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, 2001

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 (I.R.S. Employer Identification No.)
2981 Route 22 Patterson, New York (Address of principal Executive Offices)	12563-2335 (Zip Code)

Registrant's telephone number, including area code: (845) 878-3414

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

Title of each class	**Name of each exchange of which registered**
None	None

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

Common Stock, $.001 par value
Common 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. ☒

The aggregate market value of the Registrant's Common Stock held by non-affiliates as of March 22, 2002 was approximately $295 million based on the closing price of $19.11 per share. The number of shares of the Registrant's Common Stock (the Registrant's only outstanding class of stock) outstanding as of March 22, 2002 was 15,450,852.

DOCUMENTS INCORPORATED BY REFERENCE

The Registrant's definitive Proxy Statement relating to the 2002 Annual Meeting of Shareholders to be held on June 5, 2002 is incorporated by reference into Part III of this Form 10-K.

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PART I

ITEM 1: BUSINESS

GENERAL

Penwest Pharmaceuticals Co. ("Penwest" or the "Company") is engaged in the research, development and commercialization of novel drug delivery technologies. The Company is also a leader in the development, manufacture, and distribution of branded pharmaceutical excipients which are the inactive ingredients in tablets and capsules. Based on its fundamental expertise in tabletting ingredients, the Company has developed its proprietary TIMERx® controlled release drug delivery technology, which is applicable to a broad range of orally administered drugs, and ProSolv®, a high functional excipient based on co-processing technology, which, among other things, improves the performance characteristics of tablets. The Company is also exploring and developing other drug delivery technologies. The Company had revenues in 2001, 2000, and 1999 of $40.0, $42.1, and $37.3 million, respectively.

TIMERX CONTROLLED RELEASE TECHNOLOGY

The Company has developed its TIMERx delivery system to address the limitations of currently available oral controlled release delivery systems. The Company believes that the TIMERx system has advantages over other oral drug delivery technology as it is readily manufactured and is applicable to a wide variety of drug classes, including soluble drugs, insoluble drugs and drugs with a narrow therapeutic index. Pharmaceutical products containing TIMERx have been approved and are being marketed and the Company is developing products in its pipeline.

The patented TIMERx drug delivery system is a hydrophilic matrix combining primarily a heterodispersed mixture, usually polysaccharides, xanthan and locust bean gums, in the presence of dextrose. 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 third component, 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.

To date, several drug formulations utilizing the TIMERx system have received regulatory approval and are being marketed:

- Cystrin CR, a controlled release version of oxybutynin for the treatment of urge urinary incontinence, was approved in Finland in 1997 and is being marketed in Finland by Leiras OY ("Leiras");

- Slofedipine XL, a controlled release version of nifedipine for the treatment of angina, was approved in the United Kingdom in 1998 and is being marketed in the United Kingdom by Sanofi-Synthelabo S.A. ("Sanofi");

- The 30 mg strength of Nifedipine XL, a generic version of Procardia XL that is used for the treatment of hypertension and angina, was approved by the FDA in December 1999. The 30 mg strength of Nifedipine XL is not being marketed in the United States by the Company's collaborator Mylan Pharmaceuticals, Inc. ("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. As a result of the agreement, Pfizer agreed to dismiss all pending litigation against Mylan. 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, which Mylan is not marketing. Mylan has retained the marketing rights to the 30 mg strength of Nifedipine XL; and

- Cronodipin, a controlled release version of nifedipine for the treatment of angina, was approved in Brazil in 2001 and will be marketed in Brazil by Merck S.A. Industries Quimicas ("Merck") or ("E. Merck") in 2002.

The Company also has a strategic alliance with Endo Pharmaceuticals, Inc. ("Endo") to jointly develop an extended release oral version of oxymorphone which is the most advanced product in the Company's drug development pipeline. Endo is currently conducting the final Phase II and Phase III trials of the product,

which are expected to be completed in the second quarter of 2002. Assuming that the results of the trial are consistent with the results from previous trials, the Company expects Endo to submit a new drug application ("NDA") for the product in the second half of 2002. The Company and Endo have agreed to share the costs involved in the development and commercialization of this product, and share in the net profits from the sale of this product once it is marketed.

The Company believes that the TIMERx controlled release system has several advantages over other oral controlled release systems.

- *Broad Applicability as a Drug Delivery System*. The TIMERx system is adaptable to a wide range of drugs with different physical and chemical properties. For instance, the TIMERx system can be used to deliver both low dose (less than 5 mg) and high dose (greater than 700 mg) drugs as well as water soluble and insoluble drugs. Because of the high affinity of xanthan and locust bean gums, the TIMERx system permits a formulation with a high drug-to-gum ratio, which permits tablets to include a higher dosage of the active drug substance.

- *Flexible Pharmacokinetic Profile*. The Company formulates the TIMERx material to optimize the desired kinetic profile of the active drug substance. In this manner, the TIMERx system can be designed to enhance the therapeutic effect of the active drug substance. Depending on the desired release profile, the Company can formulate the drug to be released in the body (i) at a constant amount or linear rate over time, (ii) at a decreasing amount over time where the rate is dependent on drug concentration, or (iii) at a varied release rate.

- *Ease of Manufacture*. Drugs formulated using the TIMERx system are designed for production on standard pharmaceutical processing equipment. The TIMERx technology is easily and reproducibly scaled-up in a commercial manufacturing environment often utilizing the cost-effective direct compression tabletting process.

- *Cost-Effective System*. The TIMERx system is a cost-effective drug delivery system. It involves fewer and less complex ingredients than other systems and does not require the manufacturer to purchase specialized equipment. The Company believes that drug formulations using the TIMERx system can be developed more rapidly than drugs formulated with alternative controlled delivery systems and that the time to scale up to commercial quantities is minimized.

EXCIPIENTS

The Company is an established leader in the development, production and distribution of branded pharmaceutical excipients, which are the inactive components included in tablets and capsules. Over the past 50 years, the Company has consistently been innovative and has delivered novel products such as Emcompress®, Explotab® and ProSolv® to the pharmaceutical industry. Each of the excipient products carries significant brand value, representing quality, service and performance. The Company sells 31 excipient products, which are used in the formulation and manufacture of tablets by pharmaceutical and nutritional companies worldwide. The excipients product line is broadly classified into three categories: binders, disintegrants and lubricants.

These products are sold to the branded prescription, generic prescription, over-the-counter and nutritional supplement markets. In 2001, bulk excipients were sold to more than 250 customers in more than forty countries worldwide, including some of the leading pharmaceutical companies in the world.

PROSOLV®

Prosolv, a high-functionality binder for tablets, is a patented combination of microcrystalline cellulose and colloidal silicon dioxide. These two ingredients work together synergistically for optimal tabletting performance. The Company has developed three products from this technology platform: ProSolv SMCC® 50, ProSolv SMCC® 90, and ProSolv HD® as well as customized grades of ProSolv. ProSolv SMCC® can be used by manufacturers to produce harder tablets and can enable manufacturers to reduce the amount of binders used in the tablet, thereby reducing the size and cost of the tablet. Additionally, it can be used to manufacture tablets with difficult active ingredients which otherwise may not have been manufactured. ProSolv HD improves flow and compaction, and can increase throughput by increasing production speeds. Custom grades of ProSolv are designed to address specific formulation or manufacturing problems. The Company is seeking to exclusively license these custom grades to pharmaceutical and nutritional partners.

PENWEST STRATEGY

The Company's strategy is to develop pharmaceutical products, utilizing the Company's drug delivery technologies, and generally to out-license these products to a marketing partner.

Leverage the TIMERx technology through the following:

- Create Innovative Branded Controlled Release Versions of Immediate Release Pharmaceuticals — The Company is focused on the application of its TIMERx technology to the development of controlled release formulations of immediate release drugs, which will be marketed as brand name pharmaceuticals. In developing these controlled release formulations, the Company will either complete the drug development itself, or in some cases will seek to develop products in collaboration with pharmaceutical companies having a market presence in the applicable therapeutic area. Generally, the Company will seek to out-license the product at varying stages to a corporate collaborator for manufacturing and marketing. The development of these controlled release drugs is subject to the NDA approval process, although the Company and its collaborators may be permitted to rely on existing safety and efficacy data with respect to the immediate release drug in submitting the NDA.

- Apply TIMERx Technology to Generic Versions of Branded Controlled Release Pharmaceuticals — The Company also applies its TIMERx technology to the development of select generic versions of branded controlled release drugs. In selecting generic controlled release pharmaceutical candidates to develop, the Company targets high sales volume, technically-complex controlled release pharmaceuticals. The Company believes these drug candidates may be difficult to replicate and, as a result, TIMERx versions may have limited competition from other formulations.

Establish Collaborations for Development, Manufacture and Marketing

The Company maintains a portfolio of drug candidates utilizing the TIMERx technology in which it will either complete the development work itself, or in some cases will selectively look for development partners. At varying stages during the clinical development program, the Company will seek a partner for the manufacturing and marketing of the drug. The Company's principal collaborative agreements are with Mylan, Endo, Sanofi and Leiras.

The Company is seeking to enter into additional collaborations for TIMERx. The Company's existing and potential future collaborations enable the Company to secure additional financial support for its research and development activities, to obtain access to the clinical, manufacturing and regulatory resources and expertise of its collaborators and to rely on them for the sales and marketing, distribution and promotion.

TIMERx PRODUCTS

The following table provides information by therapeutic area, development status and collaborator for each of the principal products being marketed or under development utilizing the Company's TIMERx technology. The Company is also conducting development activities by itself or with collaborators on various additional controlled release formulations.

BRAND NAME (COMPOUND)	THERAPEUTIC AREA	DEVELOPMENT STATUS (1)	COLLABORATOR
BRANDED CONTROLLED RELEASE (2)			
Cystrin CR (oxybutynin)	Urge Urinary Incontinence	Approved and Marketed (3)	Leiras
Oxymorphone ER	Moderate to Severe Pain	Phase II/III Clinical Trials	Endo
GENERIC CONTROLLED RELEASE (4)			
Procardia XL (30 mg) (nifedipine)	Hypertension, Angina	Approved (5)	Mylan
Slofedipine XL (nifedipine)	Hypertension, Angina	Approved and Marketed (6)	Sanofi
Cronodipin (nifedipine)	Hypertension, Angina	Approved (7)	E. Merck

(1) There can be no assurance that the results obtained in bioequivalence studies or preclinical studies will be obtained in full scale bioequivalence studies and other late stage clinical studies or that the Company or its collaborators will receive regulatory approvals to continue clinical studies of such products or to market any such products.

(2) Controlled release formulations of immediate release products are subject to the NDA regulatory process. To the extent that the controlled release product is an extension of an FDA-approved immediate release version of the same chemical entity, the Company's collaborators may be permitted to rely on existing clinical data as to the safety and efficacy of the chemical entity in filing NDAs.

(3) Leiras received marketing approval for Cystrin CR in Finland in October 1997 and began marketing the product in Finland in January 1998.

(4) Generic versions of controlled release products are developed in three basic stages:

FORMULATION. Involves the utilization or adaptation of drug delivery technologies to the product candidate and evaluation in in-vitro dissolution studies.

BIOEQUIVALENCE STUDIES. (a) Pilot bioequivalence studies involve testing in 10 to 15 human subjects to determine if the formulation yields a blood level comparable to the existing controlled release drug; (b) Full scale bioequivalence studies involve the manufacture of at least 10% of the intended commercial lot size and the analysis of plasma concentrations of the drug in 24 or more human subjects under fasting conditions and multiple dose conditions and 18 or more human subjects under fed conditions to determine whether the rate and extent of the absorption of the drug are substantially equivalent to that of the existing drug.

ANDA FILING. An abbreviated new drug application ("ANDA") is submitted to the FDA with results of bioequivalence studies and other data such as in-vitro specifications for the formulation, stability data, analytical data, methods validation and manufacturing procedures and controls.

(5) Mylan received marketing approval for Nifedipine XL in December 1999. Mylan is not marketing the product.

(6) Sanofi received marketing approval for, and began marketing, Slofedipine XL in the United Kingdom in November 1998.

(7) Merck received marketing approval in Brazil for Cronodipin in September 2001 and intends to market the product in Brazil in the first half of 2002.

Branded Controlled Release Pharmaceuticals

The Company applies its TIMERx technology to the development of controlled release formulations of immediate release pharmaceuticals. The Company's principal branded controlled release pharmaceuticals being marketed or in development are as follows:

CYSTRIN CR. The Company and Leiras have developed a controlled release formulation of Cystrin® incorporating TIMERx technology, which is being marketed in Finland by Leiras under the tradename Cystrin CR. Leiras received marketing approval in Finland for Cystrin CR, a once-a-day version of Cystrin, in October 1997 and began marketing the product in Finland in January 1998. Cystrin is a two to three times-a-day immediate release version of the anticholinergic drug oxybutynin indicated for the treatment of urge urinary incontinence. Oxybutynin is marketed in Finland by Leiras under the trademark Cystrin.

OXYMORPHONE ER. The Company and Endo are currently developing an extended release formulation of oxymorphone incorporating TIMERx technology. Oxymorphone is a narcotic analgesic for the treatment of moderate to severe pain which is currently given in the parenteral and suppository dosage form. Oxymorphone is marketed by Endo and had sales in the United States in 2001 of approximately $250,000. Extended release Oxymorphone ER, if successfully developed, would represent the first oral extended

release version of oxymorphone and would compete in the severe analgesic market with products such as MS Contin and OxyContin, which had aggregate sales in the United States in 2001 of approximately $1.6 billion. The extended release version is being developed for twice-a-day dosing in patients suffering moderate to severe pain. In 2000, Endo completed a randomized, double-blind, placebo-controlled pivotal trial in approximately 400 evaluable patients with chronic pain resulting from osteoarthritis. The results of the study demonstrated a statistically significant reduction in pain intensity compared to placebo (p=0.0047). In 2001, Endo conducted a randomized, double-blind, placebo-controlled pivotal trial in approximately 127 patients with acute post-surgical pain. The results of the study demonstrated a statistically significant reduction in pain intensity compared to placebo (p-0.0057). Endo is currently completing the remaining clinical trials, which are scheduled to be completed in the second quarter of 2002. Assuming the trial results from this Phase III trial are consistent with the results from previoues trials, the Company expects that Endo will submit the NDA for this product in the second half of 2002.

The Company has also identified four compounds, primarily in the treatment of pain and the central nervous system, that it is currently formulating. The formulation of these compounds typically takes six to nine months and at that point a decision will be made whether to advance these into clinical development.

Generic Controlled Release Pharmaceuticals

Generic controlled release pharmaceuticals are therapeutic equivalents of brand name drugs for which patents or marketing exclusivity rights have expired. Generic controlled release pharmaceuticals are typically difficult to replicate because of: (i) formulation complexity; (ii) analytical complexity; and/or (iii) manufacturing complexity. The Company believes that such generic controlled release pharmaceuticals are less likely to suffer the same price erosion as other generic pharmaceuticals because of the difficulty in replicating controlled release pharmaceuticals and the resulting limits on competition.

When developing generic pharmaceuticals, the drug developer is required to demonstrate that the generic product candidate will exhibit in-vivo release and absorption characteristics equivalent to those of the branded pharmaceutical without infringing on any unexpired patents. During the formulation of generic pharmaceuticals, drug developers create their own version of the branded drug by using or adapting drug delivery technologies to the product candidate.

The Company's principal generic controlled release pharmaceuticals are as follows:

NIFEDIPINE XL. The Company and Mylan developed Nifedipine XL as the first generic equivalent to the 30 mg strength of Procardia XL. Procardia XL is a once-a-day controlled release formulation of nifedipine, a calcium channel blocking agent indicated for hypertension, vasospastic angina and chronic stable angina, which uses the OROS delivery system. Procardia XL is marketed in three dosage strengths (30 mg, 60 mg and 90 mg) by the Pratt Pharmaceuticals division of Pfizer and had total sales in the United States in 2001 of approximately $163.2 million.

In December 1999, Mylan's ANDA for Nifedipine XL (30 mg) was approved by the FDA. Mylan's ANDA was the first ANDA for a generic version of Procardia XL filed with the FDA for the 30 mg strength. In March 2000, Mylan 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's sales in the United States in 2001 of the 30 mg dosage strength version of Pfizer's generic Procardia XL totaled approximately $48.2 million. The term of the royalty agreement continues until such time as Mylan permanently ceases to market generic Procardia XL. Mylan has retained the marketing rights to the 30 mg strenth of Nifedipine XL.

SLOFEDIPINE XL. The Company and Sanofi received approval for and began marketing in the United Kingdom in November 1998 Slofedipine XL, a generic version of Adalat LA® (a drug marketed in Europe by Bayer) that uses TIMERx technology. Adalat LA is a once-a-day controlled release formulation of nifedipine, a calcium channel blocking agent indicated for hypertension, vasospastic angina and chronic stable angina, which uses the OROS delivery system. Adalat LA is marketed in two dosage strengths (30 mg and 60 mg) by Bayer in Europe and had sales in the United Kingdom in 2001 of approximately $60 million. Sanofi has also received marketing approval in Italy for this product.

CRONODIPIN. The Company and E. Merck received approval in Brazil in September 2001 for Cronodipin, a generic version of Adalat LA® (a drug marketed by Bayer) that uses TIMERx technology. The Company anticipates that E. Merck will begin marketing this product in Brazil in the first half of 2002.

PHARMACEUTICAL EXCIPIENTS

The Company sells 31 excipient products which are used in the manufacture of tablets by pharmaceutical and nutritional companies worldwide. The Company's product line is broadly classified into three distinct categories: binders, disintegrants and lubricants. Binders, working in conjunction with other products, are the primary tablet-forming component of excipients. Disintegrants help a tablet fall apart when consumed by drawing water into the dosage form, a necessary precursor to dissolution and ultimately absorption of the drug. Lubricants help facilitate the ease of manufacture of drugs so that they emerge from a tabletting machine with the desired physical characteristics.

The Company's excipients are sold to the prescription, over-the-counter and nutritional markets. In 2001, the Company sold bulk excipients to more than 250 customers, including some of the leading pharmaceutical companies in the world, in more than 40 countries.

The following is a list of excipient products currently being marketed in bulk by the Company:

PROSOLV SMCC® was introduced in late 1996 and the Company sells it both in bulk and through licensing arrangements under which the Company offers exclusivity. The Company believes that Prosolv SMCC offers numerous advantages over traditional microcrystalline cellulose such as enhanced drug loading capability, production of elegant, robust tablets, and has excellent disintegration properties.

PROSOLV HD™ was introduced in late 1999 and provides superior flow without losing compactibility in the manufacturing process. The addition of ProSolv HD in some formulations can increase throughput and capacity in a production line.

EMCOCEL®, or microcrystalline cellulose ("MCC"), the Company's largest selling product, is a tabletting binder used in pharmaceutical formulations worldwide. EMCOCEL is utilized in a number of products including ethical and over-the-counter brands.

EMCOMPRESS®, or dicalcium phosphate, is a binder marketed by the Company under an exclusive worldwide distribution agreement with the manufacturer Rhodia. The distribution agreement is subject to automatic extension on an annual basis unless either party gives the other party 12 months notice of its desire to terminate the agreement. EMCOMPRESS is frequently used in vitamin formulations as it serves as an additional source of dietary calcium.

EMDEX® AND CANDEX®, or dextrates, are binders that are used as directly compressible excipients in both chewable and non-chewable tablets. They are odorless with a sweet taste caused by its sugar composition. EMDEX and CANDEX are used in, among other things, chewable antacid tablets and vitamins.

EXPLOTAB®, or sodium starch glycolate, is the principal disintegrant marketed by the Company. EXPLOTAB is distributed by the Company under an exclusive worldwide distribution agreement with the manufacturer, Roquette America, Inc. The distribution agreement is automatically renewable on an annual basis unless either party gives the other party 12 months notice of its desire to terminate the agreement. EXPLOTAB is used in a number of products and is an essential component of the Tylenol family of products.

PRUV®, or sodium stearyl fumarate, is the principal lubricant marketed by the Company. PRUV is marketed under an exclusive worldwide distribution agreement with Astra-Zeneca. PRUV is used in several prescription pharmaceuticals.

The Company had revenues from the sale of pharmaceutical excipients and formulated bulk TIMERx in 2001, 2000, and 1999 of $34.8 million, $37.1 million, and $36.8 million, respectively.

COLLABORATIVE ARRANGEMENTS

The Company enters into collaborative agreements with pharmaceutical companies to facilitate and expedite the commercialization of its TIMERx drug delivery technology.

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 research and development. 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 2001 of the 30 mg dosage strength version of Pfizer's generic Procardia XL totaled approximately $48.2 million. The term of this agreement continues until such time as Mylan permanently ceases to market generic Procardia XL. In 2001 and 2000, Mylan accounted for approximately 12% and 19%, respectively, of the Company's total revenue.

SANOFI-SYNTHELABO

In February 1997, the Company entered into a product development and supply agreement with Sanofi-Synthelabo 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 would be 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, but is not marketing the Sanofi 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 who 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.

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 (the "Endo Product"). Endo is a fully integrated specialty pharmaceutical company with a market leadership in pain management. Endo has a broad product line including 12 branded products that include the 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 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"). However, the Company formulated the Endo Product and Endo is conducting all clinical studies and will prepare and file all regulatory applications and submissions. The Company has agreed to manufacture and supply TIMERx material to Endo, and Endo has agreed to manufacture and market the Endo Product in the United States. The manufacture and marketing of the Endo Product outside of the United States may be conducted by the Company, Endo or a third party, as determined by the Alliance Committee.The strategic alliance agreement may be terminated upon a material breach of the agreement by a party.

The Company and Endo share the costs involved in the development and commercialization of the Endo Product and have agreed that the party marketing the Endo Product will pay the other party royalties initially equal to 50% of net profits (as defined in the agreement). This percentage will decrease if the total U.S. net profits exceed pre-determined thresholds. This cost-sharing is subject to each party's right to terminate its participation in the funding of development and commercialization of the Endo Product. In general, the royalty payable by the marketing party to the other party will not drop below 40%; however, a one-third royalty reduction provision does apply in limited circumstances, including material breaches of the agreement by the royalty receiving party and certain bankruptcy and insolvency events involving the royalty receiving party. Endo will purchase formulated TIMERx material for use in the Endo Product exclusively from the Company at specified prices. Such prices will be reflected in the determination of net profits.

RESEARCH AND DEVELOPMENT

The Company conducts research and development activities with respect to additional applications of TIMERx technology, advances in the TIMERx technology, for additional drug delivery technologies and additional novel excipients such as Prosolv. The Company's research and development expenses in 2001, 2000, and 1999 were $17.0 million, $12.8 million, and $7.4 million, respectively. 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 currently has a laboratory and pilot manufacturing facility contiguous to its executive offices in Patterson, New York. The pilot manufacturing facility is currently used to produce one of the excipients sold by the Company. The Company does not have commercial-scale facilities to manufacture its TIMERx material in accordance with cGMP requirements prescribed by the FDA. As a result, the Company has contracted with a third-party pharmaceutical company, Draxis Pharmaceuticals, Inc. ("Draxis"), for the bulk manufacture of its TIMERx material for delivery to its collaborators under an agreement that expires in September 2004.

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 TIMERx drug delivery system is a hydrophilic matrix combining primarily a heterodispersed mixture, usually 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.

The Company currently operates two cGMP-approved manufacturing facilities for its microcrystalline cellulose ("MCC") products, including EMCOCEL and ProSolv. These facilities are located in Cedar Rapids, Iowa and Nastola, Finland and cover approximately 35,000 square feet and 15,000 square feet, respectively. The Company's MCC products are primarily made from a specialty grade of wood pulp. The Company obtains wood pulp primarily from two suppliers, however, wood pulp is widely available from a number of suppliers.

The Company has several key excipient products that are manufactured exclusively by a third-party supplier for Penwest:

Product	Contract Manufacturer
Emcompress®	Rhodia, SA
Emdex® and Candex®	Penford Products Co.
Explotab®	Roquette, Inc.
Pruv®	AstraZeneca plc

All manufacturing operations of the Company are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of certain materials and waste 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 controlled release pharmaceuticals developed based on the Company's TIMERx technology. 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.

The Company has an in-house sales force of eleven employees who market the Company's excipient products in the United States and in Europe. This sales force focuses primarily on pharmaceutical and nutritional companies. The Company also markets excipients

worldwide through the use of distributors located in over 40 countries. The Company typically sells its excipients to its largest customers under multi-year supply agreements.

PATENTS AND PROPRIETARY RIGHTS

The Company believes that patent and trade secret protection, particularly of its drug delivery technology, is important to its business and that its 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.

The Company has been issued 27 U.S. and 139 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, 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 method of treatment and methods of preparation. All these patents will expire between 2008 and 2018. The Company also has been issued an additional 15 U.S. patents and 30 foreign patents covering its ProSolv technology. These patents will expire between 2010 and 2019.

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 (i) any of the Company's future processes or products will be patentable; (ii) any pending or additional patents will be issued in any or all appropriate jurisdictions; (iii) the Company's processes or products will not infringe upon the patents of third parties; or (iv) 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.

TIMERx, Emcocel, Multicel-N, Celpac, ProSolv, Explotab, Emdex, Emdex Plus, Emcompress, Compactrol, Emcosoy, Lubritab, and Candex are registered trademarks of the Company. Other tradenames and trademarks appearing in this Annual Report on Form 10-K are the property of their respective owners.

GOVERNMENT REGULATION

FDA REGULATION OF PHARMACEUTICAL PRODUCTS

All pharmaceutical manufacturers are subject to extensive regulation by the federal government, principally the FDA, and, to a lesser extent, by state and local governments. The Federal Food, Drug and Cosmetic Act (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 ("INDA"), 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 ("GATT"), 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.

FDA REGULATION OF EXCIPIENTS

Products sold for use as excipients in finished drug products are subject to regulation by the FDA with regard to labeling, product integrity and manufacturing. The FDA will not approve a drug for marketing without adequate assurances that the excipients are safe for use in the product. The FDA presumes certain excipients that are present in approved drug products currently marketed for human use to be safe. These excipients are listed by the FDA in a document known as the Inactive Ingredient Guide, or "IIG." While the FDA does not ordinarily require applicants for NDAs or ANDAs to submit data demonstrating the safety of excipients listed in the IIG, it may require evidence of safety in certain circumstances, such as when evidence is required to demonstrate that such excipients interact safely with other components of a drug product. For excipients not listed in the IIG, the FDA will generally require data, which may include clinical data, demonstrating the safety of the excipient for use in the product at issue. In the case of generic drug products approved based on bioequivalence to a reference drug, the FDA may in some cases (e.g., products for parenteral, ophthalmic, otic or topical use) require excipients that are identical to the excipients in the reference drug. There can be no assurance that the FDA will not require new clinical safety data to approve an application for a product with a Penwest excipient or that the FDA will approve such an application even if such clinical data are submitted.

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.

The Company's European excipients manufacturing operations are subject to a variety of laws and regulations, including environmental and good manufacturing practices regulations.

OTHER REGULATIONS

The Company is governed by federal, state and local laws of general applicability, such as laws regulating working conditions and environmental protection. Certain 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's TIMERx business 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 ("Elan") and Biovail, traditional matrix systems marketed by SkyePharma, plc and other controlled release technologies marketed or under development by Andrx Corporation, among others.

A number of the products that the Company has developed or is working on 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.

The Company is also focusing its business development efforts and research and development projects on controlled 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®.

In its excipients business, the Company competes with a number of large manufacturers and other distributors of excipient products, many of which have substantially greater financial, marketing and other resources than the Company. The Company's principal competitors in this market are FMC Corporation, which markets its own line of MCC excipient products, and J. Rettenmaier & Sohne GmbH, which also competes with the Company's MCC and sodium starch glycolate products.

EMPLOYEES

As of December 31, 2001, the Company employed 148 persons, of which 84 were involved in research and development, administration and sales and marketing activities in Patterson, New York; 23 were involved in manufacturing operations at the Company's facility in Nastola, Finland; 30 were involved in manufacturing operations at the Company's facility in Cedar Rapids, Iowa; and 11 were involved in sales activities in the Company's European sales offices.

None of the Company's employees are covered by collective bargaining agreements other than the Company's employees in Finland who are covered by a national collective bargaining agreement. The Company considers its employee relations to be good.

ITEM 2: PROPERTIES

The Company's executive, administrative, research, small-scale production and warehouse facilities, comprising approximately 55,000 square feet, currently are located in a single facility on a 15 acre site owned by the Company in Patterson, New York.

The Company owns a facility in Cedar Rapids, Iowa where it manufactures and packages pharmaceutical excipients. The facility is a 35,000 square foot building containing manufacturing and administrative space. The Company also manufactures pharmaceutical excipients in a 15,000 square foot facility leased by the Company in Nastola, Finland, which lease renews annually with a two year notification of termination period for either party.

The Company believes that all its present facilities are well maintained and in good operating condition. The Company is currently exploring options to add additional laboratory space.

ITEM 3: LEGAL PROCEEDINGS

None.

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 2001.

ITEM 4a: EXECUTIVE OFFICERS OF THE REGISTRANT

NAME	AGE	TITLE	DATES
Tod R. Hamachek	56	Chairman of the Board and Chief Executive Officer President and Chief Executive Officer — Penford Corp.	1997 — current 1985 — 1997
Anand R. Baichwal, Ph.D.	47	Senior Vice President, Research & New Technology Development and Chief Scientific Officer	1997 — current 1994 — 1997
Stephen J. Berte, Jr.	46	General Manager, Excipients Business Vice President, Global Sales	2000 — current 1995 — 2000
Jennifer L. Good	37	Senior Vice President, Finance and Chief Financial Officer Corporate Controller — Penford Corp.	1997 — current 1993 — 1997

PART II

ITEM 5: 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 2001 and 2000 are set forth below. The quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

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

PERIOD 2000	HIGH	LOW
Quarter Ended March 31	$19.50	$12.25
Quarter Ended June 30	$13.63	$ 8.75
Quarter Ended September 30	$13.25	$ 8.63
Quarter Ended December 31	$12.94	$ 8.13

On March 22, 2002 there were 861 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. The Company is prohibited from paying dividends on its common stock under its existing credit facility with the CIT Group/Business Credit, Inc.

ITEM 6: SELECTED FINANCIAL DATA

The following selected financial data are derived from the consolidated financial statements of Penwest Pharmaceuticals Co., which have been audited by Ernst & Young LLP, independent auditors. The data should be read in conjunction with the consolidated financial statements, related notes, and other financial information included herein.

	YEAR ENDED DECEMBER 31,				
	2001	2000	1999	1998	1997
STATEMENT OF OPERATIONS DATA:	(IN THOUSANDS EXCEPT FOR PER SHARE DATA)				
Revenues (a)	$ 40,003	$42,058	$37,307	$29,149	$26,999
Cost of product sales (a)	24,810	25,303	25,889	21,183	20,415
Gross profit	15,193	16,755	11,418	7,966	6,584
Selling, general and administrative	13,855	12,054	11,425	11,354	8,708
Research and product development	17,003	12,820	7,371	6,054	3,681
Asset write-off (b)	—	—	—	1,341	—
IPO transaction costs (c)	—	—	—	—	1,367
Loss before cumulative effect of change in accounting principle	(15,981)	(8,376)	(7,681)	(8,829)	(7,316)
Cumulative effect of change in accounting principle (d)	—	(410)	—	—	—
Net loss	$(15,981)	$ (8,786)	$ (7,681)	$ (8,829)	$ (7,316)
Basic and diluted loss per share before cumulative effect of change in accounting principle	$ (1.15)	$ (0.68)	$ (0.69)	$ (0.80)	$ (0.66)
Cumulative effect of change in accounting principle per share	—	(0.03)	—	—	—
Net loss per share	$ (1.15)	$ (0.71)	$ (0.69)	$ (0.80)	$ (0.66)
Weighted average shares of common stock outstanding	13,905	12,330	11,103	11,037	11,037

	DECEMBER 31,				
	2001	2000	1999	1998 (e)	1997
BALANCE SHEET DATA:			(IN THOUSANDS)		
Cash and cash equivalents	$ 12,903	$ 2,204	$ 739	$ 1,476	$ 938
Marketable securities	9,609	—	—	—	—
Working capital	27,059	11,129	7,713	7,648	(33,049)
Total assets	59,613	42,294	38,120	41,082	37,820
Long-term debt	—	—	6,700	—	—
Accumulated deficit	(60,926)	(44,945)	(36,159)	(28,478)	(19,649)
Shareholders' equity (deficit)	45,624	31,017	22,509	30,032	(12,297)

(a) Reclassification recorded of amounts prior to 2000 for the adoption of EITF No. 00-10 "Accounting for Shipping and Handling Fees and Costs."

(b) 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.

(c) Represents a write-off of transaction costs associated with an abandoned initial public offering.

(d) Cumulative effect of adopting Staff Accounting Bulletin No. 101 ("SAB No. 101").

(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 (the "Distribution), 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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements which involve risks and uncertainties. The Company's actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including those set forth below under "Risk Factors."

OVERVIEW

Penwest is engaged in the research, development and commercialization of novel drug delivery technologies. The Company is also a leader in the development, manufacture, and distribution of branded pharmaceutical excipients which are the inactive ingredients in tablets and capsules. Based on its fundamental expertise in tabletting ingredients, the Company has developed its proprietary TIMERx® controlled release drug delivery technology, which is applicable to a broad range of orally administered drugs, and ProSolv® a high functional excipient based on co-processing technology, which, among other things, improves the performance characteristics of tablets. The Company is also exploring and developing other drug delivery technologies. The Company had revenues in 2001, 2000, and 1999 of $40.0, $42.1, and $37.3 million, respectively.

The Company has incurred net losses since 1994. As of December 31, 2001, the Company's accumulated deficit was approximately $60.9 million. Management expects operating losses and negative cash flows during 2002 and 2003. A substantial portion of the Company's revenues to date have been generated from the sales of the Company's pharmaceutical excipients. The Company's future profitability will depend on several factors, including the successful commercialization of TIMERx controlled release products, including in particular Oxymorphone ER, royalties from Mylan's sales of Pfizer's 30 mg generic version of Procardia XL, sales growth of the Company's pharmaceutical excipients products, as well as the level of 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 which will be formulated using the Company's 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 this area, however, is discretionary and is dependent on identifying good opportunities and the availability of funds from the Company's operations, cash resources, collaborative research and development arrangements, as well as external financing. There can be no assurance that the Company will achieve profitability or that it will be able to sustain profitability on a quarterly basis, if at all.

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. As a result of the agreement, Pfizer agreed to dismiss all pending

litigation against Mylan. In connection with that agreement, Mylan agreed to pay Penwest a royalty on all future net sales of Pfizer's 30 mg strength of generic Procardia XL, which Mylan launched at the end of March 2000. The royalty percentage is comparable to those called for in Penwest's original agreement with Mylan for Nifedipine XL, the TIMERx-based generic equivalent to Procardia XL. Mylan has retained the marketing rights to the 30 mg strength of Nifedipine XL.

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 in 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 business is conducted internationally and may be 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 transact 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.

The Company's results of operations may fluctuate from quarter to quarter depending on the volume and timing of orders of the Company's pharmaceutical excipients, royalties on Mylan's sales of the 30 mg strength of generic Procardia XL, and on variations in payments under the Company's collaborative agreements including payments upon the achievement of specified milestones. The Company's quarterly operating results may also fluctuate depending on other factors, including variations in gross margins of the Company's products, the mix of products sold, competition, regulatory actions, litigation and currency exchange rate fluctuations.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The consolidated financial statements of the Company are prepared in accordance with accounting principles generally accepted in the United States, which requires us to make estimates and assumptions. 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. Application of these policies requires the Company to make significant judgments and estimates about matters that are inherently uncertain.

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. 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 the Company is obligated to supply inventory for manufacture after the development risk has substantially ended. 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. 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.

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 has considered 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, 2001, the Company had recorded full valuation allowances totaling approximately $14.9 million against its deferred tax assets.

IMPAIRMENT OF INTANGIBLE 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. Effective January 1, 2002, the Company will adopt Statement of Financial Accounting Standards No. 142, "Goodwill and Other Intangible Assets."

RESULTS OF OPERATIONS

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 increased 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.

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.

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.

As of December 31, 2001, the Company had ten product candidates utilizing TIMERx technology, in various stages of clinical trials. 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.

The Company's most advanced product candidate, Oxymorphone ER, is currently in Phase II/Phase III clinical trials. Endo is currently conducting these clinical trials, which are scheduled to be completed in the second quarter of 2002. The Company expects that Endo will submit the NDA for this product in the second half of 2002. Assuming the results of the clinical trials are consistant with the results of previous trials, the Company expects that Endo will submit the NDA for this product in the second half of 2002. The Company anticipates spending an additional $7.5 million on this development program in 2002.

There are four product candidates that the Company is developing with collaborators whereby the collaborators are responsible for conducting and funding the clinical trials and submitting the regulatory filings. The Company has five compounds that are in the early stages of development whereby the Company is either funding the development costs of the project, or they are being shared equally with a collaborator. There can be no assurance that any of our products will be successfully developed, will receive regulatory approval, or will be successfully commercialized.

YEARS ENDED DECEMBER 31, 2000 and 1999

Total revenues increased 12.7% for the year ended December 31, 2000 to $42.1 million from $37.3 million for the year ended December 31, 1999. Product sales increased to $37.1 million for 2000 compared to $36.8 million for 1999. The increase in product sales was primarily due to shipments of formulated bulk TIMERx to Mylan in the first and third quarters of 2000. The first quarter's shipments to Mylan were in anticipation of their launch of Nifedipine XL, and prior to Mylan signing the supply and distribution agreement with Pfizer. The third quarter's shipments to Mylan were made pursuant to Penwest's March 2000 agreement with Mylan

noted above. Partially offsetting the increased sales of formulated bulk TIMERx included in product sales was a decrease in excipients revenues during the year ended December 31, 2000. This decrease in excipient revenues was due to a milder-than-expected cough/cold season resulting in reduced orders from customers, a decrease in sales volumes to two primary customers, as well as pricing pressure on Emcocel products, primarily in Europe. Royalties and licensing fees increased to $4.9 million for the year ended December 31, 2000 compared to $0.5 million for the year ended December 31, 1999. This increase was due primarily to royalties from Mylan on its sales of Pfizer's 30 mg generic version of Procardia XL.

Gross profit increased to $16.7 million, or 39.8% of total revenues, for 2000 from $11.4 million, or 30.6% of total revenues, for 1999. The increase in gross profit was primarily due to increased royalties and licensing fees noted above. Gross profit percentage on product sales increased to 31.9% from 29.6% for the year ended December 31, 2000 and 1999, respectively, primarily due to increased sales of formulated bulk TIMERx and ProSolv, which have higher overall margins than the Company's other excipient products.

Selling, general and administrative expenses increased 5.5% for the year ended December 31, 2000 to $12.1 million from $11.4 million for the year ended December 31, 1999. This increase was primarily due to additional personnel hired in sales and marketing and increased professional fees.

Research and product development expenses increased 73.9% for the year ended December 31, 2000 to $12.8 million from $7.4 million for the year ended December 31, 1999. This increase was primarily due to the Company's share of increased expenses associated with the recently completed Phase II clinical trials, as well as other studies being conducted for the development of extended release oxymorphone under the Company's collaboration with Endo, as well as increased activity in the Company's drug development pipeline.

The effective tax rates for the year ended December 30, 2000 and 1999, were an expense of 4% and a benefit of 1%, respectively. The effective rates are higher than the federal statutory rate of a 34% benefit, due primarily to the valuation allowance 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 revenues from the sale of excipients, sale 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 July 11, 2001, the Company completed a private placement of 2,447,187 shares of its common stock to selected institutional investors, resulting in proceeds of approximately $30 million, less expenses.

As of December 31, 2001, the Company had cash, cash equivalents, and short-term investments of $22.5 million. The Company has no committed sources of capital at year-end other than the Company's revolving line of credit ("Revolver") with CIT Group/Business Credit, Inc. Under the Revolver, 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. 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 that fees be paid of .5% per annum on unused portions of the Line of Credit. It also provides for early termination fees of up to .75% in the event the Cmpany terminates the Revolver prior to the end of the initial term. 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 intial term of the agreement, and restrictions on the incurrence of additional indebtedness. 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. As of March 22, 2002, there was approximately $2.9 million outstanding under the terms of the Revolver.

As of December 31, 2001, the Company did not have any material commitments for capital expenditures. As of December 31, 2001, the Company's trade receivables were $6.2 million, a decrease of $1.9 million from the December 31, 2000 balance of $8.2 million. This decrease primarily reflects the trade receivable as of December 31, 2000 associated with shipments of formulated bulk TIMERx to Mylan in 2000, which were paid by Mylan in the first half of 2001. In connection with its strategic alliance agreement with Endo, the Company expects to expend an additional $7.5 million through 2002 on the development and pre-marketing costs of

Oxymorphone ER to fund its cash needs.

The Company's major outstanding contractual obligations relate to its Revolver and its operating leases, primarily of equipment. Below is a table summarizing the contractual obligations and commercial commitments as of December 31, 2001 (in thousands):

	Total	Less than One Year	1-3 Years	4-5 Years	After 5 Years
Loan Payable under Revolver	$2,668	$2,668	$ —	$ —	$ —
Operating Leases	2,743	760	1,323	609	51
Total Contractual Cash Obligations	$5,411	$3,428	$1,323	$609	$ 51

At December 31, 2001, the Company has federal net operating loss ("NOL") carryforwards of $41,482,000 for income tax purposes, of which approximately $6,188,000, $8,407,000, $9,135,000, and $17,752,000 expire in 2018, 2019, 2020 and 2021, respectively. In addition, the Company has research and development tax credit carryforwards of approximately $455,000, of which $149,000 and $306,000 expire in 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, 2001, a valuation allowance of $14.9 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 had negative cash flow from operations in 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 as noted above. The Company had negative cash flow from operations in the year ended December 31, 2000 of $7.3 million, primarily due to net losses for the period. 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 associated with the Company strengthening its technology infrastructure to prepare for increasing drug development activities. Funds expended for intangible assets include costs to secure and defend patents on technology developed by the Company and to secure trademarks.

The Company intends to utilize available cash and short-term investments, cash from operations, and funds available under the Revolver. The Company's requirements for additional capital are substantial and will depend on many factors, including (i) the timing and amount of payments received under existing and possible future collaborative agreements; (ii) the structure of any future collaborative or development agreements, including the costs of funding research and development and clinical trials as part of cost-sharing arrangements with collaborators such as Endo; (iii) the progress of the Company's collaborative and independent development projects; (iv) revenues from the Company's sales of excipients; (v) the costs to the Company of bioequivalence studies for the Company's products and other development activities; (vi) the prosecution, defense and enforcement of patent claims and other intellectual property rights; and (vii) the costs and timing of adding drug development capabilities.

The Company anticipates that its existing capital resources, including funds available under the Revolver as well as anticipated internally generated funds from the sale of excipients and formulated bulk TIMERx, royalties from Mylan and other payments from collaborators, will enable the Company to maintain currently planned operations through the first quarter of 2003. The Company may need to raise additional funds to maintain its operations beyond such date. The Company may seek to obtain additional funds through transactions relating to its business lines and/or 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 (i) significantly curtail its product commercialization efforts, including terminating existing collaborative agreements; (ii) obtain funds through 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; (iii) significantly scale back or terminate operations and/or; (iv) seek relief under applicable bankruptcy laws.

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 and its revolving line of credit which bears interest at variable rates. The Company's foreign currency exchange risk primarily relates to its international subsidiaries. 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. Marketable securities, consisting of corporate debt and U.S. Government Agency-backed discounted notes, approximated $9.6 million at December 31, 2001. These securities have contractual maturity dates of up to two years. Due to the relatively short term maturities of these securities, management believes there is no significant market risk. 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 has a revolving line of credit with a financial institution which bears interest at a specified bank's prime rate plus 1% per annum (5.75% at December 31, 2001) on the greater of $3.0 million or on the average outstanding balance. At December 31, 2001, there was approximately $2.7 million outstanding under the line and, accordingly, a sustained increase in the interest rate of 1% would cause increased annual interest expense of approximately $30,000.

The Company's international subsidiaries transact 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. 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 June 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standard ("SFAS") No. 141, "Business Combinations" and SFAS No. 142, "Goodwill and Other Intangible Assets" effective for fiscal years beginning after December 15, 2001. Under the new rules, goodwill will no longer be amortized but will be subject to annual impairment tests. Other intangible assets will continue to be amortized over their estimated useful lives. The Company will apply the new rules on accounting for goodwill and other intangible assets beginning in the first quarter of 2002. The adoption of the new standards is not expected to have a material effect on the results of operations, financial position, or cash flows of the Company.

In October 2001, the FASB issues SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." SFAS No. 144 supersedes SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of." The primary objectives of SFAS No. 144 are to develop one accounting model based on the framework established in SFAS No. 121 for long-lived assets to be disposed of by sale, and to address significant implementation issues. The Company's adoption of SFAS No. 144 in the first quarter of 2002 is not expected to have a material effect on the results of operations, financial position, or cash flows of the Company.

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.

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K 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 risk factors listed below.

RISK FACTORS

WE HAVE NOT BEEN PROFITABLE

We have incurred net losses since 1994, including net losses of approximately $15.9 million, $8.8 million, and $7.7 million, during 2001, 2000, and 1999, respectively. As of December 31, 2001, our accumulated deficit was approximately $60.9 million. The Company expects net losses to continue at least through 2003. A substantial portion of our revenues have been generated from the sales of our pharmaceutical excipients. Our future profitability will depend on several factors, including:

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

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

We develop and commercialize our TIMERx controlled release products in collaboration with pharmaceutical companies. We are parties to collaborative agreements with third parties relating to most of our products. Under these collaborations, depending on the structure of the collaboration, we are dependent on our collaborators to fund, 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. We are also 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 without cause on short notice under certain

circumstances.

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 TIMERx controlled release 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 will 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, the Company expects 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.

In our excipients business, we compete with a number of large manufacturers and other distributors of excipient products, many of which have substantially greater financial, marketing and other resources than the Company. Our principal competitor in this market is FMC Corporation, which markets its own line of MCC excipient products and J. Rettenmaier & Sohne GmbH, a European manufacturer and marketer of MCC and sodium starch glycolate products.

WE REQUIRE ADDITIONAL FUNDING

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;
- revenues from our excipients products;
- the costs to us of clinical studies for our products;
- 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 patent claims and other intellectual property rights.

The Company has no committed sources of capital except for the CIT credit facility. The Company anticipates its existing capital resources, including the amount available (as determined by a formula based on the Company's Eligible Accounts Receivable and Eligible Saleable Inventory, as defined in the agreement,) under the $10 million financing arrangement with CIT Credit, will be sufficient to fund operations through the first quarter of 2003.

Additional financing may not be available to Penwest on acceptable terms, if at all. If adequate funds are not available, Penwest may be required to (i) significantly curtail its product commercialization efforts, including terminating existing collaborative agreements; (ii) obtain funds through 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; (iii) significantly scale back or terminate operations and/or; (iv) 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 certain of our potential products, including controlled release versions of immediate release drugs and new chemical entities, our collaborators will be required to complete clinical trials in humans to demonstrate the safety and efficacy of the products. 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, one of 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

The development, clinical testing, manufacture, marketing and sale of pharmaceutical products are subject to extensive federal, state and local regulation in the United States and other countries. This regulatory approval process can be time-consuming and expensive.

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 ANDA, the FDA may deny the application, may require additional testing or data and/or may require postmarketing 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 (NDA or ANDA). 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 violative products, to seize allegedly volative products, to obtain injunctions to close manufacturing plants allegedly not operating in conformity with current Good Manufacturing Practices and to stop shipments of allegedly violative 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 Nifedipine XL. 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 TIMERx CONTROLLED RELEASE TECHNOLOGY

The commercial success of products incorporating our controlled 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 the TIMERx 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 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. We have not yet qualified a second source of supply. In the event that 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 manufacturer fails to perform its 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 (both TIMERx material and excipients) 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 AND UPON A LIMITED NUMBER OF SUPPLIERS FOR THE WOOD PULP USED IN THE MANUFACTURE OF OUR EXCIPIENTS

Our TIMERx drug delivery system is a hydrophilic matrix combining primarily two polysaccharides, xanthan and locust bean gums, in the presence of dextrose. We purchase these gums from a sole source supplier. Emcocel and Prosolv, our two largest selling excipients, are manufactured from a specialty grade of wood pulp. 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 or to manufacture these excipients.

IF 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 million annually in the aggregate on a claims-made basis and by umbrella liability insurance in excess of $25 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 CERTIFICATE OF INCORPORATION AND BYLAWS AND OF WASHINGTON LAW, AS WELL AS THE RIGHTS AGREEMENT TO WHICH WE ARE A PARTY, MAKE A TAKEOVER OF PENWEST MORE DIFFICULT

Provisions of our Certificate of Incorporation, our Bylaws and Washington law, as well as the Rights Agreement to which we are a party, may 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 14 (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 2002 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 and incorporated herein by reference.

ITEM 11: EXECUTIVE COMPENSATION

The information set forth under "Executive Compensation", " "Director Compensation," Report of the Compensation and Benefits Committee on Executive Compensation", "Compensation Committee Interlocks and Insider Participation", and "Stock Performance Graph" in the Company's definitive Proxy Statement for the 2002 Annual Meeting of Shareholders is incorporated herein by reference.

ITEM 12: SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information set forth under "Security Ownership of Certain Beneficial Owners and Management" in the Company's definitive Proxy Statement for the 2002 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 2002 Annual Meeting of Shareholders is incorporated herein by reference.

PART IV

ITEM 14: 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, 2001 and 2000 and the related statements of operations, cash flows and shareholders' equity for each of the three years in the period ended December 31, 2001.

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 7, 2001, the Company filed a report on Form 8-K announcing its results for the third quarter ended September 30, 2001.

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: April 1, 2002

/s/ Tod R. Hamachek

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

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

Date: April 1, 2002

/s/ Tod R. Hamachek

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

Date: April 1, 2002

/s/ Jennifer L. Good

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

Directors

Paul E. Freiman*
Jere E. Goyan, Ph.D.*
Tod R. Hamachek*
Rolf H. Henel*
Robert J. Hennessey*
N. Stewart Rogers*
John N. Staniforth, Ph.D.*
Anne M. VanLent*

By /s/ Jennifer L. Good

Attorney-in-Fact*
Power of Attorney Dated March 29, 2002

Date: April 1, 2002

APPENDIX A

PENWEST PHARMACEUTICALS CO.
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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, 2001 and 2000, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2001. Our audits also included the financial statement schedule listed in the Index at Item 14(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, 2001 and 2000, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2001, 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 4, 2002

PENWEST PHARMACEUTICALS CO.

CONSOLIDATED BALANCE SHEETS
(in thousands, except share amounts)

	DECEMBER 31,	
	2001	2000
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,903	$ 2,204
Marketable securities	9,609	—
Trade accounts receivable, net of allowance for doubtful accounts of $220 and $235	6,228	8,154
Inventories	7,857	8,196
Prepaid expenses and other current assets	1,166	745
Total current assets	37,763	19,299
Fixed assets, net	15,567	17,473
Patents, net	3,545	2,827
Other assets	2,738	2,695
Total assets	$ 59,613	$ 42,294
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,174	$ 3,199
Accrued expenses	2,275	1,790
Accrued development costs	3,139	2,911
Taxes payable	448	270
Loan payable	2,668	—
Total current liabilities	10,704	8,170
Deferred income taxes	205	205
Deferred revenue	369	378
Deferred compensation	2,711	2,524
Total liabilities	13,989	11,277
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 15,276,630 shares at December 31, 2001 and 12,669,780 shares at December 31, 2000	15	13
Additional paid in capital	108,054	77,276
Accumulated deficit	(60,926)	(44,945)
Accumulated other comprehensive loss	(1,519)	(1,327)
Total shareholders' equity	45,624	31,017
Total liabilities and shareholders' equity	$ 59,613	$ 42,294

See accompanying notes.

PENWEST PHARMACEUTICALS CO.

CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	YEAR ENDED DECEMBER 31,		
	2001	2000	1999
Revenues			
Product sales	$ 34,778	$37,148	$36,768
Royalties and licensing fees	5,225	4,910	539
Total revenues	40,003	42,058	37,307
Cost of product sales	24,810	25,303	25,889
Gross profit	15,193	16,755	11,418
Operating expenses			
Selling, general and administrative	13,855	12,054	11,425
Research and product development	17,003	12,820	7,371
Total operating expenses	30,858	24,874	18,796
Loss from operations	(15,665)	(8,119)	(7,378)
Investment income	477	217	—
Interest expense	290	172	371
Loss before income taxes and cumulative effect of change in accounting principle	(15,478)	(8,074)	(7,749)
Income tax expense (benefit)	503	302	(68)
Loss before cumulative effect of change in accounting principle	(15,981)	(8,376)	(7,681)
Cumulative effect of change in accounting principle (Note 3)	—	(410)	—
Net loss	$(15,981)	$ (8,786)	$ (7,681)
Basic and diluted amounts per share:			
Loss before cumulative effect of change in accounting principle	$ (1.15)	$ (0.68)	$ (0.69)
Cumulative effect of change in accounting principle (Note 3)	—	(0.03)	—
Net loss	$ (1.15)	$ (0.71)	$ (0.69)
Weighted average shares of common stock outstanding	13,905	12,330	11,103
Pro forma amounts assuming the accounting change is applied retroactively:			
Net loss		$ (8,376)	$ (7,733)
Basic and diluted net loss per share		$ (0.68)	$ (0.70)

See accompanying notes.

PENWEST PHARMACEUTICALS CO.

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(in thousands)

	COMMON STOCK SHARES	COMMON STOCK AMOUNT	ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE LOSS	TOTAL
Balances, January 1, 1999	11,043	$11	$ 59,025	$(28,478)	$ (526)	$ 30,032
Net loss				(7,681)		(7,681)
Translation adjustments					(535)	(535)
Comprehensive loss						(8,216)
Issuance of common stock pursuant to stock compensation plans	80	—	539			539
Issuance of common stock pursuant to Stock Purchase Plan	26	—	154			154
Balances, December 31, 1999	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	12,670	13	77,276	(44,945)	(1,327)	31,017
Net loss				(15,981)		(15,981)
Translation adjustments					(244)	(244)
Unrealized gain on marketable securities					52	52
Comprehensive loss						(16,173)
Issuance of common stock — private placement	2,447	2	29,669			29,671
Issuance of common stock pursuant to stock compensation plans	149	—	985			985
Issuance of common stock pursuant to Stock Purchase Plan	11	—	124			124
Balances, December 31, 2001	15,277	$15	$108,054	$(60,926)	$(1,519)	$ 45,624

See accompanying notes.

PENWEST PHARMACEUTICALS CO.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	YEAR ENDED DECEMBER 31,		
	2001	2000	1999
Operating activities:			
Net loss	$(15,981)	$ (8,786)	$ (7,681)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	2,831	2,879	2,881
Amortization	265	213	189
Deferred income taxes	—	(18)	(353)
Deferred revenue	(10)	378	—
Deferred compensation	187	183	164
Stock compensation	119	105	142
Changes in operating assets and liabilities:			
Trade accounts receivable	1,926	(3,111)	(662)
Inventories	340	(547)	1,155
Accounts payable, accrued expenses and other	(729)	1,378	96
Net cash used in operating activities	(11,052)	(7,326)	(4,069)
Investing activities:			
Acquisitions of fixed assets, net	(955)	(1,412)	(1,116)
Intangible asset costs	(1,078)	(507)	(490)
Purchases of marketable securities	(11,511)	—	—
Proceeds from maturities of marketable securities	2,000	—	—
Net cash used in investing activities	(11,544)	(1,919)	(1,606)
Financing activities:			
Borrowings from credit facility	29,616	2,800	11,600
Repayments of credit facility	(26,947)	(9,500)	(7,100)
Issuance of common stock, net	30,661	17,454	551
Net cash provided by financing activities	33,330	10,754	5,051
Effect of exchange rate changes on cash and cash equivalents	(35)	(44)	(113)
Net increase (decrease) in cash and cash equivalents	10,699	1,465	(737)
Cash and cash equivalents at beginning of year	2,204	739	1,476
Cash and cash equivalents at end of year	$ 12,903	$ 2,204	$ 739

See accompanying notes.

PENWEST PHARMACEUTICALS CO.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. BUSINESS

Penwest Pharmaceuticals Co. ("Penwest" or the "Company") is engaged in the research, development and commercialization of novel drug delivery technologies. The Company is also a leader in the development, manufacture, and distribution of branded pharmaceutical excipients which are the inactive ingredients in tablets and capsules. Based on its fundamental expertise in tabletting ingredients, the Company has developed its proprietary TIMERx® controlled release drug delivery technology, which is applicable to a broad range of orally administered drugs, and ProSolv® a high functional excipient based on co-processing technology, which, among other things, improves the performance characteristics of tablets. The Company is also exploring and developing other drug delivery technologies. The Company had revenues in 2001, 2000, and 1999 of $40.0, $42.1, and $37.3 million, respectively. The Company has manufacturing facilities in Iowa and Finland and has customers primarily throughout North America and Europe.

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.

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, 2001 and, based on anticipated levels of operations, management expects operating losses and negative cash flows during 2002 and 2003. Management anticipates that its existing capital resources as well as internally generated funds will be sufficient to fund operations through the first quarter of 2003. 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.

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 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.

Certain other amounts in the financial statements for prior years have been reclassified to conform with the current year presentation. These reclassifications had no effect on previously reported results of operations or financial position.

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. One customer of the Company accounted for approximately 12% and 19% of total revenues in 2001 and 2000, respectively. No customers

of the Company accounted for 10% or more of total revenues in 1999.

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 credit facility (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

The Company systematically reviews the recoverability of its long-lived and intangible assets by comparing the unamortized carrying value of such assets to the related anticipated undiscounted future cash flows. Any impairment related to long-lived assets is measured by reference to the assets' fair market value, and any impairment related to goodwill is measured against discounted cash flows. Impairments are charged to expense when such determination is made.

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, 2001.

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 unrealized gains on marketable securities and foreign currency translation adjustments. Comprehensive loss for the years ended December 31, 2001, 2000, and 1999 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 2001, 2000, and 1999, 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 the Company is obligated to supply inventory for manufacture when the development risk has substantially ended. 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. 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 2001, 2000, and 1999, as the effects would be antidilutive.

Stock Based Compensation

The Company accounts for stock option grants in accordance with Accounting Principles Board Opinion ("APB") No. 25, "Accounting for Stock Issued to Employees," and, accordingly, recognizes no compensation expense for stock options granted for which the exercise price of the options was the same as the market price of the Company's common stock on the date of grant. The Company has elected to continue to account for its employee stock compensation plans under APB No. 25. As prescribed under SFAS No. 123, "Accounting for Stock Based Compensation," the Company has disclosed in Note 11, the pro forma effects on net loss and loss per share of recording compensation expense for the fair value of the options granted.

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 the Company is obligated to supply inventory for manufacture, when the development risk has substantially ended. 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. 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, 2001 and 2000, the Company recognized $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 June 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standard ("SFAS") No. 141, "Business Combinations" and SFAS No. 142, "Goodwill and Other Intangible Assets" effective for fiscal years beginning after December 15, 2001. Under the new rules, goodwill will no longer be amortized but will be subject to annual impairment tests. Other intangible assets will continue to be amortized over their estimated useful lives. The Company will apply the new rules on accounting for goodwill and other intangible assets beginning in the first quarter of 2002. The adoption of the new standards is not expected to have a material effect on the results of operations, financial position, or cash flows of the Company.

In October 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets". SFAS No. 144 supersedes FAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of." The primary objectives of FAS No. 144 are to develop one accounting model based on the framework established in FAS No. 121 for long-lived assets to be disposed of by sale, and to address significant implementation issues. The Company's adoption of FAS No. 144 in the first quarter of 2002 is not expected to have a material effect on the results of operations, financial position, or cash flows of the Company.

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 marketed securities at December 31, 2001 are as follows:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
		(IN THOUSANDS)		
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, 2001, are as follows (in thousands):

Contractual maturity:	
Maturing in one year or less	$5,371
Maturing after one year through two years	4,238
Total debt securities	$9,609

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, pharmaceutical excipients held for distribution, including manufactured bulk TIMERx, are stated at the lower of cost (first-in, first-out) or market.

Inventories are summarized as follows:

	DECEMBER 31	
	2001	2000
	(IN THOUSANDS)	
Raw materials	$1,558	$2,611
Finished products	6,299	5,585
Total inventories	$7,857	$8,196

Included in inventories are approximately $191,000 and $466,000 of TIMERx raw materials and bulk TIMERx as of December 31, 2001 and 2000, respectively. The ability to continue to sell TIMERx related inventory is dependent, in part, upon the commercialization of products by third parties utilizing bulk TIMERx and the continued use by the Company and third parties of the TIMERx related inventory in existing and new research efforts.

The Company periodically reviews and quality tests its inventory to identify obsolete, slow moving or otherwise unsaleable inventories. Inventories at December 31, 2001 and 2000, are net of allowances of $255,000 and $26,000, 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.

7. FIXED ASSETS

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

	DECEMBER 31,	
	2001	2000
	(IN THOUSANDS)	
Buildings, equipment and software	$34,264	$33,844
Land	696	696
Construction in progress	700	441
	35,660	34,981
Less: accumulated depreciation	20,093	17,508
	$15,567	$17,473

8. INTANGIBLE ASSETS

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

	DECEMBER 31,	
	2001	2000
	(IN THOUSANDS)	
Patents, net of accumulated amortization of $770 and $640	$3,545	$2,827
Goodwill, (included in other assets) net of accumulated amortization of $540 and $468	--	72

Patents include costs to secure patents on technology developed by the Company and secure trademarks. Patents are amortized on a straight-line basis over their useful lives of 17 to 20 years. Amortization expense of $193,000, $155,000, and $131,000 was recorded in the years ended December 31, 2001, 2000, and 1999, respectively.

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 quarter of 2001, the Company recorded an impairment loss of $167,000, net of accumulated amortization, relating to its patents. Such impairment loss is reflected in research and product development expense on the consolidated statement 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. Amortization expense 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 $2,738,000 and $2,623,000 as of December 31, 2001 and 2000, respectively.

10. 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.

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.

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, 2001, the interest rate on the Revolver was 5.75% and approximately $2.7 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).

Approximately $214,000, $147,000, and $303,000, of interest was paid in 2001, 2000, and 1999, respectively.

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 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 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.

	SHARES	OPTION PRICE RANGE	WTD. AVERAGE EXERCISE PRICE
BALANCE, DECEMBER 31, 1998	1,694,688	$ 3.70 - 8.67	$ 6.21
1999			
Granted	332,307	$ 4.78 - 9.21	$ 7.33
Exercised	(85,160)	$ 5.26 - 7.03	$ 6.19
Cancelled	(35,092)	$ 5.26 - 6.75	$ 6.35
Balance, December 31, 1999	1,906,743	$ 3.70 - 9.21	$ 6.41
Options Exercisable	722,818	$ 3.70 - 9.21	$ 6.00
2000			
Granted	597,925	$7.35 - 14.38	$11.82
Exercised	(105,302)	$ 4.06 - 8.67	$ 5.98
Cancelled	(136,010)	$5.26 - 12.75	$ 7.59
Balance, December 31, 2000	2,263,356	$3.70 - 14.38	$ 7.77
Options Exercisable	1,072,947	$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	(230,000)	$6.38 - 11.81	$11.72
Balance, December 31, 2001	2,280,015	$3.70 - 18.18	$ 8.26
Options Exercisable	1,381,264	$3.70 - 14.38	$ 7.28

Stock Compensation

Statement of Financial Accounting Standard No. 123 "Accounting for Stock Based Compensation" requires the Company to disclose the pro forma impact on net loss and loss per basic and diluted share as if compensation expense associated with employee stock options granted to employees of Penwest had been calculated under the fair value method of SFAS No. 123 as follows:

	YEARS ENDED DECEMBER 31,		
	2001	2000	1999
	(IN THOUSANDS, EXCEPT PER SHARE DATA)		
Net loss — as reported	$(15,981)	$(8,786)	$(7,681)
Net loss — pro forma	$(17,602)	$(9,579)	$(9,286)
Net loss per share, basic and diluted — as reported	$ (1.15)	$ (0.71)	$ (0.69)
Net loss per share, basic and diluted — pro forma	$ (1.27)	$ (0.78)	$ (0.84)

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

	2001	2000	1999
Expected dividend yield	None	None	None
Risk free interest rate	5.5%	6.1%	5.80%
Expected volatility	52%	82%	75%
Expected life of options	7.5 years	7.5 years	7.5 years

The weighted average fair value of options granted during the years ended December 31, 2001, 2000, and 1999, was $8.03, $11.92, and $5.73, respectively. The weighted average remaining contractual life of options outstanding at December 31, 2001 is 8.2 years. The weighted effect of applying SFAS No. 123 for providing pro forma disclosures for the years ended December 31, 2001, 2000, and 1999, 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.

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 10,696 shares, 20,415 shares, and 25,930 shares issued under the Plan during 2001, 2000, and 1999, 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 $683,000, $583,000, and $343,000 for the years ended December 31, 2001, 2000, and 1999, respectively.

Future minimum lease payments as of December 31, 2001 for noncancellable operating leases having initial lease terms of more than one year are as follows:

	OPERATING LEASES (IN THOUSANDS)
2002	$ 760
2003	696
2004	627
2005	307
2006	302
Thereafter	51
Total minimum lease payments	$2,743

13. INCOME TAXES

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

	2001	2000	1999
		(IN THOUSANDS)	
Federal:			
Deferred	$ —	$ —	$(218)
Foreign:			
Current	473	290	283
Deferred	—	(18)	(87)
State:			
Current	30	30	2
Deferred	—	—	(48)
	$503	$302	$ (68)

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

	2001	2000	1999
Statutory tax rate	(34)%	(34)%	(34)%
Valuation allowance	40	36	35
Foreign taxes	(1)	1	(1)
Other	(2)	1	(1)
	3%	4%	(1)%

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

	2001	2000
	(IN THOUSANDS)	
Receivable allowance	$ (85)	$ (91)
Inventory reserves and basis differences	(331)	(185)
Deferred compensation and SERP liability	(1,047)	(975)
Deferred revenue	(142)	(146)
Tax credit carryforward	(467)	(149)
Net operating loss carryforwards	(16,021)	(8,999)
Other	(164)	—
Total deferred tax assets	(18,257)	(10,545)
Depreciation and amortization	3,232	3,302
Other	337	102
Total deferred tax liabilities	3,569	3,404
Net deferred tax asset before valuation allowance	(14,688)	(7,141)

	2001	2000
	(IN THOUSANDS)	
Valuation allowance	14,893	7,346
Net deferred tax liability	$ 205	$ 205

The Company's income tax payments, primarily comprised of foreign income taxes, approximated $342,000, $371,000, and $243,000, for the years ended December 31, 2001, 2000, and 1999, respectively.

At December 31, 2001, the Company has federal net operating loss ("NOL") carryforwards of $41,482,000 for income tax purposes, of which approximately $6,188,000, $8,407,000, $9,135,000, and $17,752,000 expire in 2018, 2019, 2020, and 2021, respectively. In addition, the Company has research and development tax credit carryforwards of approximately $455,000, of which $149,000 and $306,000 expire in 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, 2001, a valuation allowance of $14.9 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 $5,043,000, $3,794,000, and $3,372,000 as of December 31, 2001, 2000, and 1999, respectively. If such earnings were to be repatriated, the income tax effect would not be significant.

Included in the loss before income taxes is foreign income of $1,651,000, $977,000, and $971,000, for the years ended December 31, 2001, 2000, and 1999, respectively.

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 $227,000, $237,000, and $212,000 for 2001, 2000, and 1999, 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 2001, 2000, or 1999.

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 2001, 2000, and 1999, the net expense for the SERP incurred by Penwest was $125,000, $122,000, and $141,000, 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):

	2001	2000
Benefit obligation at beginning of period	$1,453	$1,318
Service cost	(19)	(16)
Interest cost	108	97
Actuarial gains	38	54
Benefit obligation at December 31	$1,580	$1,453

Funded status (in thousands):

	2001	2000
Funded status (unfunded)	$(1,580)	$(1,453)
Unrecognized net transition obligation	160	220
Unrecognized prior service cost	51	99
Unrecognized net actuarial gain	(550)	(661)
Net amount recognized at December 31, (included in deferred compensation)	$(1,919)	$(1,795)

Components of net periodic benefit cost (in thousands):

	2001	2000
Service cost	$ (19)	$ (16)
Interest cost	108	97
Amortization of unrecognized transition obligation	60	60
Amortization of prior service cost	49	63
Amortization of gains	(73)	(82)
Net periodic benefit cost	$125	$122

The Plan's accumulated benefit obligation at December 31, 2001 and 2000 was $1,356,000 and $1,216,900, respectively. The Company's benefit obligation was measured using a weighted average discount rate of 7.25% and 7.50% in 2001 and 2000, respectively, and a compensation increase of 4% and 3%, in 2001 and 2000, 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 $732,000, $682,000, and $491,000, in 2001, 2000, and 1999, respectively.

15. LICENSING AGREEMENTS

The Company enters into collaborative arrangements with pharmaceutical companies to facilitate and expedite the commercialization of its TIMERx drug delivery technology.

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 (the "Endo Product"). Endo is a fully integrated specialty pharmaceutical company with a market leadership in pain management. Endo has a broad product line including 12 branded products that include the 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 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"). However, the Company formulated the Endo Product and Endo is conducting all clinical studies and will prepare and file all regulatory applications and submissions. The Company has agreed to manufacture and supply TIMERx material to Endo, and Endo has agreed to manufacture and market the Endo Products in the United States. The manufacture and marketing of the Endo Product outside of the United States may be conducted by the Company, Endo or a third party, as determined by the Alliance Committee. The strategic alliance agreement may be terminated upon a material breach of the agreement by a party.

The Company and Endo share the costs involved in the development and commercialization of the Endo Product and have agreed that the party marketing the Endo Product will pay the other party royalties initially equal to 50% of net profits (as defined in the agreement). This percentage will decrease if the total U.S. net profits exceed pre-determined thresholds. This cost-sharing is subject to each party's right to terminate its participation in the funding of development and commercialization of the Endo Product. In general, the royalty payable by the marketing party to the other party will not drop below 40%; however, a one-third royalty reduction provision does apply in limited circumstances, including material breaches of the agreement by the royalty receiving party and certain bankruptcy and insolvency events involving the royalty receiving party. Endo will purchase formulated TIMERx material for use in the Endo Product 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 2001 of the 30 mg dosage strength version of Pfizer's generic Procardia XL totaled approximately $48.2 million. The term of this agreement continues until such time as Mylan permanently ceases to market generic Procardia XL.

Approximately $16,093,000, $12,102,000, and $6,429,000, for the years ended December 31, 2001, 2000, and 1999, 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.

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 fiscal years ended December 31, 2001, 2000, and 1999 were as follows:

	NORTH AMERICA	FINLAND	OTHER	ELIMINATIONS	TOTAL
			(IN THOUSANDS)		
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
DECEMBER 31, 1999					
Total Revenues	$35,290	$5,490	$4,038	$(7,511)	$37,307
Long-lived Assets	$23,377	$ 650	$ 34		$24,061

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. QUARTERLY FINANCIAL DATA (UNAUDITED)

Summarized quarterly financial data for the years ended December 31, 2001 and 2000 is as follows (in thousands, except per share data):

	Quarter Ended			
	March 31, 2001 (Unaudited)	June 30, 2001 (Unaudited)	Sept. 30, 2001 (Unaudited)	Dec. 31, 2001 (Unaudited)
Total revenues	$10,939	$ 9,515	$ 9,801	$ 9,748
Gross profit	4.376	3,698	3,633	3,486
Net loss	$ (2,123)	$(3,166)	$(4,125)	$(6,567)
Net loss per share	$ (0.17)	$ (0.25)	$ (0.28)	$ (0.43)

	Quarter Ended			
	March 31, 2000 (Unaudited)	June 30, 2000 (Unaudited)	Sept. 30, 2000 (Unaudited)	Dec. 31, 2000 (Unaudited)
Total revenues	$11,375	$ 8,903	$11,224	$10,556
Gross profit	4.558	3,619	4,144	4,434
Loss before cumulative effect of change in accounting principle	(1,309)	(2,108)	(2,145)	(2,812)
Cumulative effect of change in accounting principle	(410)	—	—	—
Net loss	$ (1,719)	$(2,108)	$ (2,145)	$ (2,812)
Basic and diluted amounts per share:				
Loss per share before cumulative effect of change in accounting principle	$ (0.11)	$ (0.17)	$ (0.17)	$ (0.22)
Cumulative effect of change in accounting principle	(0.04)	—	—	—
Net loss per share	$ (0.15)	$ (0.17	$ 0.17)	$ (0.22)

SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS

PENWEST PHARMACEUTICALS CO.
DECEMBER 31, 2001

(IN THOUSANDS)

	Balance at Beginning of Period	Charged to Costs and Expenses	Charged to Other Accounts-Describe	Deductions-Describe		Balance at End of Period
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
Year ended December 31, 1999						
Allowance for Doubtful Accounts	$227	$ 32	—	$ 14	(a)	$245
Inventory Allowances	$132	$243	—	$ 98	(b)	$277

(a) Uncollectible accounts written off, net of recoveries.
(b) Disposals of unrecoverable inventory costs.

INDEX TO EXHIBITS

EXHIBIT NO.	DESCRIPTION
3.1*	Amended and Restated Articles of Incorporation
3.2**	Articles of Amendment to the Amended and Restated Articles of Incorporation filed on June 19, 1998.
3.3*	Amended and Restated Bylaws of the Company.
3.4**	Designation of Rights and Preference of Series A Junior Participating Preferred Stock of the Company filed on July 17, 1998.
4.1*	Specimen certificate representing the Common Stock.
4.2**	Form of Rights Agreement dated as of July 27, 1998 between the Company and the Rights Agent.
+10.1*	Product Development and Supply Agreement dated August 17, 1994 by and between the Registrant and Mylan Pharmaceuticals Inc. (“Mylan”)
+10.2*	Product Development and Supply Agreement dated August 3, 1995 by and between the Registrant and Mylan.
10.3	Intentionally Omitted.
+10.4*	Sales and Distribution Agreement dated January 3, 1997 by and between the Registrant and Mylan.
10.5**	Form of Separation and Distribution Agreement entered into between Registrant and Penford Corporation (“Penford”)
10.6	Intentionally Omitted.
+10.7*	Product Development, License and Supply Agreement dated February 28, 1997 by and between the Registrant and Sanofi Winthrop S.A., as amended.
+10.8*	Agreement dated May 26, 1995 by and between the Registrant and Leiras OY.
+10.9*	Agreement dated July 27, 1992 by and between the Registrant and Leiras, OY.
+10.10*	Strategic Alliance Agreement dated as of September 17, 1997 by and between the Registrant and Endo Pharmaceuticals Inc.
10.11*++	1997 Equity Incentive Plan.
10.12*++	1997 Employee Stock Purchase Plan.
10.13*++	1998 Spinoff Option Plan.
10.14*	Form of Excipient Supply Agreement entered into between the Registrant and Penford.
10.16**	Form of Tax Allocation Agreement entered into between the Registrant and Penford.
10.18*	Recognition and Incentive Agreement dated as of May 14, 1990 between the Registrant and Anand Baichwal, as amended.
+10.19**	License Agreement dated December 17, 1997 between Synthelabo and the Registrant.
+10.20**	Supply Agreement dated December 17, 1997 between Synthelabo and the Registrant.

EXHIBIT NO.	DESCRIPTION
10.22***	Manufacturing Agreement dated September 27, 2001 between the Company and Draxis Pharma, Inc.
21.1*	Subsidiaries.
23	Consent of Ernst & Young LLP.
24	Power of Attorney.

* Incorporated by reference to Exhibits to the Registrant's Registration Statement on Form S-1 (File No. 333-38389).

** Incorporated by reference to Exhibits to the Company's Registration Statement on Form 10 filed with the Commission on June 22, 1998 and July 31, 1998.

*** Incorporated by reference to Exhibits to the Company's Quarterly Report on Form 10Q (No.000-23467) for the quarterly period ended September 30, 2001.

\+ Confidential treatment granted as to certain portions, which portions are omitted and filed separately with the Commission.

++ Management contract or compensatory plan or arrangement required to be filed as an exhibit to this annual report on Form 10-K.