additional funds to fund its operations, the Company may seek to obtain additional funds through debt or equity financings. The additional financing may not be available to the Company on acceptable terms, if at all. If adequate funds are not available, Penwest may be required to:

- significantly curtail its product commercialization efforts, including terminating existing collaborative agreements;
- obtain funds through one or more arrangements with collaborators or others on adverse terms to Penwest that may require Penwest to relinquish rights to certain of its technologies, product candidates, or products which Penwest would otherwise pursue on its own or that would significantly dilute the Company's stockholders;
- significantly scale back or terminate operations; and/or
- seek relief under the applicable bankruptcy laws.

Contractual Obligations

The Company's major outstanding contractual cash obligations relate to its operating leases, primarily for equipment. Below is a table summarizing the Company's contractual obligations and commercial commitments, including non-cancelable operating leases having initial lease terms of more than one year, as of December 31, 2002 (in thousands):

| | <u>Total</u> | <u>Less than One Year</u> | <u>1-3 Years</u> | <u>4-5 Years</u> | <u>After 5 Years</u> |
|---|--------------|-------------------------------|----------------------|----------------------|--------------------------|
| Loans and Notes Payable | \$5,693 | \$5,693 | \$ — | \$ — | \$— |
| Operating Leases | <u>2,083</u> | <u>792</u> | <u>882</u> | <u>381</u> | <u>28</u> |
| Total Contractual Obligations | \$7,776 | \$6,485 | \$882 | \$381 | \$28 |

Net Operating Loss Carryforwards

At December 31, 2002, the Company had federal net operating loss ("NOL") carryforwards of approximately \$60.6 million for income tax purposes, of which approximately \$6.2 million, \$8.4 million, \$9.1 million, \$17.8 million and \$19.1 million expire in 2018, 2019, 2020, 2021 and 2022, respectively. In

addition, the Company had research and development tax credit carryforwards of approximately \$1.4 million of which \$299,000, \$306,000 and \$777,000 expire in 2019, 2020, and 2021, respectively. The use of the NOLs and research and development tax credit carryforwards are limited to future taxable earnings of the Company. Due to the degree of uncertainty related to the ultimate realization of such carryforwards, at December 31, 2002, a valuation allowance of approximately \$23.3 million has been recognized to offset net deferred tax assets, primarily attributable to the NOL carryforward. Utilization of the operating losses may be subject to a limitation due to the ownership change provisions of the Internal Revenue Code. The Company expects to use approximately \$10.0 million of NOL carryforwards to offset the Company's taxable capital gains and ordinary income from the sale of the excipient business.

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. The operations of the Company are exposed to financial market risks, including changes in interest rates and foreign currency exchange rates. The Company's interest rate risk primarily relates to its investments in marketable securities. The Company's foreign currency exchange risk related primarily to its international subsidiaries. As a result of the sale of the excipient business, which included the Company's international subsidiaries, the Company will have little, if any, foreign currency risk. The Company does not use derivatives to hedge the impact of fluctuations in foreign currencies or interest rates.

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.

At December 31, 2002, marketable securities consisted of corporate debt and approximated \$2.1 million. These securities have contractual maturity dates of up to eleven months. Due to the relatively short-term maturities of these securities, management believes there is no significant market risk. 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. Proceeds from the sale of the excipient business available for investment will be invested in accordance with the Company's investment policy.

At December 31, 2001, marketable securities consisted of corporate debt and U.S. Government-agency backed discounted notes and approximated \$9.6 million. These securities had contractual maturity dates of up to two years. At December 31, 2001, market values approximated carrying values. At December 31, 2001, the Company had approximately \$22.5 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 \$225,000.

The Company's international operations relating to its excipient business transacted a substantial portion of their sales and purchases in European currencies other than their functional currency, which could have resulted in the Company having gains or losses from currency exchange rate fluctuations. Where practical, the Company seeks to manage expected local currency revenues in relation to local

currency costs, and manage local currency assets in relation to local currency liabilities. The Company does not believe that the potential exposure is significant in light of the size of the Company and its business. The effect of an immediate 10% change in exchange rates would not have a material effect on the Company's results of operations, financial position or cash flows.

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 one product or service. EITF 00-21 is effective prospectively for arrangements entered into in fiscal periods beginning after June 15, 2003. The Company is currently evaluating the impact of the adoption of this consensus on the Company's financial statements.

In April 2002, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 145, "Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections". SFAS No. 145 updates, clarifies and simplifies existing accounting pronouncements and is generally effective for transactions occurring after May 15, 2002. The adoption of this statement did not have a material impact on the Company's financial position or results of operations.

In June 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities". The standard 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 standard will apply to the Company effective for exit or disposal activities initiated after December 31, 2002. The Company does not believe there will be a material effect from the adoption of this new standard.

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation—Transition and Disclosure," which amends SFAS No. 123, "Accounting for Stock-Based Compensation." 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. 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 the statement had no impact on the Company's financial position or results of operations.

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. 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

There are a number of important factors that could cause our actual results to differ materially from those indicated or implied by forward-looking statements. We believe that the material factors that we discuss below could cause or contribute to such material differences.

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

We have incurred net losses since 1994, including net losses of \$17.1 million, \$16.0 million and \$8.8 million, during 2002, 2001, and 2000, respectively. As of December 31, 2002, our accumulated deficit was approximately \$78.0 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 2000, 2001 and 2002 were reduced as a result of the operating results of our excipient business. Effective February 27, 2003, we no longer generate any revenues from the sales of excipient products and our business depends exclusively on our drug delivery 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;
- our ability to use the net proceeds from the sale of our excipient business to expand our drug development and delivery business;
- 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 extended release products which 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 full-scale bioequivalence studies and 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 full-scale bioequivalence studies and 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. We are also dependent on Sanofi and Leiras to manufacture and market Slofedipine XL

and Cystrin CR, respectively. 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 development and commercialization of products or undertake product development and commercialization activities at our own expense. Moreover, we have limited experience in conducting full-scale bioequivalence studies and 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 our perception 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 do and than certain of our collaborators do.

Our TIMERx business faces competition from numerous public and private companies and their controlled release technologies, including Johnson & Johnson's oral osmotic pump (OROS®) technology, multiparticulate systems marketed by Elan and Biovail, 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 being developed by Penwest. For instance, we expect extended release oxymorphone ER will face competition from Purdue Pharma's OxyContin®.

In addition to developing controlled release versions of immediate release products, we concentrated a significant portion of our initial development efforts on generic versions of branded

controlled release products. The success of generic versions of branded controlled release products based on our TIMERx technology 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.

We require additional funding, which may be difficult to obtain

As of December 31, 2002, the Company had cash, cash equivalents, and short-term investments of \$6.5 million. In February 2003, the Company received net proceeds from the sale of its excipient business available after closing of approximately \$35 million. The Company has no committed sources of capital other than Rettenmaier's commitment to pay the Company \$1.0 million in April 2003 and \$1.25 million in May 2004 in connection with the sale of the excipient business.

We anticipate that our existing capital resources, including the proceeds from the sale of the excipient business, and anticipated internally generated funds from the sale of formulated bulk TIMERx, royalties from Mylan and other payments from collaborators, will enable us to fund our currently planned operations, including the planned increase in our drug development and commercialization efforts, through late 2004.

We have had negative cash flows and net losses since 1994. See "—We have not been profitable and expect 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:

- the structure of any future collaborative or development agreements;
- the progress of our collaborative and independent development projects and funding obligations with respect to the projects;
- the costs to us of clinical studies for our products;
- the costs and timing of adding drug development capabilities;
- royalties received from Mylan;
- royalties from sales of TIMERx products;
- the timing and amount of payments received under existing and possible future collaborative agreements; and
- the prosecution, defense and enforcement of potential patent claims and other intellectual property rights.

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 stockholders will result. In addition, the terms of the financing may adversely affect the holdings or the rights of such stockholders.

If we are unable to obtain funding on a timely basis, we may be required to (1) significantly curtail our product commercialization efforts, including terminating or reducing our participation in existing collaborative agreements; (2) obtain funds through arrangements with collaborators or others on adverse terms to us that may require us to relinquish rights to certain of our technologies, product candidates, or products which we would otherwise pursue on our own or that would significantly dilute our shareholders; (3) significantly scale back or terminate operations; and/or (4) seek relief under applicable bankruptcy laws.

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

In order to obtain regulatory approvals for the commercial sale of our potential products, including controlled release versions of immediate release drugs and new chemical entities, 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 United States Food and Drug Administration, or 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.

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

- Cystrin CR was approved in Finland in 1997;
- Slofedipine XL was approved in the United Kingdom in 1998 and in Italy in 2001;
- The 30 mg strength of Nifedipine XL was approved by the FDA in December 1999; and
- Cronodipin was approved in Brazil in 2001.

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.

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.

Some of the controlled release products that we are developing with our collaborators are generic versions of branded controlled release products, which require the filing of ANDAs. Certain ANDA procedures for generic versions of controlled release products are the subject of petitions filed by brand name drug manufacturers, which seek changes from the FDA in the approval process for generic drugs. These requested changes include, among other things, tighter standards for certain bioequivalence studies and disallowance of the use by a generic drug manufacturer in its ANDA of proprietary data submitted by the original manufacturer as part of an original new drug application. Any changes in FDA regulations that make ANDA approvals more difficult may have a material adverse effect on our business, financial condition and results of operations.

Other 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 the Company or its 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.

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 that our collaborators will file ANDAs for our controlled release products that are generic versions of branded controlled release products that are covered by one or more patents. 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 we 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 do issue, 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 and 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 complete 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 current GMP 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.

There are a limited number of manufacturers that operate under GMP regulations capable of manufacturing our TIMERx material. Although the Company has qualified alternate suppliers with respect to these gums, if our current manufacturer 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.

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 sole source 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 in certain markets

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 certain

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 by us and our collaborators 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 amount 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.

Certain provisions of our Shareholder Rights Plan, Certificate of Incorporation and Bylaws and of Washington law make a takeover 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 stockholders might otherwise receive a premium for their shares over then current market prices. In addition, these provisions may limit the ability of stockholders 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, are listed under Item 15(a) included herein.

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

None.

PART III

ITEM 10: DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information set forth under "Election of Directors" and "Section 16(a) Beneficial Ownership Reporting Compliance" in the Company's definitive Proxy Statement for the 2003 Annual Meeting of Shareholders is incorporated herein by reference.

Information regarding executive officers of the Company is set forth in Part I, Item 4a above.

ITEM 11: EXECUTIVE COMPENSATION

The information set forth under "Executive Compensation," "Director Compensation," and "Compensation Committee Interlocks and Insider Participation", in the Company's definitive Proxy Statement for the 2003 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 the Company's definitive Proxy Statement for the 2003 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 of the Company set forth under "Certain Relationships and Related Transactions" in the Company's definitive Proxy Statement for the 2003 Annual Meeting of Shareholders is incorporated herein by reference.

ITEM 14: CONTROLS AND PROCEDURES

Within the 90-day period prior to the filing of this Annual Report on Form 10-K, an evaluation was carried out under the supervision and with the participation of our management, including Penwest's Chief Executive Officer, or CEO and Chief Financial Officer, or CFO, of the effectiveness of the design and operation of our disclosure controls and procedures. Based on that evaluation, Penwest's CEO and CFO have concluded that our disclosure controls and procedures are designed to ensure that information required to be disclosed by the Company in reports that the Company files or submits under the Securities Exchange Act of 1934 is recorded, processed, summarized, and reported within the time periods specified in SEC rules and form and are operating in an effective manner.

There were no significant changes in the Company's internal controls or in other factors that could significantly affect these controls subsequent to the date of their most recent evaluation.

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, 2002 and 2001 and the related statements of operations, cash flows and shareholders' equity for each of the three years in the period ended December 31, 2002.

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.

(a)(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 this 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 November 5, 2002, the Company filed a report on Form 8-K announcing that it had entered into a Purchase Agreement with Josef Rettenmaier Holding GmbH & Co. KG, dated November 1, 2002 and that pursuant to the Purchase Agreement, Penwest would sell its excipient business to Rettenmaier for \$39.5 million in cash and a promissory note of \$2.25 million.

On December 3, 2002, the Company filed a report on Form 8-K announcing its results for the third quarter ended September 30, 2002.

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 31, 2003

By: /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.

| <u>Name</u> | <u>Title</u> | <u>Date</u> |
|--|---|----------------|
| /s/ TOD R. HAMACHEK Tod R. Hamachek | Chairman of the Board, Chief Executive Officer and Director (Principal Executive Officer) | March 31, 2003 |
| /s/ JENNIFER L. GOOD Jennifer L. Good | Sr. Vice President, Finance and Chief Financial Officer (Principal Financial and Accounting Officer) | March 31, 2003 |
| /s/ PAUL E. FREIMAN Paul E. Freiman | Director | March 31, 2003 |
| /s/ JERE E. GOYAN Jere E. Goyan | Director | March 31, 2003 |
| /s/ ROLF H. HENEL Rolf H. Henel | Director | March 31, 2003 |
| /s/ ROBERT J. HENNESSEY Robert J. Hennessey | Director | March 31, 2003 |
| /s/ JOHN N. STANIFORTH John N. Staniforth | Director | March 31, 2003 |
| /s/ ANNE M. VANLENT Anne M. VanLent | Director | March 31, 2003 |

Certifications

I, Tod R. Hamachek, certify that:

1. I have reviewed this annual report on Form 10-K of Penwest Pharmaceuticals Co.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
 - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
 - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
 - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Dated: March 31, 2003

/s/ TOD R. HAMACHEK

Tod R. Hamachek
Chief Executive Officer

I, Jennifer L. Good, certify that:

1. I have reviewed this annual report on Form 10-K of Penwest Pharmaceuticals Co.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
 - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
 - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
 - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Dated: March 31, 2003

/s/ JENNIFER L. GOOD

Jennifer L. Good
Chief Financial Officer

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

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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, 2002 and 2001, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2002. 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, 2002 and 2001, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2002, 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.

As discussed in Note 3 to the consolidated financial statements, Penwest Pharmaceuticals Co. changed its method of accounting for revenue recognition in 2000.

/s/ ERNST & YOUNG LLP

Stamford, Connecticut
March 17, 2003

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

| | DECEMBER 31, | |
|--|--------------|-----------|
| | 2002 | 2001 |
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 4,420 | \$ 12,903 |
| Marketable securities | 2,057 | 9,609 |
| Trade accounts receivable, net of allowance for doubtful accounts of \$175 and \$220 | 6,486 | 6,228 |
| Inventories | 8,932 | 7,857 |
| Prepaid expenses and other current assets | 2,121 | 1,166 |
| Deferred transaction costs | 1,741 | — |
| Total current assets | 25,757 | 37,763 |
| Fixed assets, net | 14,413 | 15,567 |
| Intangible assets, net | 7,190 | 3,545 |
| Other assets | 2,860 | 2,738 |
| Total assets | \$ 50,220 | \$ 59,613 |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 3,133 | \$ 2,174 |
| Accrued expenses | 3,579 | 2,275 |
| Accrued development costs | 2,785 | 3,139 |
| Taxes payable | 238 | 448 |
| Loans and notes payable | 5,693 | 2,668 |
| Total current liabilities | 15,428 | 10,704 |
| Deferred income taxes | 196 | 205 |
| Deferred revenue | 284 | 369 |
| Deferred compensation | 2,889 | 2,711 |
| Total liabilities | 18,797 | 13,989 |
| Shareholders' equity: | | |
| Preferred stock, par value \$.001, authorized 1,000,000 shares, none outstanding | — | — |
| Common stock, par value \$.001, authorized 39,000,000 shares, issued and outstanding 15,506,259 shares at December 31, 2002 and 15,276,630 shares at December 31, 2001 | 16 | 15 |
| Additional paid in capital | 110,000 | 108,054 |
| Accumulated deficit | (78,025) | (60,926) |
| Accumulated other comprehensive loss | (568) | (1,519) |
| Total shareholders' equity | 31,423 | 45,624 |
| Total liabilities and shareholders' equity | \$ 50,220 | \$ 59,613 |

See accompanying notes.

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

| | YEAR ENDED DECEMBER 31, | | |
|---|-------------------------|-------------------|-------------------|
| | 2002 | 2001 | 2000 |
| Revenues | | | |
| Product sales | \$ 36,574 | \$ 34,778 | \$37,148 |
| Royalties and licensing fees | 5,385 | 5,225 | 4,910 |
| Total revenues | 41,959 | 40,003 | 42,058 |
| Cost of product sales | 25,407 | 24,810 | 25,303 |
| Gross profit | 16,552 | 15,193 | 16,755 |
| Operating expenses | | | |
| Selling, general and administrative | 15,820 | 13,855 | 12,054 |
| Research and product development | 17,567 | 17,003 | 12,820 |
| Total operating expenses | 33,387 | 30,858 | 24,874 |
| Loss from operations | (16,835) | (15,665) | (8,119) |
| Investment income | 379 | 477 | 217 |
| Interest expense | 243 | 290 | 172 |
| Loss before income taxes and cumulative effect of change in accounting principle | (16,699) | (15,478) | (8,074) |
| Income tax expense | 400 | 503 | 302 |
| Loss before cumulative effect of change in accounting principle | (17,099) | (15,981) | (8,376) |
| Cumulative effect of change in accounting principle (Note 3) | — | — | (410) |
| Net loss | <u>\$(17,099)</u> | <u>\$(15,981)</u> | <u>\$(8,786)</u> |
| Basic and diluted amounts per share: | | | |
| Loss before cumulative effect of change in accounting principle | \$ (1.11) | \$ (1.15) | \$ (0.68) |
| Cumulative effect of change in accounting principle (Note 3) | — | — | (0.03) |
| Net loss | <u>\$ (1.11)</u> | <u>\$ (1.15)</u> | <u>\$ (0.71)</u> |
| Weighted average shares of common stock outstanding | 15,462 | 13,905 | 12,330 |
| Pro forma amounts assuming the accounting change is applied retroactively: | | | |
| Net loss | | | <u>\$ (8,376)</u> |
| Basic and diluted net loss per share | | | <u>\$ (0.68)</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 LOSS | TOTAL |
|---|---------------------------|-------------|----------------------------------|------------------------|---|------------------|
| Balances, January 1, 2000 | 11,149 | \$11 | \$ 59,718 | \$(36,159) | \$(1,061) | \$ 22,509 |
| Net loss | | | | (8,786) | | (8,786) |
| Translation adjustments | | | | | (266) | (266) |
| Comprehensive loss | | | | | | (9,052) |
| Issuance of common stock—private placement | 1,399 | 2 | 16,823 | | | 16,825 |
| Issuance of common stock pursuant to stock compensation plans | 102 | — | 557 | | | 557 |
| Issuance of common stock pursuant to Stock Purchase Plan | 20 | — | 178 | | | 178 |
| Balances, December 31, 2000 | <u>12,670</u> | <u>13</u> | <u>77,276</u> | <u>(44,945)</u> | <u>(1,327)</u> | <u>31,017</u> |
| 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 | <u>15,277</u> | <u>15</u> | <u>108,054</u> | <u>(60,926)</u> | <u>(1,519)</u> | <u>45,624</u> |
| 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 | <u>15,506</u> | <u>\$16</u> | <u>\$110,000</u> | <u>\$(78,025)</u> | <u>\$ (568)</u> | <u>\$ 31,423</u> |

See accompanying notes.

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

| | <u>YEAR ENDED DECEMBER 31,</u> | | |
|---|--------------------------------|------------------|-----------------|
| | <u>2002</u> | <u>2001</u> | <u>2000</u> |
| Operating activities: | | | |
| Net loss | \$(17,099) | \$(15,981) | \$(8,786) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation | 2,934 | 2,831 | 2,879 |
| Amortization | 313 | 265 | 213 |
| Deferred income taxes | (9) | — | (18) |
| Deferred revenue | (84) | (10) | 378 |
| Deferred compensation | 178 | 187 | 183 |
| Stock compensation | 105 | 119 | 105 |
| Changes in operating assets and liabilities: | | | |
| Trade accounts receivable | (258) | 1,926 | (3,111) |
| Inventories | (1,076) | 340 | (547) |
| Accounts payable, accrued expenses and other | 1,656 | (729) | 1,378 |
| Net cash used in operating activities | <u>(13,340)</u> | <u>(11,052)</u> | <u>(7,326)</u> |
| Investing activities: | | | |
| Acquisitions of fixed assets, net | (1,751) | (955) | (1,412) |
| Intangible asset costs | (4,080) | (1,078) | (507) |
| Deferred transaction costs | (1,741) | — | — |
| Purchases of marketable securities | — | (11,511) | — |
| Proceeds from maturities of marketable securities | 7,255 | 2,000 | — |
| Net cash used in investing activities | <u>(317)</u> | <u>(11,544)</u> | <u>(1,919)</u> |
| Financing activities: | | | |
| Proceeds from loans and notes payable | 28,983 | 29,616 | 2,800 |
| Repayments of loans and notes payable | (25,958) | (26,947) | (9,500) |
| Issuance of common stock, net | 1,841 | 30,661 | 17,454 |
| Net cash provided by financing activities | <u>4,866</u> | <u>33,330</u> | <u>10,754</u> |
| Effect of exchange rate changes on cash and cash equivalents | 308 | (35) | (44) |
| Net (decrease) increase in cash and cash equivalents | (8,483) | 10,699 | 1,465 |
| Cash and cash equivalents at beginning of year | <u>12,903</u> | <u>2,204</u> | <u>739</u> |
| Cash and cash equivalents at end of year | <u>\$ 4,420</u> | <u>\$ 12,903</u> | <u>\$ 2,204</u> |

See accompanying notes.

PENWEST PHARMACEUTICALS CO.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. BUSINESS

Penwest Pharmaceuticals Co. ("Penwest" or the "Company") develops pharmaceutical products based on innovative oral drug delivery technologies. Based on its fundamental expertise in tableting ingredients, the Company has developed its proprietary TIMERx® controlled release drug delivery technology, which is applicable to a broad range of orally administered drugs.

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 (the "Asset Sale") to subsidiaries and affiliates of Josef Rettenmaier Holding GmbH & Co. KG. The Company received \$39.5 million in cash and a promissory note of \$2.25 million in consideration for the excipient business. The Company intends to use the proceeds of the sale of its excipient business to expand its drug delivery business. In the first quarter of 2003, the Company will report the results of the excipient business as a discontinued operation. During the years ended December 31, 2002, 2001 and 2000, revenues from the sale of excipient products were 87%, 86% and 79%, respectively, of total revenues (see Note 18).

Prior to the sale of its excipient business, the Company had revenues in 2002, 2001, and 2000, of \$42.0, \$40.0, and \$42.1, million, respectively. The Company had manufacturing facilities in Iowa and Finland and had customers primarily throughout North America and Europe.

The Company has incurred recurring operating losses and has had negative cash flows from operations for each of the three years in the period ended December 31, 2002 and, based on anticipated levels of operations; management expects operating losses and negative cash flows during 2003 and the first half of 2004. Management anticipates that its existing capital resources, including the proceeds from the sale of its excipient business, and anticipated internally generated funds from the sale of formulated bulk TIMERx, royalties from Mylan and other payments from collaborators, will enable the Company to fund its currently planned operations, including its planned increase in drug development and commercialization efforts, through late 2004. The Company may require additional capital to fund its future operations and working capital needs depending on its discretionary level of research and development spending to develop new products for its drug development pipeline and for research of new drug delivery technologies. Although the Company believes that it would be successful in raising additional capital, there is no guarantee that it will be able to raise such funds on terms that will be satisfactory to the Company.

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, a requirement for additional funding, 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.

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. The

PENWEST PHARMACEUTICALS CO.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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, and discounted notes backed by U.S. government agencies. Unrealized holding gains or losses are included in shareholders' equity as a separate component of accumulated other comprehensive 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 11%, 12% and 19% of total revenues in 2002, 2001 and 2000, 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 (see Note 10) and accounts payable, approximates fair value due to the short term nature of these instruments.

Long-Lived Assets

Fixed assets are recorded at cost and depreciated by the straight-line method over their estimated useful lives. Estimated useful lives by class of assets are substantially as follows:

| | |
|--|-------------|
| Buildings | 20-25 years |
| Machinery and equipment | 10-12 years |
| Office furniture, equipment and software | 5-10 years |

PENWEST PHARMACEUTICALS CO.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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 on January 1, 2002 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

Assets and liabilities of the Company's foreign operations are translated into U.S. dollars at year-end exchange rates and revenue and expenses are translated at average exchange rates. For each of the foreign operations, the functional currency is the local currency. Accumulated other comprehensive 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, 2002.

Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive loss. Other comprehensive loss includes certain changes in shareholders' equity that are excluded from net loss and include changes in unrealized gains on marketable securities and foreign currency translation adjustments. Comprehensive loss for the years ended December 31, 2002, 2001, and 2000 has been reflected in the Consolidated Statements of Shareholders' Equity.

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 2002, 2001, and

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

2000, 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. Revenue 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. 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.

Shipping and Handling

Shipping and handling costs incurred by the Company in connection with products sold are included in "cost of product sales" on the Consolidated Statements of Operations.

Advertising Costs

Advertising costs are accounted for as expenses in the period in which they are incurred.

Research and Development

Research and development expenses consist of costs related to products being developed internally as well as costs related to products subject to licensing agreements. Research and development costs are charged to expense as incurred. Certain reimbursements of costs, generally related to drug formulation on feasibility studies, are netted against research and development expense.

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 2002, 2001, and 2000, as the effects would be antidilutive.

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Stock Options

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 2002 consolidated results of operations, financial position or cash flows.

At December 31, 2002, the Company maintained two stock-based employee compensation plans (see Note 11). 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”. No stock-based employee compensation expense is reflected in net loss as all 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.

Consistent with the method described in SFAS No. 123, if compensation expense for the Company’s plans had been determined based on the fair value at the grant dates for awards under its plans, net loss and loss per share would have been increased to the pro forma amounts indicated below:

| | YEAR ENDED DECEMBER 31, | | |
|---|--|------------|-----------|
| | 2002 | 2001 | 2000 |
| | (IN THOUSANDS, EXCEPT PER SHARE DATA) | | |
| Net loss—as reported | \$(17,099) | \$(15,981) | \$(8,786) |
| Net loss—pro forma | \$(19,903) | \$(17,602) | \$(9,579) |
| Net loss per share, basic and diluted—as reported | \$ (1.11) | \$ (1.15) | \$ (0.71) |
| Net loss per share, basic and diluted—pro forma | \$ (1.29) | \$ (1.27) | \$ (0.78) |

3. CHANGE IN ACCOUNTING PRINCIPLE

Prior to the fourth quarter of 2000, the Company recognized revenue for upfront non-refundable fees when received and when all contractual obligations of the Company relating to the fees had been fulfilled. In addition, the Company previously recognized revenue relating to development milestones and other contractual fees as achieved, in accordance with the terms of the collaboration agreements. Effective January 1, 2000, the Company changed its method of accounting for upfront non-refundable fees and milestone fees. Revenue 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 state 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

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

3. CHANGE IN ACCOUNTING PRINCIPLE (Continued)

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. 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. The Company believes the change in accounting principle is preferable based on guidance provided in SEC Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" ("SAB No. 101").

In the fourth quarter of 2000, the Company adopted SAB No. 101 effective January 1, 2000. The cumulative effect of the change in accounting principle was reported as a change in the year ended December 31, 2000. The cumulative effect was initially recorded as deferred revenue that will be recognized as revenue over the remaining related collaborative or licensing and supply agreements, as appropriate. For the year ended December 31, 2000, the cumulative effect of the change on prior years was to increase the net loss by \$410,000 or \$0.03 per share. The effect of the change on loss before cumulative effect of the change for the year ended December 31, 2000 was to decrease the net loss by \$32,000. The pro forma amounts presented on the statement of operations were calculated assuming the accounting change was made retroactively to prior years. During the years ended December 31, 2002, 2001 and 2000, the Company recognized \$41,000, \$59,000 and \$204,000, respectively, of revenue/income that is included in its cumulative effect adjustment as of January 1, 2000.

4. 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 one product or service. EITF 00-21 is effective prospectively for arrangements entered into in fiscal periods beginning after June 15, 2003. The Company is currently evaluating the impact of the adoption of this consensus on the Company's financial statements.

In April 2002, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 145, "Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections." SFAS No. 145 updates, clarifies and simplifies existing accounting pronouncements and is generally effective for transactions occurring after May 15, 2002. The adoption of this statement did not have a material impact on the Company's financial position or results of operations.

In June 2002, the FASB issued 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 will apply to the Company effective for exit or disposal activities initiated after December 31, 2002. The Company does not believe there will be a material effect from the adoption of this new statement.

PENWEST PHARMACEUTICALS CO.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

4. RECENT ACCOUNTING PRONOUNCEMENTS (Continued)

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation—Transition and Disclosure," which amends SFAS No. 123, "Accounting for Stock-Based Compensation." 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. 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 the statement had no impact on the Company's financial position or results of operations (see Note 2).

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.

5. MARKETABLE SECURITIES

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

| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Estimated Fair Value |
|--|-------------------|------------------------------|-------------------------------|----------------------------|
| | (IN THOUSANDS) | | | |
| December 31, 2002 | | | | |
| Corporate debt securities | \$2,042 | \$15 | \$— | \$2,057 |
| December 31, 2001 | | | | |
| Corporate debt securities | \$7,562 | \$52 | \$— | \$7,614 |
| U.S. government agency-backed discounted notes | 1,995 | — | — | 1,995 |
| Total debt securities | \$9,557 | \$52 | \$— | \$9,609 |

Maturities of debt securities at fair value as of December 31, 2002, are as follows (in thousands):

Contractual maturity:

| | |
|--|---------|
| Maturing in one year or less | \$2,057 |
|--|---------|

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.

6. INVENTORIES

Inventories, which consist of raw materials, pharmaceutical excipients manufactured by the Company, and pharmaceutical excipients held for distribution, including manufactured bulk TIMERx, are stated at the lower of cost (first-in, first-out) or market.

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

6. INVENTORIES (Continued)

Inventories are summarized as follows:

| | DECEMBER 31, | |
|-----------------------------|----------------|---------|
| | 2002 | 2001 |
| | (IN THOUSANDS) | |
| Raw materials | \$1,511 | \$1,558 |
| Finished products | 7,421 | 6,299 |
| Total inventories | \$8,932 | \$7,857 |

Included in inventories are approximately \$461,000 and \$191,000 of TIMERx raw materials and bulk TIMERx as of December 31, 2002 and 2001, respectively.

The Company periodically reviews and quality tests its inventory to identify obsolete, slow moving or otherwise unsaleable inventories. Inventories at December 31, 2002 and 2001 are net of allowances of \$104,000 and \$255,000, respectively.

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 materials 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 drug delivery system is a hydrophilic matrix combining primarily two natural polysaccharides, xanthan and locust bean gums, in the presence of dextrose. The Company purchases these gums from a sole source supplier. Most of the Company's other excipients are manufactured from a specialty grade of wood pulp, which the Company also purchases from a sole source supplier. Although the Company has qualified alternate suppliers with respect to 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 or manufacture its other excipients, which could have a material adverse effect on the Company's business, financial condition, cash flows and results of operations.

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

7. FIXED ASSETS

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

| | DECEMBER 31, | |
|---|----------------|----------|
| | 2002 | 2001 |
| | (IN THOUSANDS) | |
| Buildings, equipment and software | \$35,618 | \$34,264 |
| Land | 696 | 696 |
| Construction in progress | 901 | 700 |
| | 37,215 | 35,660 |
| Less: accumulated depreciation | 22,802 | 20,093 |
| | \$14,413 | \$15,567 |

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 year ended December 31, 2002, the Company capitalized \$606,000 of software development costs that are primarily related to the development of the Company's enterprise-wide software systems. No such costs were capitalized for the year ended December 31, 2001. The Company includes these costs within buildings, equipment, and software and generally depreciates the software development costs over a period of five to seven years, once the systems are placed in service.

8. INTANGIBLE ASSETS

Intangible assets, net of accumulated amortization, consist of the following:

| | DECEMBER 31, | |
|--|----------------|---------|
| | 2002 | 2001 |
| | (IN THOUSANDS) | |
| Patents, net of accumulated amortization of \$990 and \$770 | \$4,240 | \$3,545 |
| Other intangibles including acquired trademarks and other intellectual property, net of accumulated amortization of \$50 in 2002 (see Note 18) | 2,950 | — |
| | \$7,190 | \$3,545 |

Patents include costs to secure patents on technology developed by the Company. Patents are amortized on a straight-line basis over their useful lives of 17 to 20 years. Amortization expense of \$313,000, \$193,000, and \$155,000, was recorded in the years ended December 31, 2002, 2001, and 2000, respectively.

Other intangibles include the cost to acquire assets including trademarks and other intellectual property related to an excipient product, Pruv, for \$3 million, from AstraZeneca AB on October 25, 2002. These assets are amortized on a straight-line basis over their estimated useful lives of 10 years. Amortization expense of \$50,000 was recorded in the year ended December 31, 2002.

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

8. INTANGIBLE ASSETS (Continued)

Recorded intangibles are evaluated for potential impairment whenever events or circumstances indicate that the undiscounted cash flows are not sufficient to recover their carrying amounts. An impairment loss is recorded to the extent the asset's carrying value is in excess of related discounted cash flows. During the fourth quarters of 2002 and 2001, the Company recorded an impairment loss of \$121,000 and \$167,000, respectively, net of accumulated amortization, relating to its patents. Such impairment loss is reflected in research and product development expense on the consolidated statements of operations.

Goodwill was amortized on a straight-line basis over ten years and was recorded upon the acquisition of the Company by its former parent company. There is no goodwill as of December 31, 2002. Amortization expense for goodwill approximated \$72,000 for 2001 and \$58,000 for 2000.

9. OTHER ASSETS

Other assets relate to cash surrender values of officer's life insurance policies, and totaled \$2,860,000, and \$2,738,000 as of December 31, 2002 and 2001, respectively.

10. LOANS AND NOTES PAYABLE

Amounts outstanding under loans and notes payable are summarized below:

| | DECEMBER 31, | |
|--|----------------|---------|
| | 2002 | 2001 |
| | (IN THOUSANDS) | |
| Revolving line of credit | \$2,807 | \$2,668 |
| Note payable to AstraZeneca AB | 2,250 | — |
| Business insurance premium financing | 636 | — |
| | \$5,693 | \$2,668 |

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 may 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, are included in the borrowing base. Amounts outstanding under the Revolver are collateralized by the Company's U.S. and Canadian accounts receivable, and its inventory and general intangibles. The Revolver has an initial term of three years, and provides for annual renewals thereafter. On February 27, 2003, the Company paid off and terminated the Revolver in connection with the sale of its excipient business (see Note 18).

The Revolver bears 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 requires fees be paid of 0.5% per annum on unused portions of the Line of Credit and provides for early termination fees of up to 0.75%, in the event the Company terminates the Revolver prior to the end of the initial term.

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

10. LOANS AND NOTES PAYABLE (Continued)

The Revolver contains 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 includes a lockbox requirement under the control of the lender, whereby collections of certain trade receivables are used to immediately reduce the balance of the Revolver.

As of December 31, 2002, the interest rate on the Revolver was 5.25% and approximately \$2.8 million was outstanding.

A \$15 million unsecured revolving credit facility, previously obtained by the Company in July 1998, was repaid in March 2000 in connection with the Company's private placement of common stock (see Note 11).

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 (see Note 8), 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 occurred in February 2003. As a result, this note was paid in full in February 2003 (see Note 18).

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 is 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 insurance policies.

Approximately \$243,000, \$214,000, and \$147,000, of total interest was paid in 2002, 2001, and 2000, respectively. The weighted average interest rate for all short term borrowings at December 31, 2002 was 2.94%.

11. SHAREHOLDERS' EQUITY

On March 6, 2000, the Company completed a private placement of its common stock to selected institutional and other accredited investors, resulting in the sale of 1,399,232 shares for approximately \$18.2 million, less expenses. Approximately \$7.7 million was used to repay the existing outstanding balance under a credit facility as required by its terms. Such credit facility is no longer available to the Company.

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, less expenses. The Company is using the net proceeds of this offering primarily for the development of drug

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

11. SHAREHOLDERS' EQUITY (Continued)

delivery products as well as to fund the research and development of new oral drug delivery technologies.

Penwest Stock Option Plans

As of December 31, 2001 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 2,660,000 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 1998, a total of 52,500 restricted shares were granted. No such shares were granted in 2002, 2001, 2000 or 1999.

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 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.

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

11. SHAREHOLDERS' EQUITY (Continued)

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, 1999 | 1,906,743 | \$ 3.70- 9.21 | \$ 6.41 |
| 2000 | | | |
| Granted | 597,925 | \$ 7.35-14.38 | \$11.82 |
| Exercised | (105,302) | \$ 4.06- 8.67 | \$ 5.98 |
| Cancelled | <u>(136,010)</u> | \$ 5.26-12.75 | \$ 7.59 |
| Balance, December 31, 2000 | <u>2,263,356</u> | \$ 3.70-14.38 | \$ 7.77 |
| Options Exercisable | <u>1,072,947</u> | \$ 3.70-10.78 | \$ 6.30 |
| 2001 | | | |
| Granted | 382,501 | \$ 8.58-18.18 | \$12.65 |
| Exercised | (135,842) | \$ 3.70- 8.88 | \$ 6.38 |
| Cancelled | <u>(230,000)</u> | \$ 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 | <u>(8,875)</u> | \$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 |

The weighted average fair value of options granted during the years ended December 31, 2002, 2001, and 2000, was \$11.51, \$8.03, and \$11.92, respectively. The weighted average remaining contractual life of options outstanding at December 31, 2002 is 5.5 years. The weighted effect of applying SFAS No. 123 for providing pro forma disclosures for the years ended December 31, 2002, 2001, 2000, 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.

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

| | <u>2002</u> | <u>2001</u> | <u>2000</u> |
|--------------------------------|-------------|-------------|-------------|
| Expected dividend yield | None | None | None |
| Risk free interest rate | 4.9% | 5.5% | 6.1% |
| Expected volatility | 69% | 52% | 82% |
| Expected life of options | 7.5 years | 7.5 years | 7.5 years |

PENWEST PHARMACEUTICALS CO.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

11. SHAREHOLDERS' EQUITY (Continued)

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 12,282 shares, 10,696 shares, and 20,415 shares issued under the Plan during 2002, 2001, and 2000, 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.

12. COMMITMENTS

Leases

The Company's manufacturing facility in Finland is leased under a three-year operating lease which includes renewal options with annual rental expense of approximately \$216,000 plus additional charges determined on a month-to-month basis for equipment and warehouse usage. In addition, certain of the Company's property, plant and equipment is leased under operating leases ranging from one to fifteen years and includes periodic escalation clauses based on rental market conditions as well as insurance rent payments. Rental expense under operating leases was \$828,000, \$683,000, and \$583,000, for the years ended December 31, 2002, 2001, and 2000, respectively.

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

12. COMMITMENTS (Continued)

Future minimum lease payments as of December 31, 2002 for noncancellable operating leases having initial lease terms of more than one year are as follows:

| | OPERATING LEASES |
|------------------------------------|-----------------------------|
| | (IN THOUSANDS) |
| 2003 | \$ 792 |
| 2004 | 515 |
| 2005 | 367 |
| 2006 | 353 |
| 2007 | 28 |
| Thereafter | 28 |
| Total minimum lease payments | \$2,083 |

13. INCOME TAXES

The provision (benefit) for federal, state and foreign income taxes consists of the following:

| | 2002 | 2001 | 2000 |
|----------------|--------------|--------------|--------------|
| Federal: | | | |
| Deferred | \$ — | \$ — | \$ — |
| Foreign: | | | |
| Current | 386 | 473 | 290 |
| Deferred | (9) | — | (18) |
| State: | | | |
| Current | 23 | 30 | 30 |
| Deferred | — | — | — |
| | \$400 | \$503 | \$302 |

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

| | 2002 | 2001 | 2000 |
|---------------------------|-------------|-------------|-------------|
| Statutory tax rate | (34)% | (34)% | (34)% |
| Valuation allowance | 37 | 40 | 36 |
| Foreign taxes | (1) | (1) | 1 |
| Other | — | (2) | 1 |
| | 2% | 3% | 4% |

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

13. INCOME TAXES (Continued)

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

| | <u>2002</u> | <u>2001</u> |
|---|-----------------|-----------------|
| | (IN THOUSANDS) | |
| Trade accounts receivable allowance | \$ (68) | \$ (85) |
| Inventory allowance and basis differences | (274) | (331) |
| Deferred compensation and SERP liability | (1,115) | (1,047) |
| Deferred revenue | (110) | (142) |
| Tax credit carryforward | (1,396) | (467) |
| Net operating loss carryforwards | (23,393) | (16,021) |
| Other | (151) | (164) |
| Total deferred tax assets | <u>(26,507)</u> | <u>(18,257)</u> |
| Depreciation and amortization | 2,934 | 3,232 |
| Other | 477 | 337 |
| Total deferred tax liabilities | <u>3,411</u> | <u>3,569</u> |
| Net deferred tax asset before valuation allowance | (23,096) | (14,688) |
| Valuation allowance | 23,292 | 14,893 |
| Net deferred tax liability | <u>\$ 196</u> | <u>\$ 205</u> |

The Company's income tax payments, primarily comprised of foreign income taxes, approximated \$655,000, \$342,000, and \$371,000, for the years ended December 31, 2002, 2001, and 2000, respectively.

At December 31, 2002, the Company has federal net operating loss ("NOL") carryforwards of \$60,573,000 for income tax purposes, of which approximately \$6,188,000, \$8,407,000, \$9,135,000, \$17,752,000 and \$19,091,000 expire in 2018, 2019, 2020, 2021, and 2022 respectively. In addition, the Company has research and development tax credit carryforwards of approximately \$1,382,000, of which \$299,000, \$306,000 and \$777,000 expire in 2019, 2020, and 2021 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, 2002, a valuation allowance of \$23.3 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.

The Company's policy is to permanently reinvest foreign earnings. Accumulated foreign earnings, for which no deferred taxes have been provided, amounted to \$5,922,000, \$5,043,000, and \$3,794,000 as of December 31, 2002, 2001, and 2000, respectively. If such earnings were to be repatriated, the income tax effect would not be significant (see Note 18).

Included in the loss before income taxes is foreign income of \$1,247,000, \$1,651,000, and \$977,000 for the years ended December 31, 2002, 2001, and 2000, respectively.

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

14. 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. The Company's expense under the Plan was \$296,000, \$227,000, and \$237,000 for 2002, 2001 and 2000, 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 2002, 2001, or 2000.

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 2002, 2001, and 2000, the net expense for the SERP incurred by Penwest was \$106,000, \$125,000, and \$122,000, respectively. The Company does not fund this liability and no assets are held by the Plan. The following disclosures summarize information relating to the Plan.

Change in benefit obligation (in thousands):

| | <u>2002</u> | <u>2001</u> |
|---|----------------|----------------|
| Benefit obligation at beginning of period | \$1,580 | \$1,453 |
| Service cost | (22) | (19) |
| Interest cost | 113 | 108 |
| Actuarial gains | 168 | 38 |
| Benefit obligation at December 31, | <u>\$1,839</u> | <u>\$1,580</u> |

Funded status (in thousands):

| | <u>2002</u> | <u>2001</u> |
|---|------------------|------------------|
| Funded status (unfunded) | \$(1,839) | \$(1,580) |
| Unrecognized net transition obligation | 100 | 160 |
| Unrecognized prior service cost | 31 | 51 |
| Unrecognized net actuarial gain | <u>(318)</u> | <u>(550)</u> |
| Net amount recognized at December 31, (included in deferred compensation) | <u>\$(2,026)</u> | <u>\$(1,919)</u> |

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

14. RETIREMENT PLANS AND OTHER EMPLOYEE BENEFITS (Continued)

Components of net periodic benefit cost (in thousands):

| | <u>2002</u> | <u>2001</u> |
|--|---------------|---------------|
| Service cost | \$ (22) | \$ (19) |
| Interest cost | 113 | 108 |
| Amortization of unrecognized transition obligation | 60 | 60 |
| Amortization of prior service cost | 20 | 49 |
| Amortization of gains | <u>(65)</u> | <u>(73)</u> |
| Net periodic benefit cost | <u>\$ 106</u> | <u>\$ 125</u> |

The Plan's accumulated benefit obligation at December 31, 2002 and 2001 was \$1,363,000 and \$1,356,000, respectively. The Company's benefit obligation was measured using a weighted average discount rate of 6.75% and 7.25% in 2002 and 2001, respectively, and a compensation increase of 4% and 4% in 2002 and 2001, respectively. The amortization of prior service cost is determined using a straight-line amortization of the cost over the average remaining service period of the employee expected to receive benefits under the Plan.

Health Care and Life Insurance Benefits

The Company offers health care and life insurance benefits to most active employees. Costs incurred for these benefits were \$873,000, \$732,000, and \$682,000, in 2002, 2001, and 2000, respectively.

15. LICENSING AGREEMENTS

The Company enters into collaborative arrangements with pharmaceutical companies for the completion of late-stage clinical development, manufacturing and marketing of its products under development.

In September 1997, the Company entered into a strategic alliance agreement with Endo with respect to the development of an extended release formulation of oxymorphone based on the Company's TIMERx technology. Endo is a fully integrated specialty pharmaceutical company with a market leadership in pain management. Endo has a broad product line including 20 branded products that include the 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 Endo 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 manufacture and 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 gave Endo notice that it is discontinuing its

PENWEST PHARMACEUTICALS CO.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

15. LICENSING AGREEMENTS (Continued)

participation in the funding of the development and marketing of oxymorphone ER. The Company believes that its current strategic focus should be on funding products in its development pipeline. As a result of this termination, 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. Endo may recoup such development costs solely through a temporary adjustment in the royalty rate payable to Penwest which shall return to its pre-adjustment level once Endo has recovered such costs. 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). 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 ER exclusively from the Company at specified prices, such prices will be reflected in the determination of net profits.

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 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 2002 of the 30 mg dosage strength version of Pfizer's generic Procardia XL totaled approximately \$34.9 million. The term of this agreement continues until such time as Mylan permanently ceases to market generic Procardia XL.

Approximately \$16,958,000, 16,093,000, and \$12,102,000 for the years ended December 31, 2002, 2001, and 2000, respectively, of research and development expense principally related to applications of TIMERx technology to products covered by the Company's collaborative agreements. Since the collaborative agreements can be terminated by either party, the costs associated with such agreements could be discontinued by the Company. Such costs are typically incurred prior to the receipt of milestones, royalties and other payments.

16. 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.

PENWEST PHARMACEUTICALS CO.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

17. SEGMENT INFORMATION

The Company is engaged in the research, development and commercialization of novel oral drug delivery products and technologies, and has extensive expertise in developing, manufacturing, and selling excipient ingredients for the pharmaceutical industry. The Company's product portfolio ranges from excipients that are sold in bulk, to more technically advanced and patented excipients that are licensed to customers, and conducts its business primarily in North America and Europe. The European operations consist of a manufacturing facility in Nastola, Finland and sales offices in Reigate, England, and Bodenheim, Germany. None of the European locations, other than Finland, is individually significant. Intercompany sales include a profit component for the selling company. Intercompany sales and profits are eliminated in consolidation. Corporate operating expenses are not allocated to the European operations. Operating profit represents gross profit less selling, general and administrative expenses and, for North America, research and development expense.

The Company's geographic area data for each of the three years ended December 31, 2002, 2001, and 2000 were as follows:

| | <u>NORTH AMERICA</u> | <u>FINLAND</u> | <u>GERMANY AND UNITED KINGDOM</u> | <u>ELIMINATIONS</u> | <u>TOTAL</u> |
|-----------------------------|--------------------------|----------------|---------------------------------------|---------------------|--------------|
| | (IN THOUSANDS) | | | | |
| DECEMBER 31, 2002 | | | | | |
| Total Revenues | \$32,069 | \$6,699 | \$12,284 | \$(9,093) | \$41,959 |
| Long-lived Assets | \$23,800 | \$ 626 | \$ 37 | | \$24,463 |
| DECEMBER 31, 2001 | | | | | |
| Total Revenues | \$38,412 | \$6,912 | \$ 3,650 | \$(8,971) | \$40,003 |
| Long-lived Assets | \$21,268 | \$ 557 | \$ 25 | | \$21,850 |
| DECEMBER 31, 2000 | | | | | |
| Total Revenues | \$40,922 | \$5,708 | \$ 2,948 | \$(7,520) | \$42,058 |
| Long-lived Assets | \$22,371 | \$ 604 | \$ 20 | | \$22,995 |

Neither the revenues nor long-lived assets in Germany or the United Kingdom, individually or in the aggregate, exceed 10% of total revenues or long-lived assets, respectively, of the Company.

18. Subsequent Events

On February 27, 2003, Penwest sold substantially all of the assets used in the Company's excipient business (the "Asset Sale") to subsidiaries and affiliates of Josef Rettenmaier Holding GmbH & Co. KG ("Rettenmaier") for \$41.75 million, plus the assumption of specified liabilities, subject to a working capital adjustment. 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 do business in the UK, Germany and Finland. The purchase price included \$39.5 million in cash and a promissory note of \$2.25 million, with \$1.0 million due April 25, 2003 and \$1.25 million due May 25, 2004. In the first quarter of 2003, the Company expects to record a gain on the Asset Sale of approximately \$9.5 million before taxes, and to report 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 at December 31, 2002 was approximately \$29 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 \$4.2 million. The estimated gain on the Asset Sale is net of transaction related costs, primarily

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

18. Subsequent Events (Continued)

consisting of professional and advisory fees. As of December 31, 2002 these costs approximated \$1.7 million and are reflected in the deferred transaction costs on the consolidated balance sheet. During the years ended December 31, 2002, 2001 and 2000, revenues from the sale of excipient products were 87%, 86% and 79%, respectively.

Prior to the sale of the excipient business, the Company had a revolving line of credit with a financial institution. On February 27, 2003, the Company fully paid down and terminated the Revolver in connection with the Asset Sale.

As part of the Company's agreement with AstraZeneca AB 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 AstraZeneca AB in the principal amount of \$2.25 million. These assets were included in the Asset Sale (see above). The note required the Company to pay all indebtedness outstanding under the note upon the closing of the Asset Sale. As a result, this note was paid in full on February 27, 2003.

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 sale of the excipient business, the Company transferred these properties and assigned its lease of a pharmaceutical excipient manufacturing facility in Nastola, Finland. 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. 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, and requires that monthly base rents of approximately \$20,000 be paid through the initial lease term. The Company plans to move its corporate offices to Danbury effective March 31, 2003.

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

19. QUARTERLY FINANCIAL DATA (UNAUDITED)

Summarized quarterly financial data for the years ended December 31, 2002 and 2001 is as follows (in thousands, except per share data):

| | Quarter Ended | | | |
|------------------------------|------------------------------|------------------------------|-------------------------------|-------------------------------------|
| | Mar. 31, 2002 (Unaudited) | June 30, 2002 (Unaudited) | Sept. 30, 2002 (Unaudited) | Dec. 31, 2002 (Unaudited) (a) |
| Total revenues | \$10,313 | \$10,261 | \$11,049 | \$10,336 |
| Gross profit | 3,719 | 4,031 | 4,604 | 4,198 |
| Net loss | <u>\$ (4,318)</u> | <u>\$ (5,318)</u> | <u>\$ (4,476)</u> | <u>\$ (2,987)</u> |
| Net loss per share | <u>\$ (0.28)</u> | <u>\$ (0.34)</u> | <u>\$ (0.29)</u> | <u>\$ (0.19)</u> |

| | Quarter Ended | | | |
|------------------------------|------------------------------|------------------------------|-------------------------------|-------------------------------------|
| | Mar. 31, 2001 (Unaudited) | June 30, 2001 (Unaudited) | Sept. 30, 2001 (Unaudited) | Dec. 31, 2001 (Unaudited) (b) |
| Total revenues | \$10,939 | \$ 9,515 | \$ 9,801 | \$ 9,748 |
| Gross profit | 4,376 | 3,698 | 3,633 | 3,486 |
| Net loss | <u>\$ (2,123)</u> | <u>\$ (3,166)</u> | <u>\$ (4,125)</u> | <u>\$ (6,567)</u> |
| Net loss per share | <u>\$ (0.17)</u> | <u>\$ (0.25)</u> | <u>\$ (0.28)</u> | <u>\$ (0.43)</u> |

(a) 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, as a reduction of research & development expense.
- 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.

(b) During the fourth quarter of 2001, the following adjustment was recorded:

- i) The Company recorded an impairment loss of approximately \$167,000, net of accumulated amortization, relating to its patents.

During years ended December 31, 2002 and 2001, revenues from the sale of excipient products were 87% and 86%, respectively, of total revenues. See Note 18 for further details.

SCHEDULE II—VALUATION AND QUALIFYING ACCOUNTS

PENWEST PHARMACEUTICALS CO.

DECEMBER 31, 2002

(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, 2002 | | | | | |
| Allowance for Doubtful Accounts | \$220 | \$ 12 | — | \$ 57 (a) | \$175 |
| Inventory Allowances | \$255 | \$ 64 | — | \$215 (b) | \$104 |
| Year ended December 31, 2001 | | | | | |
| Allowance for Doubtful Accounts | \$235 | \$ 25 | — | \$ 40 (a) | \$220 |
| Inventory Allowances | \$ 26 | \$324 | — | \$ 95 (b) | \$255 |
| Year ended December 31, 2000 | | | | | |
| Allowance for Doubtful Accounts | \$245 | \$(31) | — | \$(21)(a) | \$235 |
| Inventory Allowances | \$277 | \$334 | — | \$585 (b) | \$ 26 |

(a) Uncollectible accounts written off, net of recoveries.

(b) Disposals of unrecoverable inventory costs.

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CORPORATE DIRECTORY AND SHAREHOLDER INFORMATION

OFFICERS

Tod R. Hamachek
Chairman of the Board
and Chief Executive Officer

Jennifer L. Good
Senior Vice President, Finance
and Chief Financial Officer

Anand R. Baichwal, Ph.D.
Chief Scientific Officer and Senior Vice
President, Research & New Technology

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

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.

PENWEST HEADQUARTERS

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

Website

www.penwest.com

SHAREHOLDER INFORMATION

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

Penwest's common stock, \$.001 par value,
is listed with and trades on the Nasdaq
National Market under the symbol "PPCO."
The high and low closing prices of the
Company's common stock during 2002 and
2001 are set forth below.

| 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 |

| Period 2001 | High | Low |
|----------------------------|---------|---------|
| Quarter Ended March 31 | \$14.63 | \$ 9.81 |
| Quarter Ended June 30 | \$16.05 | \$11.06 |
| Quarter Ended September 30 | \$20.30 | \$14.20 |
| Quarter Ended December 31 | \$20.19 | \$15.00 |

On March 20, 2003 there were 823 shareholders of record.

The Company has never paid cash dividends on its common stock. The Company presently intends to retain earnings, if any, for use in the operation of its business, and therefore does not anticipate paying any cash dividends in the foreseeable future.

Annual Meeting

11:00 a.m., June 4, 2003

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 statements 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 statements. There are a number of important factors that could cause the Company's 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, 2002.

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