2007 Annual Report

Dear Fellow Shareholders,

2007 was a year of mixed results for Penwest. Internally, we made important progress in several key areas, which I believe is significant to our Company's long-term growth prospects and the diversification of our business. At the same time, we were affected by certain events, largely external to our operations, that negatively impacted our share price. I will address both the positives of this year, as well as how we are responding to particular issues that arose.

Sales Growth of Opana® ER

Sales of Opana ER, which is marketed by our partner Endo Pharmaceuticals, continued to grow over the course of the year. For 2007, the first full calendar year of sales, Endo reported net sales of $107 million for the Opana franchise. The Opana franchise includes both an immediate release product as well as an extended release (ER) product, which is the product we co-developed with Endo using our Timerx technology. According to IMS, Opana ER represents approximately 78% of these sales. Furthermore, monthly script trends for Opana ER have continued to grow steadily into 2008, and Endo continues to dedicate significant corporate resources to the growth of the product. For example, in the fourth quarter of 2007, Endo increased its specialty sales force by an additional 95 representatives, bringing its total sales force at year end to 690 representatives – and Opana ER is in the first detail position for the majority of this sales force. Based on Opana ER's current growth and Endo's sales forecast for 2008, we anticipate that Penwest will begin to receive royalty payments from Endo in the second half of 2008.

One challenge we faced in 2007 with Opana ER was the threat of generics. In late 2007, we listed three additional patents in the Orange Book for this product. However, in late 2007 and early 2008, Penwest and Endo were notified by two generic companies that the FDA had accepted their Abbreviated New Drug Applications (ANDAs) for generic versions of Opana ER that contained Paragraph IV Certifications against our Orange Book listed patents. In response, Penwest and Endo jointly filed lawsuits against both of these companies for patent infringement. We believe that we are entitled to a 30-month stay against the first generic filer under the Hatch Waxman Act expiring in June 2010.

Protecting the intellectual property around Opana ER is a top priority for both Endo and Penwest, and we intend to pursue all available legal and regulatory avenues defending Opana ER. In this regard, both Penwest and Endo are diligently prosecuting additional patent applications covering Opana ER that, if issued, would further strengthen its patent protection.

In addition to defending and strengthening Opana ER's intellectual property estate, Endo has an active life cycle management program for the product, the first step of which was the launch during the first quarter of 2008 of three new strengths of Opana ER. Penwest and Endo are collaborating further on continuing efforts to enter into an alliance for Opana ER in Europe under which a partner would obtain regulatory approval and market this drug in Europe. Under our agreement with Endo, we share worldwide rights to Opana ER and will share equally in the proceeds and economic benefits of any deal that is signed.

Opana ER is an important financial asset for Penwest, and we continue to collaborate with Endo to ensure that we realize the full potential value of this product.

Progress of Product Pipeline

Penwest has a clear, well defined growth strategy: to leverage our capabilities in drug delivery and drug formulation to develop a portfolio of products targeting disorders of the nervous system. We made important progress during 2007 in advancing our own evolving internal product pipeline, with current development programs in the areas of pain, Parkinson's disease, and mitochondrial respiratory chain disorders. Our portfolio includes existing drugs with enhanced clinical profiles, which we plan to develop using the 505(b)2 regulatory pathway, as well as selected new chemical entities in niche neurological orphan diseases. We firmly believe that by improving upon existing drugs and developing new chemical entities in tandem, we help balance the risk and reward in our portfolio and provide strong support for our go-to-market strategy in neurology.

Our lead program is nalbuphine ER, which we are developing for the treatment of moderate chronic pain. This is a product that is currently available in an acute hospital setting as a subcutaneous injection, which we are developing for oral administration. We believe the profile of nalbuphine ER may be attractive in the treatment of moderate chronic pain compared to current options because it should provide a better balance of stronger efficacy, low abuse potential and low side effects.

We are pleased with the development of this product to date: we have finalized formulations for four different strengths, conducted several Phase I studies characterizing the formulation, and completed two Phase II trials in acute and chronic pain to establish the proof of concept, both safety and efficacy, for the product. We believe the results of the Phase II trials support trends of efficacy for nalbuphine ER across multiple endpoints and patient populations and indicate that the drug appears to be safe. We are planning for a Phase IIb trial that we expect to commence in the second half of 2008, subject to the availability of capital resources to conduct such a study. In parallel with our development effort in the U.S., we are pursuing licensing

discussions with potential partners in Europe, who can bring pain expertise in the region and share the financial risk of development.

In July 2007, we entered into a collaboration and licensing agreement with Edison Pharmaceuticals. Under this agreement, we are developing A0001, a small molecule that can be delivered orally, which we believe could have the potential to treat defects in the mitochondrial respiratory chain pathway. These defects are strongly associated with several orphan progressive neurodegenerative disorders that are both chronic and serious in nature. There are currently no approved therapies for most of these disorders, and A0001 has received orphan drug designation from the FDA for the treatment of inherited mitochondrial respiratory chain diseases. We have completed the early toxicology studies for A0001, and we anticipate submitting an IND and beginning our Phase I safety program by mid-year. At the same time, we are planning the clinical strategy for this molecule and are already working with investigators in several different patient populations.

In addition to our efforts on nalbuphine ER and A0001, we are engaged in ongoing formulation work on a compound – one to treat Parkinson's disease which we plan to advance this year.

All in all, we are very excited about the products in our pipeline and believe each of them has the ability to fulfill unaddressed medical needs in the marketplace and present commercially meaningful opportunities for Penwest.

Financial Outlook

While we are enthusiastic about the potential of the product candidates in our pipeline, we do recognize the financial realities within which we must operate the Company. In addition to our existing operating cash burn, capital has become very expensive in the current financial environment. We have been, and plan to continue to be, disciplined about reducing all non-essential spending within the Company and will pace the development of our own internal portfolio at an affordable rate. We recently raised approximately $23 million, net of expenses, through an equity financing. Based on our expectations regarding third party royalties, our goal is to fund our ongoing operations until at least the second half of 2009.

Priorities for 2008

With 2008 now well underway, we are excited about the growth potential for Opana ER as well as advancing our pipeline of drugs through tangible milestones. To that end, our priorities for 2008 are to:

- Advance our existing pipeline while retaining ownership of the neurology products;
- Continue to prosecute additional patents around Opana ER, as well as to support Endo's life cycle management initiatives for the product;
- Complete our licensing efforts related to Opana ER in Europe and secure a European partner for nalbuphine ER;
- Leverage the value of our drug delivery technology by completing technology licensing agreements to help fund the overhead of our drug development team and provide additional potential revenue sources; and
- Aggressively manage our cash to ensure that our operations are adequately funded into the second half of 2009.

Board of Directors

During 2007, we welcomed three outstanding individuals to Penwest's Board of Directors: David P. Meeker, M.D., president of the Lysosomal Storage Diseases Therapeutics Business Unit of Genzyme Corporation; W. James O'Shea, former vice chairman of Sepracor, Inc.; and Christophe Bianchi, M.D., Executive Vice President and Head of Commercial Operations at Millennium Pharmaceuticals, Inc. We are pleased that they have joined Penwest and are already benefitting from their experience and expertise.

As we welcome these new members to the Board, we thank one of our founding directors, Rolf Henel, who retired this past year after 10 years of service. Rolf was an active contributor who brought a wealth of experience and contacts to our Company. During his tenure, he served on the Audit Committee, the Nominating and Governance Committee and as Chairman of the Compensation Committee. He was a vocal advocate of strong corporate governance and the role the Board plays in ensuring active oversight. Rolf made a meaningful impact at Penwest; we are grateful for his time and contributions, and wish him the very best.

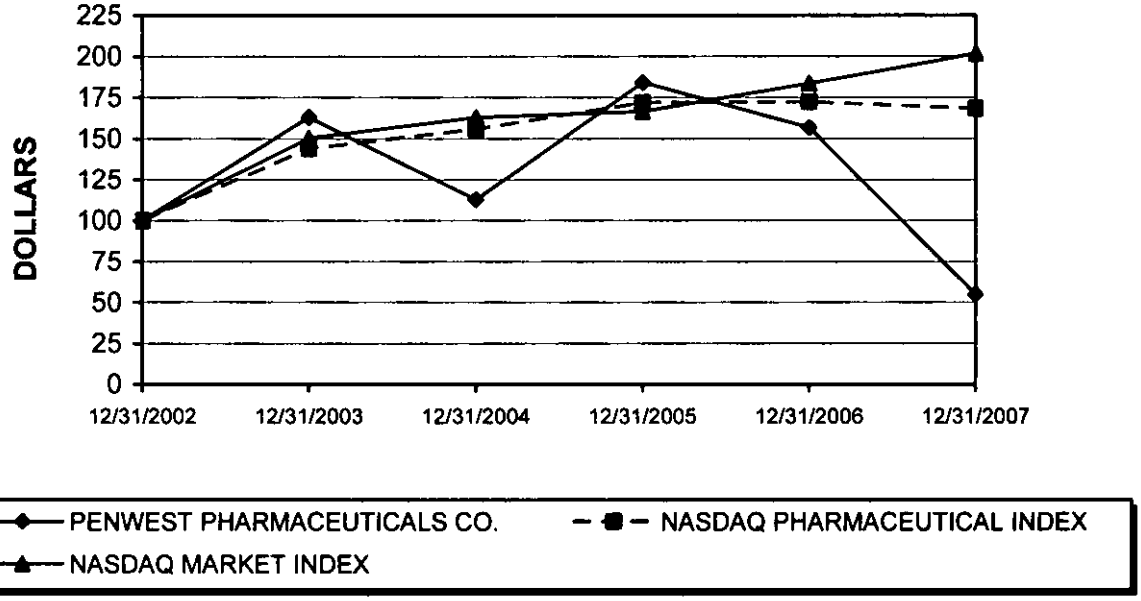
In 2008, the Company's management team and employees are focused on continuing to address our challenges and creating opportunities for growth. As always, we rely on the talent and hard work of the employees of Penwest to accomplish our goals, and we thank them for their contributions. And we thank you, our shareholders, for your continued support and we look forward to keeping you apprised of our progress.

Sincerely,

Jennifer L. Good

President and Chief Executive Officer

COMPARISON OF 5-YEAR CUMULATIVE TOTAL RETURN
AMONG PENWEST PHARMACEUTICALS CO.,
NASDAQ MARKET INDEX AND NASDAQ PHARMACEUTICAL INDEX



ASSUMES $100 INVESTED ON DECEMBER 31, 2002
ASSUMES DIVIDEND REINVESTED
MEASUREMENT POINTS ARE ON THE LAST TRADING DAYS OF THE YEARS ENDED DECEMBER 31, 2003, DECEMBER 31, 2004, DECEMBER 31, 2005, DECEMBER 31, 2006 AND DECEMBER 31, 2007

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, 2007

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	**91-1513032**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
39 Old Ridgebury Road Suite 11 Danbury, Connecticut	**06810-5120**
(Address of Principal Executive Offices)	*(Zip Code)*

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

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

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, par value $.001 (Including Associated Preferred Stock Purchase Rights)	The NASDAQ Stock Market

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated filer ☑ Non-accelerated filer ☐ Smaller reporting company ☐
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☑

The aggregate market value of the Registrant's Common Stock held by non-affiliates as of June 29, 2007 was approximately $287,619,000 based on the last sale price of the Registrant's Common Stock on the Nasdaq National Market on June 29, 2007. The number of shares of the Registrant's Common Stock outstanding as of March 11, 2008 was 31,621,039

DOCUMENTS INCORPORATED BY REFERENCE

Portions of our definitive Proxy Statement relating to the 2008 Annual Meeting of Shareholders to be held on June 11, 2008 are incorporated by reference into Part III of this Form 10-K.

PENWEST PHARMACEUTICALS CO.

INDEX TO FORM 10-K

Forward Looking Statements

This annual report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. All statements, other than statements of historical facts, included or incorporated in this report regarding our strategy, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words "believes," "anticipates," "estimates," "plans," "expects," "intends," "may," "projects," "will," and "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. There are a number of important factors that could cause our actual results to differ materially from those indicated or implied by forward-looking statements. These important factors include those set forth under "Risk Factors" in Item 1A. In addition, any forward-looking statements represent our estimates only as of the date this annual report is filed with the SEC and should not be relied upon as representing our estimates as of any subsequent date. We do not assume any obligation to update any forward-looking statements.

PART I

ITEM 1. *BUSINESS*

Overview

We are a drug development company dedicated to bringing to the marketplace innovative products that help improve the lives of patients. Our goal is to identify, develop and commercialize products that address unmet medical needs, primarily for disorders of the nervous system. We are currently applying our drug development and drug delivery expertise to a pipeline of potential products that are in various stages of development, and that we intend to commercialize independently or through third party alliances.

On June 22, 2006, the United States Food and Drug Administration, or FDA, approved Opana® ER. Opana ER, an extended release formulation of oxymorphone hydrochloride, is a product that we developed with Endo Pharmaceuticals Inc., or Endo, using our proprietary TIMERx® drug delivery technology. Opana ER is approved for twice-a-day dosing in patients with moderate to severe pain requiring continuous, around-the-clock opioid therapy for an extended period of time and is being marketed by Endo in the United States.

We are currently developing product candidates designed for the treatment of pain, epilepsy, Parkinson's disease and diseases related to the mitochondrial respiratory chain. We are developing nalbuphine ER, a controlled release formulation of nalbuphine hydrochloride, for the treatment of moderate chronic pain. In addition, we are developing A0001, a product candidate designed for the treatment of inherited mitochondrial respiratory chain diseases, under a collaboration and license agreement with Edison Pharmaceuticals, Inc., or Edison, that we entered into in July 2007. Under the Edison agreement, we have agreed with Edison to collaborate on the development of A0001 and up to one additional drug candidate of Edison's, initially for the treatment of inherited mitochondrial respiratory chain diseases. Finally, we have two other product candidates in formulation development for the treatment of epilepsy and Parkinson's disease, respectively.

Our strategy includes developing drug candidates to treat disorders of the nervous system. We expect to leverage our expertise in drug formulation and drug development to advance these products. We also expect to expend resources on product candidates obtained through in-licenses or acquisitions. Our spending in this area, however, is discretionary and is subject to identifying appropriate opportunities, as well as the availability of funds from our operations, cash resources, collaborative research and development arrangements, and external financing.

Products

Opana® ER. Opana ER is an oral extended-release opioid analgesic, which we developed with Endo using our proprietary TIMERx® technology. In June 2006, the FDA approved for marketing Opana ER for twice-a-day dosing in patients with moderate to severe pain requiring continuous, around-the-clock opioid therapy for an extended period of time. Under the terms of our strategic alliance agreement with Endo, Endo is responsible for the marketing of Opana ER in the United States. Endo launched Opana ER in the United States in July 2006 in 5 mg, 10 mg, 20 mg and 40 mg tablets. In March 2008, Endo announced the launch of three new dosage strengths of Opana ER, 7.5 mg, 15 mg and 30 mg. Under the terms of the agreement with Endo, any fees, royalties payments or other revenues received by the parties in connection with any collaborator outside of the United States will be divided equally. We and Endo are currently seeking a collaborator for Opana ER in Europe. Opana ER has not been approved in Europe.

In January 2007, we entered into an amendment to the strategic alliance agreement between us and Endo. Under the terms of this amendment, we and Endo agreed that royalties payable to us for U.S. sales of Opana ER would be calculated based on net sales of the product rather than on operating profit. We expect Endo to initiate the payment of royalties to us on U.S. sales of Opana ER in the second half of 2008. A description of this amendment is included below under the caption "Collaborative Agreements."

Opana ER competes in the market for long acting, strong opioid analgesics with products such as Purdue Pharma's OxyContin® and MS Contin, Johnson and Johnson's Duragesic® patch, King Pharmaceuticals' Avinza® and Alpharma's Kadian®, as well as generic versions of some of these products. Products in the long acting, strong opioids market had aggregate sales in the United States in 2007 of approximately $4.1 billion.

We and Endo are parties to two lawsuits against Impax Laboratories, Inc., or IMPAX, in connection with IMPAX's Abbreviated New Drug Application, or ANDA, for Opana ER in four strengths, 5 mg, 10 mg, 20 mg and 40 mg. IMPAX notified Endo and us in October and November of 2007 that its ANDA contained Paragraph IV certifications for our patents, U.S. Patent Nos. 5,662,933, 5,958,456, and 7,276,250, listed in the Orange Book for Opana ER. We and Endo originally filed a lawsuit against IMPAX in the United States District Court for the District of Delaware, or U.S. Dist. Delaware, on November 15, 2007 alleging infringement of certain these patents, and seeking a declaratory judgment that, among other things, IMPAX had no basis to trigger the ANDA patent litigation process under the Hatch-Waxman Act because the FDA, according to IMPAX's press releases, had rescinded its acceptance of IMPAX's original ANDA before the date of IMPAX Paragraph IV certification notices. In addition, we and Endo asked the court to declare that these Paragraph IV certification notices to be null, void and of no legal effect.

On December 14, 2007, we received a letter from IMPAX notifying us that the refiling of its ANDA was accepted by the FDA as of November 23, 2007. The notice letter stated that IMPAX's ANDA contained Paragraph IV certifications for the three patents noted above and that the FDA had required IMPAX to notify Endo and us of these certifications. In this December notice, IMPAX also stated that it would not withdraw its prior Paragraph IV certification notices because it believed they were properly provided and because IMPAX was continuing its efforts to convince the FDA to assign an earlier filing date to its ANDA. As a result of the FDA's determination of IMPAX's ANDA filing date and the receipt of the new Paragraph IV certification notice, on December 20, 2007, we and Endo filed a notice of dismissal of the portion of our November 15, 2007 complaint seeking declaratory judgment as noted above. We and Endo did not dismiss the patent infringement claims in the November lawsuit because IMPAX refused to withdraw its prior Paragraph IV certification notices. On January 25, 2008, we and Endo filed a second lawsuit against IMPAX in U.S. Dist. Delaware, alleging infringement of two of these patents above in response to IMPAX's December notice. Given the FDA's acceptance of IMPAX's ANDA as of November 23, 2007, we believe that we are entitled to a 30-month stay under the Hatch-Waxman Act beginning on December 14, 2007. Endo and we intend to pursue all available legal and regulatory avenues defending Opana ER. A description of this litigation is included in "Part I. Item 3-Legal Proceedings."

On February 14, 2008, we received a notice from Actavis South Atlantic LLC, or Actavis, advising of the filing by Actavis of an ANDA containing a Paragraph IV certification under 21 U.S.C. Section 355(j) for Opana ER in four strengths, 5 mg, 10 mg, 20 mg and 40 mg. The Actavis Paragraph IV certification notice refers to our patents, U.S. Patent Nos. 5,128,143, 5,662,933, 5,958,456, and 7,276,250, which cover the formulation of Opana ER. These patents are listed in the FDA's Orange Book and expire in 2008, 2013, 2013 and 2023, respectively. We and Endo are currently reviewing the details of this notice from Actavis.

Nalbuphine ER. We are developing nalbuphine ER, a controlled release formulation of nalbuphine hydrochloride, for the treatment of moderate chronic pain. Nalbuphine ER, which we formulated using our TIMERx drug delivery technology, is designed to be taken as a tablet twice daily. Nalbuphine hydrochloride is a synthetic opioid agonist/antagonist analgesic that interacts with certain opioid receptors. The agonist/antagonist mechanism of action of nalbuphine ER may reduce the potential for abuse of nalbuphine ER. Nalbuphine hydrochloride is currently only available as a sterile solution suitable for subcutaneous, intramuscular or intravenous injection for acute pain under the brand name Nubain® and in a generic version. The annual sales of Nubain and its generic version were approximately $11.2 million in 2007, but we believe the market for nalbuphine hydrochloride is limited by currently available formulations of the drug. We expect that nalbuphine ER, if approved, would compete in the moderate chronic pain market. Physicians currently treat patients with moderate chronic pain with a range of treatments from non-steroidal anti-inflammatory drugs, or NSAIDs, to strong opioids. These treatments include products such as Tramadol® ER and products containing hydrocodone, codeine or propoxyphene, such as Vicodin and Darvon. We believe the profile of nalbuphine ER may be attractive in the treatment of moderate chronic pain compared to current options because it should provide a better balance of good efficacy, low abuse potential and low side effects.

We conducted multiple Phase I studies of various formulations of nalbuphine ER in 2005 to establish the pharmacokinetic profile and generate safety data. In December 2005, we completed a Phase IIa trial of nalbuphine ER designed to determine the degree and duration of pain relief of two different dose levels of

nalbuphine ER in an acute dental pain model. The goal of this study was to establish the proof of efficacy in oral dosing. Results from this Phase IIa study demonstrated that nalbuphine ER reduced mean pain intensity in a dose-dependent manner over the twelve-hour period of the study. No unusual side effects were reported during the twelve-hour dosing interval.

In 2006, we conducted some reformulation work to develop the product for chronic pain and conducted several Phase I studies. In January 2007, we commenced a Phase I dose escalation to steady state trial. The intent of this trial was to collect additional safety and pharmacokinetic information which was used to bridge the safety data from the acute pain trial we conducted in 2005 to a chronic pain trial we initiated in June 2007. The June 2007 Phase IIa trial was designed to determine the safety and efficacy of nalbuphine ER compared to placebo for treatment of moderate chronic pain. It was a randomized, double-blind, placebo controlled design, with a forced weekly dose escalation. The main objective of the trial was to evaluate the analgesic efficacy of nalbuphine ER in a patient population experiencing chronic pain. There were 138 patients in the intent-to-treat population with chronic pain secondary to osteoarthritis of the knee or hip. Patients enrolled in the trial were given the lowest dose of the drug for week one, increased to a mid-dose level for week two, and increased to the highest dose studied for week three. The study group included a 2-to-1 randomization of patients on drug versus placebo. We designed the trial with multiple endpoints related to clinical pain relief in an effort to understand the activity of the drug and provide the basis for designing a Phase IIb study. Based on the Phase IIa results, we have concluded that nalbuphine ER demonstrated trends of efficacy sufficient to support continued development of the drug. The adverse events were typical opioid-type side effects. In the study, 24% of the nalbuphine ER patients reported no side effects, 66% reported side effects that were characterized as mild or moderate in severity, and 10% reported side effects that were severe. No drug-related serious adverse events were reported during the trial. The adverse events in the trial appear to have occurred only in the first week of the trial and were not chronic adverse events that continued throughout the study.

We are planning for a Phase IIb trial which we expect to commence in the second half of 2008, subject to the availability of capital resources to conduct such study. We expect that the goals of the Phase IIb trial will be to demonstrate statistically significant analgesic efficacy of the drug versus placebo using an accepted clinical endpoint and to characterize a clinically meaningful titration regimen. We believe that this trial will take approximately one year to complete. We expect that if we complete all the clinical trials required by the FDA for nalbuphine ER, we would seek FDA approval through the filing of a 505(b)(2) NDA. We expect to seek collaborators in the United States and Europe to complete the development of this product and to share marketing rights with the collaborators.

A0001. A0001 is a drug candidate we in-licensed from Edison under our collaboration and license agreement with Edison. A0001, a coenzyme Q molecular analog, has shown biological activity in cell assays developed by Edison to test the ability of this class of compounds to improve mitochondrial function. Impairment of mitochondrial function is commonly believed to be a significant factor in a number of inherited disorders, including Friedreich's Ataxia, Leber's Hereditary Optical Neuropathy, Coenzyme Q10 Deficiency Syndrome and MELAS syndrome. A0001 is commonly known to be orally bioavailable in humans and has received orphan drug designation from the FDA for the treatment of inherited mitochondrial respiratory chain diseases. We have completed the Investigational New Drug Application, or IND, enabling toxicology studies for A0001 and we intend to submit an IND for certain of these indications and commence Phase 1 development on this compound in the second half of 2008.

Additional Product Candidates. We have two other product candidates in formulation development:

PW4153	Parkinson's disease
PW4110	Epilepsy

We are currently developing formulations and plan to conduct pilot scale Phase I clinical studies on these product candidates to obtain pharmacokinetic data. If the Phase I clinical studies of any of these product candidates show the desired plasma level profiles, we expect to advance the product candidate into further clinical trials after consideration of a number of factors, including our available resources at such time, the regulatory pathway and the development status of our other product candidates. We will also determine how to

advance the product, for example, whether to develop the product on our own and, if not, when to seek a collaborator.

In the third quarter of 2007, we completed a scientific review of our development programs, which we conducted to align our efforts with our corporate strategy and internal resources. As a result of this review, we determined to cease development of torsemide ER, a controlled release formulation of torsemide, that we were developing for the treatment of chronic edema resulting from congestive heart failure. In addition, we made the decision to cease efforts on two Phase I programs.

Under a collaboration agreement with Mylan Pharmaceuticals Inc., or Mylan, we developed Nifedipine XL, a generic version of Procardia XL, based on our TIMERx technology. In March 2000, Mylan announced that it had signed a supply and distribution agreement with Pfizer Inc., or Pfizer, to market Pfizer's generic versions of all three strengths (30 mg, 60 mg, 90 mg) of Procardia XL. In connection with that agreement, Mylan decided not to market Nifedipine XL, and agreed to pay us a royalty on all future net sales of the 30 mg strength of Pfizer's generic Procardia XL.

Our Strategy

Our business strategy is to build a drug development company that identifies, develops and commercializes products that address unmet medical needs, primarily for disorders of the nervous system. The elements of our strategy include:

- *Focus on products that address disorders of the nervous system.* We are focusing on products that address disorders of the nervous system. We believe the market for treating nervous system disorders is attractive because many of these disorders are chronic in nature and are largely treated by specialist physicians that can be addressed with a relatively small sales force. In addition, we believe many of the currently approved products for the treatment of nervous system disorders can be enhanced by drug delivery technologies. If, however, we believe that we could develop a product that would address an unmet medical need and have a substantial market value, we may also selectively develop product candidates for disorders outside of the nervous system.
- *Develop product candidates that have the potential for at least five years of exclusivity in the marketplace.* We intend to expand our portfolio to include product candidates for which we or our collaborators could obtain at least five years of exclusivity in the marketplace following marketing approval. This exclusivity could arise from meeting certain regulatory criteria for market exclusivity with the FDA, for example, in connection with the approval of new chemical entities or orphan drugs, or from intellectual property protection.
- *Seek alternative regulatory pathway when appropriate.* When appropriate, we intend to utilize a "505(b)(2) regulatory strategy" to seek approval for products we develop by reformulating existing drugs utilizing proprietary drug delivery technologies. Under this strategy, we would file a section 505(b)(2) New Drug Application, or a section 505(b)(2) NDA, which would rely on the FDA's previous findings for the safety and effectiveness of the existing drug, in addition to the data we generate regarding our reformulated drug. Because a section 505(b)(2) NDA may rely on the FDA's previous findings, the trials that need to be conducted are generally more limited. Therefore, the development of a drug using the 505(b)(2) regulatory strategy is generally less costly and time consuming than the full NDA process.
- *Continue to leverage and expand our expertise in drug development and the use of our proprietary drug delivery technologies.* We believe that we have significant expertise in drug formulation and in oral drug delivery technologies. Our proprietary drug delivery technologies, TIMERx controlled release, Geminex® dual delivery, and SyncroDose® and Gastrodose™ site-specific deliveries are applicable to a wide range of drugs with different physical and chemical properties including water soluble and insoluble drugs, as well as high dose and low dose drugs. Using these technologies, we believe that we can formulate drugs with precise release profiles and improve the characteristics of existing drugs. We have made, and plan to continue to make, these technologies available to collaborators in traditional

drug delivery arrangements to leverage the potential breadth and financial value of our proprietary technologies.

- *Commercialize product candidates independently and in collaboration with third parties.* We currently do not have any sales infrastructure. Opana ER is marketed by Endo; other marketed products using our TIMERx technology are marketed by other collaborators. We expect that in the future, we will independently seek regulatory approval for most of our product candidates designed for the treatment of disorders of the nervous system. By retaining the rights to these products through approval, we believe that we can retain more value of such products if they are approved. In addition, we may retain marketing rights, or co-promotion rights, for our products that would be marketed to specialist physicians and build a relatively small specialty sales force to market these products. For those products that we selectively develop for the treatment of disorders outside of the nervous system, we plan to seek collaborators for the marketing of those products. The timing of seeking a collaborator will depend on a number of factors, including the costs of clinical development and our financing needs.

Drug Delivery Technologies

We currently have four proprietary drug delivery technologies: TIMERx, a controlled-release technology; Geminex, a technology enabling drug release at two different rates; SyncroDose, a technology enabling controlled release at the appropriate site in the body; and our GastroDose system, a technology enabling drug delivery to the upper gastrointestinal tract. We believe our drug delivery technologies have broad applicability across multiple therapeutic areas. To date, our TIMERx technologies have been used in four products that have received regulatory approval, one in the United States and the others in countries in Europe or South America.

TIMERx

We developed our proprietary TIMERx delivery technology to address some limitations of other oral drug delivery technologies. We believe that the TIMERx technology has advantages over other oral drug delivery technologies because it is readily manufactured, adaptable to soluble and insoluble drugs, and flexible for a variety of controlled release profiles. We continue to develop additional products in our pipeline using TIMERx and seek to outlicense the technology to third parties for products outside of our strategic focus.

The TIMERx drug delivery platform is based on a hydrophilic matrix combining a heterodispersed mixture composed primarily of two polysaccharides, xanthan gum and locust bean gum, in the presence of dextrose. Under the TIMERx delivery system, drug release is controlled by the rate of water penetration from the gastrointestinal, or GI, tract into the TIMERx gum matrix, which expands to form a gel and subsequently releases the active drug substance. We can precisely control the release of the active drug substance in a tablet using the TIMERx technology by varying the proportion of the gums, together with the tablet coating and the tablet manufacturing process. Drugs using TIMERx technology are formulated by combining the active drug substance, the TIMERx matrix and additional excipients, and compressing the mixture into a tablet.

Opana ER was formulated using our TIMERx technology. We have also developed the formulation for nalbuphine ER with our TIMERx technology. To date, several other drug formulations utilizing our TIMERx technology have received regulatory approval in the United States, United Kingdom, Italy and Finland. In the United States, Nifedipine XL, a generic version of Pfizer's Procardia® XL for the treatment of hypertension and angina that we developed with Mylan, is approved for sale. Mylan, which has the marketing rights for Nifedipine XL, is not marketing Nifedipine XL as a result of its acquisition from Pfizer of the right to market Pfizer's generic versions of three strengths of Procardia XL under Pfizer's NDA.

Geminex

Our patented Geminex dual release technology provides the independent release of one or more active ingredients in a single bi-layer tablet. The release of the active ingredients can be achieved at different rates involving two different controlled release profiles, or a controlled release and an immediate release profile. The technology is based on a bi-layer tablet that utilizes TIMERx matrix in the controlled release layer or layers.

SyncroDose

Our patented SyncroDose drug delivery system delivers the active drug substance within a specific site in the GI tract or at the optimal time after ingestion, which is referred to as chronotherapeutic delivery. We believe that there are several disease states that can benefit from chronotherapeutic delivery including arthritis, cardiovascular disorders, asthma, neurological disorders and site-specific diseases such as GI cancers. SyncroDose is a technology based on our underlying TIMERx technology. The SyncroDose technology utilizes the TIMERx gum matrix in the coating of the tablet.

GastroDose

We developed our gastroretentive drug delivery system to provide controlled delivery of drugs in the upper GI tract. Drugs delivered orally are mostly absorbed in the stomach and the upper portions of the GI tract. By targeting delivery in the part of the stomach where a drug is absorbed, we believe we can increase the bioavailability of the drug, which could result in increased efficacy or a lower required dose of the drug.

Collaborative Agreements

We enter into collaborative agreements with pharmaceutical companies to develop, market or manufacture some of our products. Under these agreements, we may jointly fund research and development with our collaborators. In some of these arrangements, we may pay up-front licensing fees or milestone payments and may agree to pay royalties on the sales of the products developed under these agreements. We may also license our TIMERx technology to collaborators who agree to be responsible for the development and marketing of a product using our technology in exchange for up-front licensing fees, milestone payments, and royalties on our collaborators' sales of the products covered by such collaborative arrangements. In some of these arrangements, we may be entitled to payments for the purchase of formulated TIMERx material by our collaborators.

In the future, we may enter into collaborative agreements involving the outlicensing of a product candidate after we complete some or all of the development work on the product candidate. We anticipate that we would receive up-front licensing fees, milestone payments and royalties. For those product candidates which we seek to license prior to a regulatory filing, we would expect the collaborator to fund some of the development costs, as well as to market or co-promote the products upon approval. In determining whether and when to enter into such a collaborative agreement for a product, we will consider the complexity, the risk and cost of the development program, the level of marketing information required during development and the diseases for which the drug is intended.

Endo Pharmaceuticals Inc.

In September 1997, we entered into a strategic alliance agreement with Endo with respect to the development of Opana ER. This agreement was amended and restated in April 2002, and was further amended in January 2007.

During the development of the product, we formulated Opana ER, and Endo conducted all clinical studies, and prepared and filed all regulatory applications. We agreed to supply bulk TIMERx material to Endo, and Endo agreed to manufacture and market Opana ER in the United States. We also agreed with Endo that any development and commercialization of Opana ER outside the United States would be accomplished through licensing to third parties approved by both Endo and us, and that we and Endo would divide equally any fees, royalties, payments or other revenue received by the parties in connection with such licensing activities. We and Endo are currently seeking a collaborator to develop and commercialize Opana ER in Europe.

Prior to April 17, 2003, we shared with Endo the costs involved in the development of Opana ER. On April 17, 2003, we exercised our option under the terms of the agreement and discontinued our participation in the funding of the development of Opana ER. As a result of this termination of funding, Endo completed the development of Opana ER and had the right to recoup the portion of development costs incurred by Endo that otherwise would have been funded by us, in accordance with the terms described below.

In January 2007, we entered into an amendment to the Endo agreement as part of the resolution of a dispute between the parties with regard to the sharing of marketing expenses during the period prior to when Opana ER reaches profitability. Under the terms of the amendment, we and Endo agreed that royalties payable to us for U.S. sales of Opana ER would be calculated based on net sales of the product rather than on operating profit. In connection with this change, we and Endo agreed:

- Endo would pay us royalties on U.S. sales of Opana ER calculated based on a royalty rate starting at 22% of annual net sales of the product up to $150 million of annual net sales, with the royalty rate then increasing, based on agreed-upon levels of annual net sales achieved, from 25% up to a maximum of 30%.
- No royalty payments would be due to us for the first $41 million of royalties that would otherwise have been payable beginning from the time of the product launch in July 2006, a period we refer to as the royalty holiday. If we were not subject to the $41 million royalty holiday, we believe that we would have received royalties from Endo of approximately $18.6 million for the twelve months ended December 31, 2007, and that cumulatively, through December 31, 2007, approximately $19.7 million has been applied against the royalty holiday. We expect Endo to initiate the payment of royalties to us on U.S. sales of Opana ER commencing in the second half of 2008.
- Endo would pay us a percentage of any sublicense income it receives and milestone payments of up to $90 million based upon the achievement of agreed-upon annual net sales thresholds.
- Our share of the development costs for Opana ER that we opted out of funding in April 2003 will be fixed at $28 million and will be recouped by Endo through a temporary 50% reduction in royalties. This temporary reduction in royalties will not apply until the threshold for the $41 million royalty holiday has been met.

Under our collaboration with Endo, we supply bulk TIMERx materials to Endo, and Endo is responsible for the manufacture of Opana ER. Endo has outsourced the commercial manufacture of Opana ER to a sole source third party manufacturer with which it has entered into a long-term manufacturing and development agreement.

Edison Pharmaceuticals, Inc.

On July 16, 2007, we entered into a collaboration and license agreement with Edison. Under our agreement, we and Edison have agreed to collaborate on the development of A0001 and up to one additional drug candidate, initially directed to the treatment of inherited mitochondrial respiratory chain diseases.

During the initial 18 months of the agreement, Edison is obligated to present to us at least one compound identified by Edison that satisfies agreed-upon criteria for consideration as a development candidate under the collaboration, in addition to A0001. We have the option, exercisable upon payment of a one-time fee, to select any such compound for development. We are working collaboratively with Edison to identify a compound, but to date have not yet selected the additional compound for development. If A0001, or any compound as to which we have exercised our option, fails in toxicology studies during this 18 month research period or any extended research period, we have the right to select a replacement compound, without any additional fee, which may be identified by Edison during the remainder of the research period.

Under the Edison agreement, we have exclusive, worldwide rights to develop and commercialize A0001 and any other compound as to which we have exercised our option, or any replacement compound, for the treatment of all indications, subject to other terms and conditions in the Edison agreement.

In consideration for the rights granted to us under the Edison agreement, we paid Edison an upfront cash payment of $1.0 million upon entering into the Edison agreement and agreed to loan Edison up to an aggregate principal amount of $1.0 million, with the right to draw upon such loan commitment in one or more installments at any time prior to the earliest of July 16, 2012, the occurrence of an event of default, a change in control of Edison or the termination of the Edison agreement, solely to fund Edison's research and development. We are also required to make payments to Edison upon achievement of specified milestones set forth in the Edison agreement and royalty payments based on net sales of products containing A0001, any other compound as to which we have exercised our option, or any replacement compound.

On February 5, 2008, we loaned Edison $1.0 million pursuant to the loan agreement provisions of the Edison agreement. The loan bears interest at an annual rate of one month LIBOR at the time of the loan plus 5% , or a total of 8.14%, which rate is fixed for the term of the loan. The loan matures as of the earlier of July 16, 2012 and the occurrence of an event of default, as defined the in Edison agreement. All accrued and unpaid interest is payable on the maturity date; however, interest accruing on any outstanding loan amount after July 16, 2010 is due and payable monthly in arrears. As of March 11, 2008, $1.0 million is outstanding under this loan.

We also agreed to pay Edison a total of $5.5 million over the initial 18 months of the research period to fund Edison's discovery and research activities during the period. This funding is in the form of payments made in advance each quarter. As of December 31, 2007, we have paid $2.8 million of the $5.5 million to Edison. We have the option to extend the term of the research period for up to three consecutive six month periods, subject to our funding of Edison's activities in amounts to be agreed upon. During the initial 18 months of the research period and during any extension of the research period in which our funding exceeds a specified amount, Edison has agreed not to develop or commercialize any compounds, by itself or with or on behalf of any third party, for the treatment of certain inherited mitochondrial diseases, other than under the collaboration with us, or under specified circumstances. In addition, until 60 days after the later of the presentation of a development candidate by Edison, or the expiration of the research period, and in other specified circumstances, Edison has agreed not to disclose or provide to another party, or enter into any agreement with another party granting any options or rights to, any compound believed to have activity in the treatment of certain inherited mitochondrial diseases.

Following the end of the research period, the license of any compound under the Edison agreement ends, on a country-by-country, product-by-product basis, when neither we nor Edison have any remaining royalty payment obligations to each other with respect to such compound. Each party's royalty payment obligation ends upon the later of expiration of the last-to-expire claim of all licensed patents covering such party's product or expiration of the FDA's designation of such product as an orphan drug. The Edison agreement may be terminated by us with 120 days prior written notice to Edison; provided that we pay Edison a termination fee equal to 25% of the amount remaining to be paid over the initial 18 months of the research period as of the effective date of such termination. The Edison agreement may also be terminated by either party in the event of the other party's uncured material breach or bankruptcy.

Mylan Pharmaceuticals Inc.

On March 2, 2000, Mylan announced that it had signed a supply and distribution agreement with Pfizer to market generic versions of all three strengths (30 mg, 60 mg, 90 mg) of Pfizer's generic Procardia XL. In connection with that agreement, Mylan decided not to market Nifedipine XL, a generic version of Procardia XL that we have developed in collaboration with Mylan. As a result, Mylan entered into a letter agreement with us whereby Mylan agreed to pay us a royalty on all future net sales of Pfizer's generic version of Procardia XL 30 mg. The royalty percentage was comparable to the percentage called for in our original agreement with Mylan for Nifedipine XL 30 mg. Mylan has retained the marketing rights to Nifedipine XL 30 mg. Mylan's sales in the United States in 2007 of Pfizer's generic version of Procardia XL 30 mg totaled approximately $21.3 million. The term of the letter agreement continues until such time as Mylan permanently ceases to market Pfizer's generic version of Procardia XL 30 mg. In 2007, 2006 and 2005, royalties from Mylan were approximately $2.6 million, $3.1 million and $3.9 million, respectively, or 77%, 89% and 63%, respectively, of our total revenue.

Otsuka Pharmaceutical Co., Ltd.

We signed a research and development agreement with Otsuka Pharmaceutical Co., Ltd. or Otsuka, of Japan effective August 14, 2007 to develop a formulation of an Otsuka compound utilizing Penwest's TIMERx drug delivery technology. In connection with the agreement, we received an initial nonrefundable up-front payment which we recorded as deferred revenue and which we will recognize as revenue over the contractual performance period. We will also be reimbursed for development costs incurred in the formulation of the

compound, up to specified amounts. Additionally, under the agreement, we may receive milestone payments upon the achievement of specified events.

Research and Development

We conduct research and development activities on the development of product candidates utilizing readily available excipients and our own existing drug delivery technologies, as well as external drug delivery technologies we access through collaborators. Our research and development expenses in 2007, 2006 and 2005 were $23.6 million, $22.9 million and $17.8 million, respectively. These expenses do not include amounts incurred by our collaborators in connection with the development of products under our collaboration agreements, such as expenses for clinical trials performed by our collaborators or our collaborators' share of funding.

Manufacturing

We currently have no internal commercial scale manufacturing capabilities. Under our existing collaboration agreements, our collaborators manufacture the pharmaceutical products and we supply bulk TIMERx materials to the collaborators. We have outsourced the commercial manufacture of bulk TIMERx materials to a third-party pharmaceutical company, Draxis Specialty Pharmaceuticals Inc. Under our manufacturing and supply agreement with Draxis, Draxis has agreed to exclusively manufacture TIMERx materials for us, and we have agreed to purchase from Draxis at least 50% of our annual requirements for these TIMERx materials. The agreement has an initial term that expires in November 2009, and will renew automatically for successive one-year periods unless either party gives notice of its intention not to renew the agreement at least 180 days prior to the then-current term. Either Draxis or we may terminate the agreement for the other's bankruptcy, uncured breach, or for convenience on 18 months notice. We also agreed to purchase finished TIMERx materials and certain raw materials purchased by Draxis, under certain conditions, upon termination or expiration of the agreement. We currently do not have a second supplier of TIMERx materials. We have taken steps toward qualifying a second contract manufacturer as a second source of supply, including the completion of initial validation work. However, there is additional work required before the site is validated. We believe that there are a limited number of manufacturers that comply with current good manufacturing practices, or cGMP, regulations and are capable of manufacturing bulk TIMERx materials.

Our TIMERx technology is based on a hydrophilic matrix combining a heterodispersed mixture primarily composed of two polysaccharides, xanthan gums and locust bean gums, in the presence of dextrose. We and Draxis purchase these gums from a primary supplier. We have also qualified alternate suppliers with respect to these gums. To date we have not experienced difficulty acquiring these materials.

Under our collaboration with Endo, we supply bulk TIMERx materials to Endo, and Endo is responsible for the manufacture of Opana ER. Endo has outsourced the commercial manufacture of Opana ER to a sole source third party manufacturer with which it has entered into a long-term manufacturing and development agreement.

Marketing and Distribution

We do not have a sales force for any products. We currently market our products through collaborators. Pursuant to our collaborative agreements, our collaborators have responsibility for the marketing and distribution of any pharmaceuticals developed based on our drug delivery technologies. In selecting a collaborator for a drug candidate, some of the factors we consider include the collaborator's market presence in the therapeutic area targeted by the drug candidate, and the collaborator's sales force and distribution network.

If we successfully develop one or more of the products for disorders of the nervous system and determine to retain the rights to market or co-promote, we plan to build or acquire a relatively small specialty sales force of approximately 50 to 100 sales representatives which targets specialty physicians to market these products. We believe that high prescribers of products for the treatment of disorders of the nervous system can be effectively targeted with a sales force of this size.

Patents and Proprietary Rights

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

As of December 31, 2007, we owned a total of 35 U.S. patents and 229 foreign patents. The U.S. patents principally cover our technologies and their modifications and improvements, including the combination of xanthan gum and locust bean gum. Our patents also cover the application of those drug delivery technologies to various active drug substances in different dosage forms and the methods of preparation for such formulations. Our patents expire between 2008 and 2023.

We own four issued U.S. patents listed in the Orange Book for Opana ER. These patents expire in 2008, 2013, 2013 and 2023. They cover the formulation of Opana ER. The patents on which we have sued IMPAX expire in 2013. We and Endo are each prosecuting several additional patent applications related to Opana ER. These applications cover sustained release formulations of Opana ER, methods of making and using the same formulation and various properties of the formulation.

We also rely on trade secrets and proprietary knowledge, which we generally seek to protect by confidentiality and non-disclosure agreements with employees, consultants, licensees and other companies we conduct business with.

Patent Litigation

There has been substantial litigation in the pharmaceutical industry with respect to the manufacture, use and sale of drug products that are the subject of contested patent rights. Under the Hatch-Waxman Act, when an applicant files a 505(b)(2) NDA or an ANDA, with the FDA with respect to a product covered by an unexpired patent listed in the Orange Book, the application must contain a certification with respect to each such patent stating that either final approval of the section 505(b)(2) NDA or ANDA will not be sought until the expiration of the patent, which is referred to as a Paragraph III certification, or that the patent will not be infringed by the applicant's product or is invalid or unenforceable, which is referred to as a Paragraph IV certification. If the applicant makes a Paragraph IV certification, the applicant must give notices to the patent owner and the sponsor of the NDA for the brand name product. If the patent was listed in the Orange Book before the section 505(b)(2) NDA or ANDA was deemed to be accepted for filing by the FDA, and the patent owner or the sponsor files a patent infringement lawsuit within 45 days of the receipt of such notice, the FDA will not grant final marketing approval to the Section 505(b)(2) NDA or the ANDA applicant until the earlier of a court decision on the patent suit in favor of the applicant or 30 months (or such longer or shorter period as a court may determine) from the date of the receipt of the notice. We evaluate the risk of patent infringement litigation with respect to each product we determine to develop.

We have filed patent infringement suits against IMPAX in connection with IMPAX's Paragraph IV certification notices. A description of the litigation is included in "Part I. Item 3 — Legal Proceedings."

Trademarks

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

Government Regulation

Government authorities in the United States and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing of drug products. In the United States, the FDA regulates drug products under the Federal Food, Drug and Cosmetic Act, or FDCA, and implements regulations and other laws. Failure to comply with applicable FDA requirements, both before and after approval, may subject us to administrative and judicial sanctions, such as

rejection or delayed review of pending applications, FDA warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, monetary penalties and/or criminal prosecutions.

In addition, in September 2007, the President of the United States signed the Food and Drug Administration Amendments Act of 2007, or FDAAA. FDAAA grants significant new powers to the FDA, many of which are aimed at improving the safety of drug products before and after approval. In particular, the new law authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information, and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. It also significantly expands the federal government's clinical trial registry and results databank and creates new restrictions on the advertising and promotion of drug products. Under the FDAAA, companies that violate these and other provisions of the new law are subject to substantial civil monetary penalties.

Before a drug product may be marketed in the United States, it must be approved by the FDA. The approval process requires substantial time, effort and financial resources. We cannot be sure that any approval will be granted or granted on a timely basis. There are several kinds of applications that may be submitted to obtain FDA approval of drug products, including NDAs, section 505(b)(2) NDAs or ANDAs. An NDA is a New Drug Application in which the information required for approval, including investigations of safety and effectiveness, comes from studies conducted by or for the sponsor of the NDA, or for which the sponsor has obtained a right of reference. A section 505(b)(2) NDA is an NDA in which at least some of the information required for approval comes from studies not conducted by or for the sponsor, and for which the sponsor has not obtained a right of reference. An ANDA is an application that utilizes for proof of safety and effectiveness data demonstrating that the drug is the same as a "bioequivalent" to a drug which the FDA has previously approved.

NDAs: The steps required for the approval of an NDA include pre-clinical laboratory and animal tests and formulation studies; submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin; adequate and well-controlled clinical trials to establish the safety and effectiveness of the product candidate for each indication for which approval is sought; submission to the FDA of the application; satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug or product components are produced to assess compliance with current Good Manufacturing Practices, or cGMP; and FDA review and approval of the NDA.

Pre-clinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies, the conduct of which must comply with federal regulations and requirements including the FDA's good laboratory practice regulations. The results of the pre-clinical tests, together with manufacturing information, analytical data, a proposed clinical trial protocol and other information, must be submitted to the FDA as part of an IND, which must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the proposed clinical trials outlined in the IND. Any concerns or questions raised by the FDA must be resolved before clinical trials may begin.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified physician-investigators and healthcare personnel. Clinical trials must be conducted in compliance with federal regulations and requirements including good clinical practices, under protocols detailing, for example, the parameters to be used in monitoring patient safety, and the safety and effectiveness criteria, or end points, to be evaluated.

Clinical trials are typically conducted in three phases; however, these phases may overlap or be combined. Each trial and the informed consent information for subjects in clinical trials must be reviewed and approved by an independent Institutional Review Board, or IRB, before it can begin. Phase 1 usually involves the initial introduction of the investigational drug candidate into a small number of healthy subjects to evaluate its safety, dosage tolerance, pharmacodynamics and, if possible, to gain an early indication of its effectiveness. Phase 2 usually involves trials in a limited patient population to evaluate dosage tolerance and appropriate dosage; identify possible adverse side effects and safety risks; and preliminarily evaluate the effectiveness of the drug

candidate for specific indications. Phase 3 trials usually further evaluate clinical effectiveness and test further for safety by administering the drug candidate in its final form in an expanded patient population. We, our collaborators, an IRB or the FDA may suspend clinical trials at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk.

Assuming successful completion of the required clinical testing, the results of the preclinical studies and the clinical studies, together with other detailed information, including information on the manufacture and composition of the product, are submitted in an NDA requesting approval to market the product for one or more indications. Before approving an application, the FDA usually will inspect the facility or the facilities at which the product candidate is manufactured to ensure that cGMP compliance is satisfactory. The FDA will approve an NDA only if it satisfies all regulatory criteria for approval. If the FDA determines the NDA does not meet all regulatory criteria, the FDA may reject the application as not approvalable or outline the deficiencies in the NDA and request additional information. If the submission of the requested additional testing or information does not sufficiently address the deficiencies, the FDA ultimately may reject the application as not approvable.

505(b)(2) NDAs: Section 505(b)(2) NDAs provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved drug products. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The 505(b)(2) NDA applicant may rely, in part, on the FDA's previous findings of safety and efficacy of an approved product, publicly available data or published literature, in support of its application. The FDA may also require companies to perform additional studies or measurements to support the modification from the approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

The FDCA provides that the final approval of 505(b)(2) NDAs will be subject to certain conditions in various circumstances. For example, the holder of the NDA for the already-approved drug may be entitled to a period of market exclusivity, during which the FDA cannot finally approve the 505(b)(2) NDA. Also, if the already-approved drug is covered by one or more unexpired patents that are listed in the Orange Book, the 505(b)(2) NDA must contain a Paragraph III or Paragraph IV certification. If the 505(b)(2) NDA contains a Paragraph IV certification to a patent listed prior to the official filing date of the 505(b)(2) NDA and a timely lawsuit is filed, the FDA will not finally approve the 505(b)(2) NDA until the earlier of a court decision in favor of the 505(b)(2) NDA applicant or the expiration of 30 months from the date of certification, a period that may be shortened or extended by the court. The regulations governing marketing exclusivity and patent protection are complex and often uncertain.

ANDAs: The FDA may approve an ANDA if the product is the same in specified respects as an already approved drug, or if the FDA has declared the drug suitable for an ANDA submission. An ANDA must contain the same manufacturing and composition information as the NDA for the listed drug, but applicants need not submit preclinical and clinical safety and effectiveness data. Instead, they must submit studies showing that the product is bioequivalent to the already approved drug. Drugs are bioequivalent if the rate and extent of absorption of the drug does not show a significant difference from the rate and extent of absorption of the already-approved drug. Conducting bioequivalence studies is generally less time-consuming and costly than conducting pre-clinical and clinical studies necessary to support an NDA. However, bioequivalence for extended release drugs is often difficult to interpret and is sometimes subject to challenge by the reference listed drug holder.

As is the case for 505(b)(2) NDAs, final approvals of ANDAs are subject to delay in various circumstances such as when the holder of the NDA for the already approved drug is entitled to a period of marketing exclusivity during which the FDA cannot finally approve the 505(b)(2) NDA. In addition, if the ANDA applicant has provided a Paragraph IV certification to a patent listed prior to submission of the ANDA and a timely lawsuit is filed, final approval of the ANDA cannot occur until the earlier of a court decision in favor of the ANDA applicant or the expiration of 30 months from the date of certification, a period that may

be shortened or extended by the court. The regulations governing marketing exclusivity and patent certification relating to ANDAs are complex and often uncertain.

Orphan Drug Designation: The FDA may grant orphan drug designation to drugs intended to treat a "rare disease or condition" that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting an application for marketing authorization. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Also, competitors may receive approval of other different drugs or biologics for the indications for which the orphan product has exclusivity.

Other FDA Requirements: After the marketing approval of a drug product by the FDA, certain changes to the approved product, such as adding new indications, manufacturing changes or additional labeling claims are subject to further FDA review and approval.

In addition, regardless whether approval is sought under an NDA, a section 505(b)(2) NDA or an ANDA, we and our collaborators are required to comply with a number of FDA requirements both before and after approval. For example, the owner of an approved product is required to report certain adverse reactions and production problems to the FDA, and to comply with requirements concerning advertising and promotion for the product. The FDA may also require post-approval testing, including Phase 4 studies, and surveillance to monitor the product's safety or efficacy after approval and may impose other conditions on an approval that could restrict the distribution or use of the product. Also, quality control and manufacturing procedures must continue to conform with cGMP after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP. Accordingly, manufacturers must continue to expend time, money and effort in all areas of regulatory compliance, including production and quality control to comply with cGMP. In addition, discovery of previously unknown problems such as safety issues with the product or manufacturing process may result in changes in labeling, or restrictions on a product manufacturer or NDA holder, and could include removal of the product from the market.

Competition

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

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

- the safety and efficacy of our products;
- the relative speed with which we can develop products;
- generic competition for any product that we develop;
- our ability to protect the intellectual property surrounding our products;
- our ability to differentiate our products from our competitors' products; and
- external factors affecting pricing and/or reimbursement.

Opana ER is approved for the treatment of moderate to severe chronic pain and competes with OxyContin and MS Contin, the Duragesic patch, Avinza, Kadian and the generic versions of some of these drugs. These products are potential treatment options for a physician managing a patient with moderate to severe chronic pain.

We believe that the product candidates we are developing will face competition from drug products marketed by other companies for the same indications as our product candidates. For instance, we believe nalbuphine ER would compete with products containing tramadol, hydrocodone, codeine or propoxyphene such as Ultram, Vicodin and Darvon, and the generic versions of some of these drugs. A0001 and the Edison drug candidate we acquire in the future may face competition from products that are under development by other companies for the same indications, such as Santhera Pharmaceuticals and Sitris Pharmaceuticals. Santhera's coenzyme Q analog molecule, idebenone, is in active clinical development in the diseases of Friedreich's ataxia, Duchenne muscular dystrophy, and Leber's Hereditary Optic Neuropathy. Sirtris is targeting the mitochondrial metabolic pathways and is planning to study the mitochondrial respiratory chain disease MELAS (mitochondrial myopathy, encephalopathy, lactic acidosis and stroke) syndrome. To the extent that the development of our product candidates involve the reformulation of existing drugs, these product candidates will face competition from generic and branded formulations of the existing drugs we reformulate. Our drug delivery technologies will compete with existing drug delivery technologies, as well as new drug delivery technologies that may be developed or commercialized in the future.

Employees

As of December 31, 2007, we employed approximately 75 people, of whom 51 were primarily involved in research and development activities, and 24 were primarily involved in selling, general and administrative activities. As of December 31, 2007, none of our employees were covered by collective bargaining agreements. We consider our employee relations to be good.

Information Available on the Internet

Our internet address is www.penwest.com. We make available, free of charge through our website, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to these reports filed or furnished pursuant to Section 12(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file such materials with the Securities and Exchange Commission, or SEC.

ITEM 1A. — *RISK FACTORS*

Investing in our common stock involves a high degree of risk, and you should carefully consider the risks and uncertainties described below in addition to the other information included or incorporated by reference in this annual report on Form 10-K. If any of the following risks actually occurs, our business, financial condition or results of operations would likely suffer, possibly materially. In that case, the trading price of our common stock could fall.

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

We have incurred net losses since 1994, including net losses of $34.5 million, $31.3 million and $22.9 million during 2007, 2006 and 2005, respectively. As of December 31, 2007, our accumulated deficit was approximately $207.0 million.

Our strategy includes developing drug candidates to treat disorders of the nervous system. As a result, we expect to incur net losses in 2008 and beyond as we continue to conduct development of and seek regulatory approvals for our product candidates. These net losses have had and will continue to have an adverse effect on our shareholders' equity, total assets and working capital.

Our future profitability will depend on several factors, including:

- the commercial success of Opana ER, and the timing and amount of royalties from Endo's sales of Opana ER which may be affected by any potential generic entry;
- our ability to successfully defend our intellectual property protecting our products;
- the level of our investment in research and development activities, including the timing and costs of conducting our clinical trials of nalbuphine ER;
- the timing and amount of payments to Edison in connection with the Edison agreement, as well as our costs of development for drug candidates to which we acquire rights under the Edison agreement;
- the successful development and commercialization of product candidates in our portfolio;
- the level of investment for acquisitions or in-licensing of compounds or technologies intended to support our growth; and
- royalties from Mylan's sales of Pfizer's generic Procardia XL 30 mg.

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

As of December 31, 2007, we had cash, cash equivalents and short-term investments of $23.0 million. On March 11, 2008, we sold units representing an aggregate of 8,140,600 shares of our common stock, together with warrants to purchase an aggregate of 4,070,301 shares of common stock, in a private placement, for a total purchase price of approximately $25.1 million. We expect net proceeds to be approximately $23.2 million after deducting the placement agent's fees and other estimated expenses. A description of the private placement is included in "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" under the caption "Sources of Liquidity."

We anticipate that, based upon our current operating plan, our existing capital resources together with the net proceeds we expect to received from of the private placement and expected royalties from third parties will be sufficient to fund our operations on an ongoing basis through at least the first quarter of 2009. We currently anticipate that we will begin to receive royalty payments related to Opana ER from Endo in the second half of 2008. In addition, we are currently taking measures to reduce our spending and manage our costs more closely. These cost management measures may include adjusting the pace and timing of our clinical programs to match these costs with our financial resources. Finally, we plan to seek to enter into collaboration and licensing agreements for nalbuphine ER and other of our products and technologies. Our goal with these efforts is to fund our ongoing operations until at least the second half of 2009 without seeking additional funding from the capital markets. If the anticipated Opana ER royalties are delayed or less than we anticipate, if we are not successful in controlling our costs, or if we are unable to enter into collaboration and licensing agreements for our products or technologies on favorable terms or at all, we may need to seek financing sooner than we anticipate.

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

- the commercial success of Opana ER;
- the timing and amount of payments received under collaborative agreements, including in particular our agreement with Endo with respect to Opana ER and our agreement with Mylan with respect to Pfizer's generic Procardia XL 30 mg;
- our ability to access the second $12 million term loan under the credit facility and the timing of the availability of this $12 million;
- the timing and amount of payments to Edison in connection with the Edison agreement, as well as our internal costs of development for drug candidates for which we acquired rights under this agreement;
- the progress of other collaborative and independent development projects, funding obligations with respect to the projects, and the related costs to us of clinical studies for our product candidates;
- the level of investment for the acquisition or in-licensing of technologies or compounds intended to support our growth;

- the structure and terms of any future collaborative agreements;
- the prosecution, defense and enforcement of our patents and other intellectual property rights, such as our Orange Book listed patents for Opana ER including our costs associated with the IMPAX litigation and any other litigation in which we become involved;
- the level of our investments in capital expenditures for facilities and equipment; and
- our success in reducing our spending and managing our costs.

If we raise additional funds by issuing equity securities, it will result in further dilution to our then-existing shareholders. Debt financing, such as the credit facility noted above, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt or equity financing may also contain terms, such as liquidation and other preferences, that are not favorable to us or our shareholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies, research programs or potential products or grant licenses on terms that may not be favorable to us. Additional financing may not be available in amounts or on terms acceptable to us, if at all. If we are unable to obtain additional financing, we may be required to delay, reduce the scope of, or eliminate one or more of our planned research, development and commercialization activities, including our planned clinical trials, which could harm our business, financial condition and operating results.

Our ability to generate revenues depends heavily on the success of Opana ER

We made a significant investment of our financial resources in the development of Opana ER. In the near term, our ability to generate significant revenues will depend primarily on the growth of Opana ER sales by Endo. Opana ER, which was approved by the FDA in June 2006 and launched by Endo in July 2006, may not be accepted by customers in the pharmaceutical market. Opana ER competes with a number of approved drugs manufactured and marketed by major pharmaceutical companies and generic versions of some of these drugs. It may have to compete against new drugs and generic versions of Opana ER that may enter the market in the future.

The degree of market success of Opana ER depends on a number of factors, including:

- the safety and efficacy of Opana ER as compared to competitive products;
- Endo's ability to educate the medical community about the benefits, safety profile and efficacy of Opana ER;
- the effectiveness of Endo's sales and marketing activities;
- Endo's ability to manufacture and maintain suitable inventory for sale on an ongoing basis;
- the reimbursement policies of government and third party payors with respect to Opana ER;
- the pricing of Opana ER;
- the level of stocking of Opana ER by wholesalers and retail pharmacies; and
- the availability of generic versions of Opana ER and the timing of generic competition.

IMPAX has filed an ANDA for Opana ER in four strengths, 5 mg, 10 mg, 20 mg and 40 mg, which ANDA was accepted for filing by the FDA as of November 23, 2007. We and Endo filed patent infringement suits against IMPAX in connection with its ANDA. A description of the litigation is included in "Part I. Item 3. Legal Proceedings."

On February 14, 2008, we received a notice from Actavis advising of the filing of its ANDA containing a Paragraph IV certification under the the Hatch-Waxman Act for Opana ER in four strengths, 5 mg, 10 mg, 20 mg and 40 mg. The Actavis Paragraph IV certification notice refers to our Orange-Book listed patents, U.S. Patent Nos. 5,128,143, 5,662,933, 5,958,456, and 7,276,250, which cover the formulation

of Opana ER. These patents expire in 2008, 2013, 2013 and 2023, respectively. We are currently reviewing the details of this notice from Actavis.

We and Endo intend to pursue all available legal and regulatory avenues defending Opana ER. We believe that we are entitled to a 30-month stay beginning on December 14, 2007. However, IMPAX has announced that it is seeking to reinstate an earlier filing date of its ANDA. If it is successful in reinstating this earlier filing date or if we and Endo are unsuccessful in our Hatch-Waxman suit, Opana ER could be subject to generic competition as early as June 2009 when the new dosage form exclusivity expires. We expect that generic competition would adversely affect the pricing of Opana ER, the royalties that we expect to receive from Endo and our results of operations and financial condition.

If Opana ER sales do not grow steadily or substantially, it would have a material adverse effect on our business, financial condition and results of operations.

In the event that we are able to obtain regulatory approval of any of our other products candidates, the success of those products would also depend upon their acceptance by physicians, patients, third party payors or the medical community in general. There can be no assurance as to market acceptance of our drug products or our drug delivery technologies.

Our success depends on our ability to protect our patents and other intellectual property rights

Our success depends in significant part on our ability to obtain patent protection for our products, both in the United States and in other countries, and our ability to enforce these patents. Patent positions can be uncertain and may involve complex legal and factual questions. Patents may not be issued from any patent applications that we own or license. If patents are issued, the claims allowed may not be as broad as we have anticipated and may not sufficiently cover our drug products or our technologies. In addition, issued patents that we own or license may be challenged, invalidated or circumvented and we may not be able to bring suit to enforce these patents. We have four issued U.S. patents listed in the Orange Book for Opana ER. As the owner of the patents listed in the Orange Book for Opana ER, we may become a party to Hatch-Waxman litigation. We and Endo filed patent infringement suits against IMPAX in connection with its ANDA for Opana ER. A description of the litigation is included in "Part I. Item 3. Legal Proceedings." We believe that we are entitled to a "30-month stay" available under the Hatch-Waxman Act because we initiated the suit within 45 days of our receipt of IMPAX's notice letter. However, IMPAX has publicly disclosed that it is seeking to reinstate an earlier filing date of its ANDA. If IMPAX is successful, we will not be entitled to the 30-month stay. If we proceed with the Hatch-Waxman litigation, we may not prevail on defending our patents. Litigation is inherently unpredictable and unfavorable rulings do occur. An unfavorable ruling or loss of 30-month stay could subject Opana ER to generic competition as early as June 2009 when the new dosage form exclusivity for Opana ER expires. We have also received Paragraph IV certification notice from Actavis. A description of this notice is included in "Notes to Financial Statements, Item 18. Subsequent Events". We expect that generic competition would adversely affect the pricing of Opana ER, the royalties that we expect to receive from Endo and results of our operations and financial condition.

Our research, development and commercialization activities or any products in development may infringe or be claimed to infringe patents of competitors or other third parties. In such event, we may be ordered to pay such third party lost profits or punitive damages. We may have to seek a license from a third party and pay license fees or royalties. Awards of patent damages can be substantial. Licenses may not be available or available on acceptable terms, or the licenses may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. If we or our collaborators are not able to obtain a license, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations.

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

We are dependent on our collaborators to manufacture and commercialize our products

We have historically collaborated with partners to facilitate the manufacture and commercialization of our products and product candidates. We continue to depend on our collaborators to manufacture, market and sell our products. In particular, we are dependent on Endo to manufacture, market and sell Opana ER in the United States and on Mylan to market and sell Pfizer's generic Procardia XL 30 mg.

We have limited experience in manufacturing, marketing and selling pharmaceutical products. Accordingly, if we cannot maintain our existing collaborations or establish new collaborations with respect to our products, we will have to establish our own capabilities or discontinue commercialization of the affected products. Developing our own capabilities may be expensive and time consuming and could delay the commercialization of the affected products. There can be no assurance that we will be successful in developing these capabilities.

Our existing collaborations may be subject to termination on short notice under certain circumstances such as upon a bankruptcy event or if we breach the agreement. If any of our collaborations are terminated, we may be required to devote additional internal resources to the product, seek a new collaborator on short notice or abandon the product. The terms of any additional collaborations or other arrangements that we establish may not be favorable to us.

We are also at risk that these collaborations or other arrangements may not be successful. Factors that may affect the success of our collaborations include:

- Our collaborators may be pursuing alternative technologies or developing alternative products, either on their own or in collaboration with others, that may be competitive to the product on which we are collaborating, which could affect our collaborator's commitment to our collaboration.

- Our collaborators may reduce marketing or sales efforts, or discontinue marketing or sales of our products. This could reduce the revenues we receive on the products.

- Our collaborators may pursue higher priority programs or change the focus of their commercialization programs, which could affect the collaborator's commitment to us. Pharmaceutical and biotechnology companies re-evaluate their priorities from time to time, including following mergers and consolidations, which have been common in recent years in these industries.

- Disputes may arise between us and our collaborators from time to time regarding contractual or other matters. In 2006, we were engaged in a dispute with Endo with regard to the sharing of marketing expenses during the period prior to when Opana ER reaches profitability. In January 2007, we resolved our dispute as part of an amendment to the strategic alliance agreement between us and Endo. Any other such disputes with Endo or other collaborators could be time consuming and expensive, and could impact our anticipated rights under our agreements with those collaborators.

We have limited experience in developing, manufacturing, marketing and selling pharmaceutical products

We have limited experience in developing, manufacturing, marketing and selling pharmaceutical products. In the past, we have relied on our collaborators to manufacture, market and sell our products. We intend to develop more drug candidates independently and be responsible for the manufacturing, marketing and selling of these products. Under our collaboration with Edison, we are responsible for pharmaceutical and clinical development, seeking regulatory approvals, manufacturing, and marketing of the products we license from Edison. Accordingly, we will have to continue to develop our own capabilities in these areas.

If we cannot establish our own capabilities successfully and on a timely basis, we may not be able to develop or commercialize these drug candidates. Developing our own capabilities may be expensive and time consuming and could delay the commercialization of the products we are developing.

The Drug Enforcement Agency, or DEA, limits the availability of the active drug substances used in Opana ER. As a result, Endo's procurement quota may not be sufficient to meet commercial demand

Under the Controlled Substances Act of 1970, the DEA regulates chemical compounds as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. The active drug substance in Opana ER, oxymorphone hydrochloride, is listed by the DEA as a Schedule II substance. Consequently, the manufacture, shipment, storage, sale, prescribing, dispensing and use of Opana ER are subject to a higher degree of regulation. For example, all Schedule II drug prescriptions must be written and signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription.

Furthermore, the DEA limits the availability of the active drug substance used in Opana ER. As a result, Endo's procurement quota of the active drug substance may not be sufficient to meet commercial demands. Endo must apply to the DEA annually for procurement quota in order to obtain the substance. Any delay or refusal by the DEA in establishing the procurement quota could cause trade inventory disruptions, which could have a material adverse effect on our business, financial condition and results of operations.

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

The pharmaceutical industry is highly competitive and is affected by new technologies, governmental regulations, healthcare legislation, availability of financing and other factors. Many of our competitors have:

- significantly greater financial, technical and human resources than we have and may be better equipped to develop, manufacture and commercialize drug products;
- more extensive experience than we have in conducting preclinical studies and clinical trials, obtaining regulatory approvals, and manufacturing and marketing pharmaceutical products;
- competing products that have already received regulatory approval or are in late-stage development; or
- collaborative arrangements in our target markets with leading companies and research institutions.

We face competition based on the safety and effectiveness of our products, the timing and scope of regulatory approvals, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, pricing, patent position and other factors. Our competitors may develop or commercialize more effective, safer or more affordable products, or obtain more effective patent protections. Accordingly, our competitors may commercialize products more rapidly or effectively than we do, which would adversely affect our competitive position, the likelihood that our product will achieve initial market acceptance and our ability to generate meaningful revenues from our products. Even if our products achieve initial market acceptance, competitive products may render our products obsolete or noncompetitive. If our products are rendered obsolete, we may not be able to recover the expenses of developing and commercializing those products.

We face competition from numerous public and private companies and their extended release technologies, including the oral osmotic pump (OROS) technology marketed by Johnson & Johnson, multiparticulate systems marketed by Elan Corporation plc, Biovail Corporation and KV Pharmaceutical Company, and traditional matrix systems marketed by SkyePharma plc.

Opana ER faces, and our products in development will face, competition from products with the same indication. For instance, Opana ER competes in the moderate to severe long acting opioid market with products such as OxyContin and MS Contin, Duragesic patch, Avinza and Kadian and the generic versions of some of these drugs. Opana ER may also be subject to competition from generic versions of the product, such as the generic version being developed by IMPAX.

Nalbuphine ER, if approved, will face competition from products in the moderate chronic pain market. A number of pharmaceutical companies currently market and sell products to treat moderate chronic pain that we expect will compete with nalbuphine ER ranging from NSAIDs to strong opioids and including products containing tramadol, hydrocodone, codeine or propoxyphine such as Ultram, Vicodin and Darvon.

Products developed through our collaboration with Edison may compete against products being developed by numerous private and public companies for at least some of the indications we may pursue. Various companies and institutions are conducting studies in the area of inherited mitochondrial disease. At least two companies have announced that they are pursuing programs based upon mitochondrial disease pathways. Santhera Pharmaceuticals is developing the coenzyme Q analog molecule, idebenone. They are in active clinical development in the diseases of Friedreich's ataxia, Duchenne muscular dystrophy, and Leber's Hereditary Optic Neuropathy. Sirtris Pharmaceuticals is targeting the mitochondrial metabolic pathways and is planning to study the mitochondrial respiratory chain disease MELAS (mitochondrial myopathy, encephalopathy, lactic acidosis and stroke) syndrome. If these companies are able to receive regulatory approvals for their products before we do, it may negatively impact our ability to achieve market acceptance of our products. If their products are more effective, safer or more affordable, our products may not be competitive.

Some of the products we are developing are proprietary products that are based on active drug substances that are not protected by patents. These products will compete against other products developed using the same or a similar active drug substances, including branded products, as well as their generic versions, based primarily on price. In addition, our products may compete against other competitive products in the same therapeutic class.

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

In order to obtain regulatory approvals for the commercial sale of our products, we or our collaborators will be required to complete clinical trials in humans to demonstrate the safety and efficacy of the products. However, we may not be able to commence or complete these clinical trials in any specified time period, either because the FDA or other regulatory agencies object or for other reasons. With respect to our approved products, including Opana ER, we have relied on our collaborators to conduct clinical trials and obtain regulatory approvals. We intend to develop the product candidates we obtain under our collaboration with Edison independently, including controlling the clinical trials and regulatory submissions with the FDA. We have limited experience in conducting Phase II and Phase III clinical trials and to date have not obtained approval for the marketing of a drug product. In 2005, we submitted an NDA for a product we were developing, PW 2101, but we received a non-approvable letter from the FDA and terminated the development program.

Even if we complete a clinical trial of one of our potential products, the clinical trial may not prove that our product is safe or effective to the extent required by the FDA, the European Commission, or other regulatory agencies to approve the product. We or our collaborators may decide, or regulators may require us or our collaborators, to conduct additional clinical trials. For example, Endo received an approvable letter for Opana ER from the FDA in response to its NDA for Opana ER, which required Endo to conduct an additional clinical trial and which significantly delayed the approval of Opana ER. In addition, regulators may require post-marketing testing and surveillance to monitor the safety and efficacy of a product.

Some of the drug candidates we are developing are in the early stages of development. There is limited information and understanding of the safety and efficacy of these drug candidates. There may not be any clinical data available. We will have to conduct preclinical testing and clinical studies to demonstrate the safety and efficacy of these drug candidates. The results from preclinical testing of a product that is under development may not be predictive of results that will be obtained in human clinical trials. In addition, the results of early human clinical trials may not be predictive of results that will be obtained in larger scale advanced stage clinical trials. Furthermore, we, our collaborators, and IRB 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.

If clinical trials do not show any potential product to be safe or efficacious, if we are required to conduct additional clinical trials or other testing of our products in development beyond those that we currently contemplate or if we are unable to successfully complete our clinical trials or other testing, we may:

- be delayed in obtaining marketing approval for our products;
- not be able to obtain marketing approval for our products; or
- not be able to obtain approval for indications that are as broad as intended.

Our product development costs may also increase if we experience delays in testing or approvals. In addition, significant delays in clinical trials could allow our competitors to bring products to market before we do and impair our ability to commercialize our products.

We have received Orphan Drug designation for A0001 from the FDA for the treatment of inherited mitochondrial respiratory chain diseases. We plan to file for orphan drug status for A0001 in the European Union. The FDA and the European Union regulatory authorities grant Orphan Drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States and fewer than five in 10,000 individuals in the European Union.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to orphan drug exclusivity. Orphan drug exclusivity means that another application to market the same drug for the same indication may not be approved for a period of up to 10 years in the European Union, and for a period of seven years in the United States, except in limited circumstances set forth in the U.S. Federal Food, Drug and Cosmetic Act. Obtaining orphan drug designations and orphan drug exclusivity for our products for the treatment of inherited mitochondrial respiratory chain diseases may be critical to the success of these products. If our competitor receives marketing approval before we do for a drug that is considered the same as our drug candidate for the same indication we are pursuing, we will be prevented from receiving marketing approval for our drug candidate during the orphan drug exclusivity period of the competitor.

Even if we obtain orphan drug exclusivity for any of our potential products, we may not be able to maintain it. If a competitor product, containing the same drug as our product and seeking approval for the same indication, is shown to be clinically superior to our product, any orphan drug exclusivity we have obtained will not block the approval of such competitor product. In addition, if a competitor develops a different drug for the same indication as our approved indication, our orphan drug exclusivity will not prevent the competitor drug from obtaining marketing approval.

Orphan Drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Obtaining Orphan Drug designation may not provide us with a material commercial advantage.

Even if we are able to obtain regulatory approvals for any of our product candidates, if they exhibit harmful side effects after approval, our regulatory approvals could be revoked or otherwise negatively impacted, and we could be subject to costly and damaging product liability claims

Even if we receive regulatory approval for A0001 or any other drug candidate developed through our collaboration with Edison, we will have tested them in only a small number of carefully selected patients during our clinical trials. If our applications for marketing are approved and more patients from the general population begin to use our products, new risks and side effects associated with our products may be discovered. As a result, regulatory authorities may revoke their approvals. In addition, we may be required to conduct additional clinical trials, make changes in labeling of our products, reformulate our product or make changes and obtain new approvals for our and our suppliers' manufacturing facilities. We might have to withdraw or recall our products from the marketplace. We may also experience a significant drop in the potential sales of our product if and when regulatory approvals for such product are obtained, experience harm to our reputation in the marketplace or become subject to lawsuits, including class actions. Any of these

results could decrease or prevent any sales of our approved product or substantially increase the costs and expenses of commercializing and marketing our product.

Our controlled release drug delivery technologies rely on the ability to control the release of the active drug substances and our business would be harmed if it was determined that there were circumstances under which the active drug substances from one of our extended release products would be released rapidly into the blood stream

Our controlled release products and product candidates rely on our ability to control the release of the active drug substance. Some of the active ingredients in our controlled release products, including Opana ER, contain levels of active drug substance that could be harmful, even fatal, if the full dose of active drug substance were to be released over a short period of time, which is referred to as dose-dumping.

In 2005, Purdue Pharma voluntarily withdrew from the market its product Palladone® (hydromorphone hydrochloride extended release capsules), after acquiring new information that serious and potentially fatal adverse reactions can occur when the product is taken together with alcohol. The data, gathered from a study testing the potential effects of the drug with alcohol use, showed that when Palladone is taken with alcohol, the extended release mechanism can fail and may lead to dose-dumping. In anticipation of questions from the FDA with respect to the potential dose-dumping effect of Opana ER given the FDA's experience with Palladone, Endo conducted both *in vitro* and human testing of the effect of alcohol on Opana ER. In the *in vitro* testing, Endo did not find any detectible effect of alcohol on the time release mechanism of the product. In the human testing in the presence of alcohol, there was evidence of an increase in blood levels. The FDA received this data before approving the NDA and required that the Opana ER labeling specifically warn against taking the drug with alcohol of any kind.

We are subject to extensive government regulation including the requirement of approval before our products may be marketed. Even if we obtain marketing approval, our products will be subject to ongoing regulatory review

We, our collaborators, our products, and our product candidates are subject to extensive regulation by governmental authorities in the United States and other countries. Failure to comply with applicable requirements could result in warning letters, fines and other civil penalties, delays in approving or refusal to approve a product candidate, product recall or seizure, withdrawal of product approvals, interruption of manufacturing or clinical trials, operating restrictions, injunctions and criminal prosecution.

Our products cannot be marketed in the United States without FDA approval. Obtaining FDA approval requires substantial time, effort and financial resources, and there can be no assurance that any approval will be granted on a timely basis, if at all. We have had only limited experience in preparing applications and obtaining regulatory approvals. If the FDA does not approve our product candidates or does not approve them in a timely fashion, our business and financial condition may be adversely affected. Furthermore, the terms of marketing approval of any application, including the labeling content, may be more restrictive than we desire and could affect the marketability of our products.

Certain products containing our controlled release technologies require the submission of a full NDA. A full NDA must include complete reports of preclinical, clinical and other studies to prove adequately that the product is safe and effective. These studies may involve, among other things, full clinical testing, which requires the expenditure of substantial resources. The drug candidates we are developing in collaboration with Edison will also require submission of full NDAs. In certain other cases when we seek to develop a controlled release formulation of an FDA-approved drug with the same active drug substance, we may be able to rely on previous FDA determinations of safety and efficacy of the approved drug to support a section 505(b)(2) NDA. We can provide no assurance, however, that the FDA will accept a submission of a section 505(b)(2) NDA for any particular product. Even if the FDA did accept such a submission, the FDA may not approve the application in a timely manner or at all. The FDA may also require us to perform additional studies to support the modifications of the reference listed drug.

In addition, both before and after regulatory approval, we, our collaborators, our products, and our product candidates are subject to numerous FDA regulations, among other things, covering testing, manufacturing, quality control, current Good Manufacturing Practices or cGMP, adverse event reporting, labeling, advertising, promotion, distribution and export of drug products. We and our collaborators are subject to surveillance and periodic inspection by the FDA to ascertain compliance with these regulations. The relevant law and regulations may also change in ways that could affect us, our collaborators, our products and our product candidates. Failure to comply with regulatory requirements could have a material adverse impact on our business.

Recently enacted FDAAA may make it more difficult and costly for us to obtain regulatory approval of our product candidates and to produce, market and distribute products after approval.

The FDAAA grants a variety of new powers to the FDA, many of which are aimed at improving the safety of drug products before and after approval. Under the FDAAA, companies that violate the new law are subject to substantial civil monetary penalties. While we expect the FDAAA to have a substantial effect on the pharmaceutical industry, the extent of that effect is not yet known. As the FDA issues regulations, guidances and interpretations relating to the new legislation, the impact on the industry, as well as our business, will become clearer. The new requirements and other changes that the FDAAA imposes may make it more difficult, and likely more costly, to obtain approval of new pharmaceutical products and to produce, market and distribute products after approval.

Opana ER contains a narcotic ingredient. As a result of reported misuse and abuse of prescription narcotics, the sale of Opana ER is subject to additional regulations, including compliance with risk management programs, which may prove difficult or expensive to comply with; and we and Endo may face lawsuits

Opana ER contains a narcotic ingredient. Misuse or abuse of drugs containing narcotic ingredients can lead to physical or other harm. In the past few years, for example, reported misuse and abuse of OxyContin, a product containing the narcotic oxycodone, resulted in the strengthening of warnings on its labeling. The sponsor of OxyContin also faced numerous lawsuits, including class action lawsuits, related to OxyContin misuse or abuse. Misuse or abuse of Opana ER could also lead to additional regulation of Opana ER and subject us and Endo to litigation.

We may become involved in patent litigation or other proceedings relating to our products or processes, which could result in liability for damages or termination of our development and commercialization programs

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

- We or our collaborators may initiate litigation or other proceedings against third parties to enforce our intellectual property rights.
- 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 our rights in such proceedings.

An adverse outcome in any litigation or other proceeding could subject us to significant liabilities and/or 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 to obtain it on commercially acceptable terms.

The cost of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. We could incur significant costs in participating or assisting in the litigation. Our competitors may have

substantially greater resources to sustain the cost of such litigation and proceedings more effectively than we can. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

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

We lack commercial scale facilities to manufacture our TIMERx materials or other products we are developing. We currently rely on Draxis for the bulk manufacture of our TIMERx materials under a manufacturing and supply agreement with an initial term that expires in November 2009. The agreement automatically renews for successive one-year periods, unless either party gives notice of its intent not to renew the agreement at least 180 days prior to the end of the then-current term. We are not a party to any agreements with our third party manufacturers for the products that we are currently evaluating in clinical trials, except for purchase orders or similar arrangements.

We believe that there are a limited number of manufacturers that comply with cGMP regulations who are capable of manufacturing our TIMERx materials. Although we have qualified alternate suppliers with respect to the xanthan gum and locust bean gum used to manufacture our TIMERx materials, we currently do not have a second supplier of TIMERx materials. If Draxis is unable to manufacture the TIMERx materials in the required quantities or fails to do so on a timely basis, or if Draxis does not agree to renew our agreement when it expires or renew it on terms acceptable to us, we may not be able to obtain alternative contract manufacturing or obtain such manufacturing on commercially reasonable terms. In addition, if we are unable to enter into longer-term manufacturing arrangements for our products on acceptable terms, particularly as drug candidates advance through clinical development and move closer to regulatory approval, our business and the development and commercialization of our products could be materially adversely affected. There can be no assurance that Draxis or any other third parties we rely on for supply of our TIMERx materials or other products will perform. Any failures by third party manufacturers may delay the development of products or the submission for regulatory approval, impair our or our collaborators' ability to commercialize products as planned and deliver products on a timely basis, require us or our collaborators to cease distribution or recall some or all batches of products or otherwise impair our competitive position, which could have a material adverse effect on our business, financial condition and results of operations.

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

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

We may not be able to successfully develop our own manufacturing capabilities. If we decide to develop our own manufacturing capabilities, we will need to recruit qualified personnel and build or lease the requisite facilities and equipment we currently do not have. Moreover, it may be very costly and time consuming to develop such capabilities.

The manufacture of our products is subject to regulations by the FDA and similar agencies in foreign countries. Any delay in complying or failure to comply with such manufacturing regulations 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 materials

Our TIMERx drug delivery systems are based on a hydrophilic matrix combining a heterodispersed mixture primarily composed of two polysaccharides, xanthan gum and locust bean gum, in the presence of dextrose. These gums are also used in our Geminex, gastroretentive and SyncroDose drug delivery systems. We and Draxis purchase these gums from a primary supplier. We have qualified alternate suppliers with

respect to such materials, but we can provide no assurance that interruptions in supplies will not occur in the future. Any interruption in these supplies could have a material adverse effect on our ability to manufacture bulk TIMERx materials for delivery to our collaborators.

If we or our collaborators fail to obtain an adequate level of reimbursement by governmental or third party payors for Opana ER or any other products we develop, we may not be able to successfully commercialize the affected product

The availability of reimbursement by governmental and other third party payors affects the market for any pharmaceutical products, including Opana ER. These third party payors continually attempt to contain or reduce the costs of health care by challenging the prices charged for pharmaceutical products. In certain foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system. Further proposals are likely. The final adoption of these proposals may affect our or our collaborators' ability to set prices which provide an adequate return on our investment.

We expect Endo to experience pricing pressure with respect to Opana ER. We may experience similar pressure for other products for which we obtain marketing approvals in the future due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. Neither we nor our collaborators may be able to sell products profitably if access to managed care or government formularies is restricted or denied, or 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 that are inherent in the testing, manufacturing, marketing and sale of pharmaceutical products. Product liability claims might be made by consumers, healthcare providers, other pharmaceutical companies, or third parties that sell our products. These claims may be made even with respect to those products that are manufactured in regulated facilities or that otherwise possess regulatory approval for commercial sale.

We are currently covered by a primary product liability insurance in amounts of $15 million per occurrence and $15 million annually in the aggregate on a claims-made basis, and by excess product liability insurance in the amount of $10 million. This coverage may not be adequate to cover all 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 potential liability claims. Claims that are not covered by product liability insurance could have a material adverse effect on our business, financial condition and results of operations.

If we are unable to retain our key personnel and continue to attract additional professional staff, we may not be able to maintain or expand our business

Because of the scientific nature of our business, our ability to develop products and compete with our current and future competitors will remain highly dependent upon our ability to attract and retain qualified scientific, technical, commercial and managerial personnel. The loss of key scientific, technical, commercial or managerial personnel or the failure to recruit additional key scientific, technical, commercial or managerial personnel could have a material adverse effect on our business. We do not have employment agreements with our key executives and we cannot guarantee that we will succeed in retaining all of our key personnel. There is intense competition for qualified personnel in our industry, and there can be no assurance that we will be able to continue to attract and retain the qualified personnel necessary for the success of our business.

The market price of our common stock may be volatile

The market price of our common stock, like the market prices for securities of other pharmaceutical, biopharmaceutical and biotechnology companies, has been volatile. For example, the high and low closing prices of our common stock were $16.92 per share and $4.83 per share, respectively, for the twelve months ended December 31, 2007. On March 11, 2008, the closing price of our common stock was $2.80. The market from time to time experiences significant price and volume fluctuations that are unrelated to the operating performance of particular companies. The market price of our common stock may also fluctuate as a result of our operating results, sales of Opana ER, future sales of our common stock, announcements of technological innovations, new therapeutic products or new generic products by us or our competitors, announcements regarding collaborative agreements, clinical trial results, government regulations, 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 other general market conditions.

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

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

ITEM 1B. *UNRESOLVED STAFF COMMENTS*

Not Applicable.

ITEM 2. *PROPERTIES*

Our corporate offices comprise approximately 21,500 square feet and are located in Danbury, Connecticut. We lease these offices under a lease that currently expires on December 31, 2009, although we may extend this lease for up to two six month renewals, through December 31, 2010 by giving written notice at least three months prior to the expiration of the then-current term of the lease.

We also lease research facilities, comprising approximately 15,500 square feet, in Patterson, New York, which we owned prior to the sale of our excipient business to Josef Rettenmaier Holding GmbH & Co. KG. in 2003. Our lease for this facility expires February 28, 2009, although we may extend this lease through December 31, 2009 by giving written notice by January 31, 2009.

The space we currently lease in Danbury, Connecticut and Patterson, New York is adequate for our present needs.

ITEM 3. *LEGAL PROCEEDINGS*

On October 3, 2007, we received a letter from IMPAX notifying us of its filing of an ANDA containing a Paragraph IV certification under the Hatch-Waxman Act § 355(j) for Opana ER in four strengths, 5 mg, 10 mg, 20 mg and 40 mg . This Paragraph IV certification notice referred to our patent, U.S. No. 7,276,250, which covers the formulation of Opana ER and was listed in the Orange Book as of October 2, 2007. On October 4, 2007, IMPAX announced in a press release that the FDA had rescinded the acceptance of IMPAX's ANDA filing. On November 5, 2007, we received a letter from IMPAX notifying us of additional Paragraph IV certifications relating to our patents, U.S. Nos. 5,622,933 and 5,958,456, which were listed in the Orange Book as of October 19, 2007. On November 15, 2007, in response to these notices, we and Endo filed a

lawsuit against IMPAX in the U.S. Dist. Delaware. The lawsuit against IMPAX not only alleged infringement of certain Orange Book-listed U.S. patents that cover the Opana ER formulation, but also sought declaratory judgment that, among other things, IMPAX had no legitimate basis to trigger the Hatch-Waxman ANDA patent litigation process because the FDA, according to IMPAX, had rescinded its acceptance of IMPAX's ANDA. It further asked the court to declare that the Paragraph IV certification notices that IMPAX served on Endo and us are null, void and of no legal effect.

On December 14, 2007, we received a letter from IMPAX notifying us of a refiling of its ANDA for Opana ER that was accepted by the FDA as of November 23, 2007. The notice letter stated that IMPAX's ANDA contained Paragraph IV certifications for the three patents noted above and that the FDA had required IMPAX to notify Endo and us of these certifications. In this December notice, IMPAX also stated that it would not withdraw its prior Paragraph IV certification notices because it believed they were properly provided and because IMPAX was continuing its efforts to convince the FDA to assign an earlier filing date to its ANDA. As a result of the FDA's determination of IMPAX's ANDA filing date and the receipt of the new Paragraph IV certification notice, on December 20, 2007, we and Endo filed a notice of dismissal of the portion of our November 15, 2007 complaint seeking declaratory judgment that, among other things, IMPAX had no basis to trigger the Hatch-Waxman ANDA patent litigation process and that any Paragraph IV certification notices served prior to November 23, 2007 were null, void and of no legal effect. We and Endo did not dismiss the patent infringement claims in the November lawsuit because IMPAX refused to withdraw its prior Paragraph IV certification notices. On January 25, 2008, we and Endo filed a lawsuit against IMPAX in U.S. Dist. Delaware, alleging infringement of certain Orange Book-listed patents in response to IMPAX's December notice. Given the FDA's acceptance of IMPAX's ANDA as of November 23, 2007, we believe that we are entitled to a 30-month stay under the Hatch-Waxman Act beginning on December 14, 2007. We and Endo intend to pursue all available legal and regulatory avenues defending Opana ER.

ITEM 4. *SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS*

Not Applicable.

EXECUTIVE OFFICERS OF THE REGISTRANT

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

Name	Age	Title	Dates
Jennifer L. Good	43	President and Chief Executive Officer	2006 — current
		President, Chief Operating Officer and Chief Financial Officer	2005 — 2006
		Senior Vice President, Finance and Chief Financial Officer	1997 — 2005
Anand R. Baichwal, Ph.D.	53	Senior Vice President, Licensing and Chief Scientific Officer	2006 — current
		Senior Vice President, Research & New Technology Development and Chief Scientific Officer	1997 — 2006
Amale Hawi, Ph.D.	53	Senior Vice President, Pharmaceutical Development	2007 — current
		President, A. Hawi Consulting Ltd.	2002 — 2007
Paul F. Hayes	52	Vice President, Strategic Marketing	2005 — current
		Senior Director, Marketing, Oscient Pharmaceuticals	2002 — 2005
		Deputy Director, Marketing, Bayer Healthcare Pharmaceuticals	1999 — 2002
Frank P. Muscolo	51	Controller and Chief Accounting Officer	2007 — current
		Controller	1997 — 2007
Benjamin L. Palleiko	42	Senior Vice President, Corporate Development and Chief Financial Officer	2006 — current
		Director, Investment Banking, Sun Trust Robinson Humphrey	2003 — 2006
		Vice President, Investment Banking, Robertson Stephens, Inc.	2000 — 2002
Thomas Sciascia, M.D.	54	Senior Vice President and Chief Medical Officer	2001 — current

PART II

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

Our common stock, $.001 par value, is listed with and trades on the Nasdaq Global Market under the symbol "PPCO." The high and low sale prices of our common stock during 2007 and 2006 are set forth below. These prices reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not necessarily represent actual transactions.

	High	Low
PERIODS IN 2007		
Quarter Ended March 31	$17.50	$ 9.43
Quarter Ended June 30	$13.99	$ 9.92
Quarter Ended September 30	$14.60	$10.57
Quarter Ended December 31	$11.64	$ 4.68
PERIODS IN 2006		
Quarter Ended March 31	$23.70	$19.00
Quarter Ended June 30	$23.10	$15.73
Quarter Ended September 30	$22.74	$16.20
Quarter Ended December 31	$19.35	$15.67

On December 31, 2007, we had 626 shareholders of record.

We have never paid cash dividends on our common stock. We presently intend to retain earnings, if any, for use in the operation of our business, and are precluded from paying any cash dividends under the terms of our credit facility with Merrill Lynch Capital.

ITEM 6. *SELECTED FINANCIAL DATA*

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

	Year Ended December 31,				
	2007	2006	2005	2004	2003
	(In thousands, except for per share data)				
STATEMENT OF OPERATIONS DATA:					
Revenues	$ 3,308	$ 3,499	$ 6,213	$ 5,108	$ 4,678
Cost of revenues	605	231	39	104	169
Gross profit	2,703	3,268	6,174	5,004	4,509
Selling, general and administrative	14,260	14,075	13,247	9,485	10,361
Research and product development	23,561	22,857	17,797	20,205	20,590
Investment income	1,770	2,352	1,974	906	476
Interest expense	(1,117)	—	—	—	(34)
Loss from continuing operations	(34,465)	(31,312)	(22,898)	(23,785)	(26,006)
Earnings from discontinued operations, net of income tax expense	—	—	—	—	177
Gain on sale of discontinued operations(a)	—	—	—	—	9,894
Total discontinued operations	—	—	—	—	10,071
Net loss	$(34,465)	$(31,312)	$(22,898)	$(23,785)	$(15,935)
Basic and diluted loss per share:					
Continuing operations	$ (1.48)	$ (1.38)	$ (1.05)	$ (1.28)	$ (1.56)
Discontinued operations	—	—	—	—	0.60
Net loss per share	$ (1.48)	$ (1.38)	$ (1.05)	$ (1.28)	$ (0.96)
Weighted average shares of common stock outstanding	23,216	22,751	21,711	18,627	16,678

	December 31,				
	2007	2006	2005	2004	2003
	(In thousands)				
BALANCE SHEET DATA:					
Cash and cash equivalents	$ 15,680	$ 16,182	$ 15,917	$ 14,249	$ 8,241
Marketable securities	7,293	24,408	39,377	60,121	55,652
Working capital	17,891	38,254	53,912	71,946	60,697
Total assets	36,982	52,742	67,021	87,522	78,503
Long term obligations-deferred compensation	2,588	2,763	2,977	3,314	3,104
Long term debt	9,595	—	—	—	—
Accumulated deficit	(206,893)	(172,428)	(141,116)	(118,218)	(94,433)
Shareholders' equity(b)	$ 16,237	$ 45,121	$ 60,411	$ 78,801	$ 67,696

(a) On February 27, 2003, Penwest sold substantially all of the assets used in its former excipients business to subsidiaries and affiliates of Josef Rettenmaier Holding GmbH & Co. KG for $41.75 million, plus the assumption of specified liabilities. The purchase price included $39.5 million in cash and a non-interest bearing promissory note of $2.25 million, with $1.0 million paid to Penwest in April 2003 and $1.25 million paid to Penwest in May 2004.

(b) On March 11, 2008, Penwest sold units representing an aggregate of 8,140,600 shares of its common stock, together with warrants to purchase an aggregate of 4,070,301 shares of its common stock, in a private placement, for a total purchase price of approximately $25.1 million. The Company expects net proceeds to be approximately $23.2 million from this private placement, after deducting the placement agent's fees and other estimated expenses. The financial impact of this private placement is not included in this Balance Sheet Data.

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

Overview

We are a drug development company dedicated to bringing to the marketplace innovative products that help improve the lives of patients. Our goal is to identify, develop and commercialize products that address unmet medical needs, primarily for disorders of the nervous system. We are currently applying our drug development and drug delivery expertise to a pipeline of potential products that are in various stages of development, and that we intend to commercialize independently or through third party alliances.

On June 22, 2006, the FDA approved Opana® ER. Opana ER, an extended release formulation of oxymorphone hydrochloride, is a product that we developed with Endo Pharmaceuticals Inc., using our proprietary TIMERx® drug delivery technology. Opana ER is approved for twice-a-day dosing in patients with moderate to severe pain requiring continuous, around-the-clock opioid therapy for an extended period of time and is being marketed by Endo in the United States.

We are currently developing product candidates designed for the treatment of pain, epilepsy, Parkinson's disease and diseases related to the mitochondrial respiratory chain. We are developing nalbuphine ER, a controlled release formulation of nalbuphine hydrochloride, for the treatment of moderate chronic pain. In addition, we are developing A0001, a product candidate designed for the treatment of diseases related to inherited mitochondrial respiratory chain, under a collaboration and license agreement with Edison that we entered into in July 2007. Under the Edison agreement, we have agreed with Edison to collaborate on the development of A0001 and up to one additional drug candidate of Edison's, initially for the treatment of inherited mitochondrial respiratory chain diseases. Finally, we have two other product candidates in formulation development for treatment of epilepsy and Parkinson's disease.

Our strategy includes developing drug candidates to treat disorders of the nervous system. We expect to leverage our expertise in drug formulation and drug development to advance these products. We also expect to expend resources on product candidates obtained through in-licenses or acquisitions. Our spending in this area, however, is discretionary and is subject to identifying appropriate opportunities, as well as the availability of funds from our operations, cash resources, collaborative research and development arrangements, and external financing.

On March 11, 2008, we sold units representing an aggregate of 8,140,600 shares of our common stock, together with warrants to purchase an aggregate of 4,070,301 shares of our common stock, in a private placement, for a total purchase price of approximately $25.1 million. We expect net proceeds to be approximately $23.2 million from this private placement, after deducting the placement agent's fees and other estimated expenses.

The warrants are exercisable on or prior to March 11, 2013 at an exercise price of $3.62 per share. The warrants may also be exercised pursuant to cashless exercise provisions under certain circumstances.

Pursuant to the securities purchase agreement entered into in connection with the private placement, we agreed to file a registration statement with the SEC by April 10, 2008, registering for resale the shares and shares issuable under the warrants. We also agreed to use our reasonable best efforts to have the registration statement declared effective as soon as practicable after the filing date of the registration statement, but in any event within 90 days after the filing date of the registration statement. The failure to file the registration statement on or prior to April 10, 2008, or the failure to have the registration statement declared effective by the SEC within 90 days after we file the registration statement will result in financial penalties to us. We have agreed to maintain the registration statement's effectiveness until the earlier of (i) the later of (A) the twelve month anniversary of March 11, 2008, the closing date of the private placement or (B) the twelve month anniversary of the last date on which warrant shares are issued upon exercise of warrants and (ii) the date all of the shares and warrant shares have been resold by the original purchasers.

Products

Opana® ER. Opana ER is an oral extended-release opioid analgesic, which we developed with Endo using our proprietary TIMERx® technology. In June 2006, the FDA approved for marketing Opana ER, for twice-a-day dosing in patients with moderate to severe pain requiring continuous, around-the-clock opioid treatment for an extended period of time. Under the terms of our collaboration with Endo, Endo launched Opana ER in the United States in July 2006 in 5 mg, 10 mg, 20 mg and 40 mg tablets. In March 2008, Endo also announced the launch of three new dosage strengths of Opana ER including 7.5 mg, 15 mg, and 30 mg tablets.

In January 2007, we entered into an amendment to the strategic alliance agreement between us and Endo. Under the terms of this amendment, we and Endo agreed that royalties payable to us for U.S. sales of Opana ER would be calculated based on net sales of the product rather than on operating profit. We expect Endo to initiate the payment of royalties to us on U.S. sales of Opana ER in the second half of 2008. A description of this amendment is included above under the caption "Collaborative Agreements." Under the terms of the agreement with Endo, any fees, royalties, payments or other revenues received by the parties in connection with any collaborator outside of the United States will be divided equally. We and Endo are currently seeking a collaborator to develop and commercialize Opana ER in Europe.

Opana ER competes in the market for long acting, strong opioid analgesics with products such as Purdue Pharma's OxyContin® and MS Contin, Johnson and Johnson's Duragesic® patch, King Pharmaceuticals' Avinza® and Alpharma's Kadian®, as well as generic versions of some of these products. Products in the long acting, strong opioids market had aggregate sales in the United States in 2007 of approximately $4.1 billion.

We and Endo are parties to two lawsuits against IMPAX in connection with IMPAX's ANDA for Opana ER in four strengths, 5 mg, 10 mg, 20 mg and 40 mg. IMPAX notified Endo and us in October and November of 2007 that its ANDA contained Paragraph IV certifications for our patents, U.S. Patent Nos. 5,662,933, 5,958,456, and 7,276,250, listed in the Orange Book for Opana ER. We and Endo originally filed a lawsuit against IMPAX in the U.S. Dist. Delaware on November 15, 2007 alleging infringement of certain these patents, and seeking a declaratory judgment that, among other things, IMPAX had no basis to trigger the ANDA patent litigation process under the Hatch-Waxman Act because the FDA, according to IMPAX's press releases, had rescinded its acceptance of IMPAX's original ANDA before the date of IMPAX Paragraph IV certification notices. In addition, we and Endo asked the court to declare that these Paragraph IV certification notices to be null, void and of no legal effect.

On December 14, 2007, we received a letter from IMPAX notifying us that the refiling of its ANDA was accepted by the FDA as of November 23, 2007. The notice letter stated that IMPAX's ANDA contained Paragraph IV certifications for the three patents noted above and that the FDA had required IMPAX to notify Endo and us of these certifications. In this December notice, IMPAX also stated that it would not withdraw its prior Paragraph IV certification notices because it believed they were properly provided and because IMPAX was continuing its efforts to convince the FDA to assign an earlier filing date to its ANDA. As a result of the FDA's determination of IMPAX's ANDA filing date and the receipt of the new Paragraph IV certification notice, on December 20, 2007, we and Endo filed a notice of dismissal of the portion of our November 15, 2007 complaint seeking declaratory judgment as noted above. We and Endo did not dismiss the patent infringement claims in the November lawsuit because IMPAX refused to withdraw its prior Paragraph IV certification notices. On January 25, 2008, we and Endo filed a second lawsuit against IMPAX in U.S. Dist. Delaware, alleging infringement of two of these patents above in response to IMPAX's December notice. Given the FDA's acceptance of IMPAX's ANDA as of November 23, 2007, we believe that we are entitled to a 30-month stay under the Hatch-Waxman Act beginning on December 14, 2007. Endo and we intend to pursue all available legal and regulatory avenues defending Opana ER. A description of this litigation is included in "Part I. Item 3-Legal Proceedings."

In February 2008, we along with Endo, received a notice from Actavis advising of the filing by Actavis of an ANDA containing a Paragraph IV certification under 21 U.S.C. Section 355(j) for Opana ER in four strengths, 5 mg, 10 mg, 20 mg and 40 mg. The Actavis Paragraph IV certification notice refers to our patents,

U.S. Patent Nos. 5,128,143, 5,662,933, 5,958,456, and 7,276,250, which cover the formulation of Opana ER. These patents are listed in the FDA's Orange Book and expire in 2008, 2013, 2013, and 2023, respectively. We and Endo are currently reviewing the details of this notice from Actavis.

Nalbuphine ER. We are developing nalbuphine ER, a controlled release formulation of nalbuphine hydrochloride, for the treatment of moderate chronic pain. Nalbuphine ER, which we formulated using our TIMERx drug delivery technology, is designed to be taken as a tablet twice daily. Nalbuphine hydrochloride is a synthetic opioid agonist/antagonist analgesic that interacts with certain opioid receptors. The agonist/antagonist mechanism action of nalbuphine ER may reduce the potential for abuse of nalbuphine ER. Nalbuphine hydrochloride is currently only available as a sterile solution suitable for subcutaneous, intramuscular or intravenous injection for acute pain under the brand name Nubain® and in a generic version. The annual sales of Nubain and its generic version were approximately $11.2 million in 2007, but we believe the market for nalbuphine hydrochloride is limited by currently available formulations of the drug. We expect that nalbuphine ER, if approved, would compete in the moderate chronic pain market. Physicians currently treat patients with moderate chronic pain with a range of treatments from non-steroidal anti-inflammatory drugs, or NSAIDs, to strong opioids. These treatments include products such as Tramadol® ER and products containing hydrocodone, codeine or propoxyphene, such as Vicodin and Darvon. We believe the profile of nalbuphine ER may be attractive in the treatment of moderate chronic pain compared to current options because it should provide a better balance of good efficacy, low abuse potential and low side effects.

We conducted multiple Phase I studies on various formulations of nalbuphine ER to establish the pharmacokinetic profile and generate safety data. In December 2005, we completed a Phase IIa trial of nalbuphine ER designed to determine the degree and duration of pain relief of two different dose levels of nalbuphine ER in an acute dental pain model. The goal of this study was to establish the proof of efficacy in oral dosing. Results from this Phase IIa study demonstrated that nalbuphine ER reduced mean pain intensity in a dose-dependent manner over the twelve-hour period of the study. No unusual side effects were reported during the twelve-hour dosing interval.

In 2006, we conducted some reformulation work to develop the product for chronic pain and conducted Phase I studies. In January 2007, we commenced a Phase I dose escalation to steady state trial. The intent of this trial was to collect additional safety and pharmacokinetic information which was used to bridge the safety data from the acute pain trial we conducted in 2005 to the chronic pain trial we initiated in June 2007. The June 2007 Phase IIa trial was designed to determine the safety and efficacy of nalbuphine ER compared to placebo for treatment of moderate chronic pain. It was a randomized, double-blind, placebo controlled design, with a forced weekly dose escalation. The main objective of the trial was to evaluate the analgesic efficacy of nalbuphine ER in a patient population experiencing chronic pain. There were 138 patients in the intent-to-treat population with chronic pain secondary to osteoarthritis of the knee or hip. Patients enrolled in the trial were given the lowest dose of the drug for week one, increased to a mid-dose level for week two, and increased to the highest dose studied for week three. The study group included a 2-to-1 randomization of patients on drug versus placebo. We designed the trial with multiple endpoints related to clinical pain relief in an effort to understand the activity of the drug and provide the basis for designing a Phase IIb study. Based on the Phase IIa results, we have concluded that nalbuphine ER demonstrated trends of efficacy sufficient to support continued development of the drug. The adverse events were typical opioid-type side effects. In the study 24% of the nalbuphine ER patients reported no side effects, 66% reported side effects that were characterized as mild or moderate in severity, and 10% reported side effects that were severe. No drug-related serious adverse events were reported during the trial. The adverse events in the trial appear to have occurred only in the first week of the trial and were not chronic adverse events that continued throughout the study.

We are planning for a Phase IIb trial which we expect to commence in the second half of 2008 subject to the availability of capital resources to conduct such study. We expect that the goals of the Phase IIb trial will be to demonstrate statistically significant analgesic efficacy of the drug versus placebo using an accepted clinical endpoint, and to characterize a clinically meaningful titration regimen. We believe that this trial will take approximately one year to complete. We expect that if we complete all the clinical trials required by the FDA for nalbuphine ER, we would seek FDA approval of nalbuphine ER through the filing of a 505 (b)(2)

NDA. We expect to seek collaborators in the United States and Europe to complete the development of this product and to share marketing rights with the collaborators.

A0001. A0001 is a drug candidate we in-licensed from Edison under our collaboration and license agreement. A0001, a coenzyme Q molecular analog, has shown biological activity in cell assays developed by Edison to test the ability of this class of compounds to improve mitochondrial function. Impairment of mitochondrial function is commonly believed to be a significant factor in a number of inherited disorders, including Friedreich's Ataxia, Leber's Hereditary Optical Neuropathy, Coenzyme Q10 Deficiency Syndrome and MELAS syndrome. A0001 is commonly known to be orally bioavailable in humans and has received orphan drug designation from the FDA for the treatment of inherited mitochondrial respiratory chain diseases. We have completed the IND enabling toxicology studies for A0001. We intend to submit an Investigational New Drug Application, or IND, for certain of these indications and commence Phase 1 development on this compound in the second half of 2008.

In consideration for the rights granted to us under the Edison agreement, we paid Edison an upfront cash payment of $1.0 million upon entering into the Edison agreement and agreed to loan Edison up to an aggregate principal amount of $1.0 million, solely to fund its research and development, with the right to draw upon such loan commitment subject to certain limitations. We are also required to make payments to Edison upon achievement of specified milestones set forth in the Edison agreement and upon exercise of our option to develop another of Edison's compounds as noted above, and royalty payments based on net sales of products containing A0001 and any other compound as to which we exercise our option, or any replacement compound, as provided for in the agreement.

On February 5, 2008, we loaned Edison $1.0 million pursuant to the loan provisions of the Edison agreement. The loan bears interest at an annual rate of one month LIBOR at the time of the loan, plus 5%, or a total of 8.14%, which rate is fixed for the term of the loan. The loan matures on the earlier of July 16, 2012 and the occurrence of an event of default, as defined in the Edison agreement. All accrued and unpaid interest is payable on the maturity date; however, interest accruing on any outstanding loan amount after July 16, 2010 is due and payable monthly in arrears. As of March 11, 2008, $1.0 million is outstanding under this loan. We are currently assessing the collectability of the loan made to Edison. At the present time, we have not completed our initial assessment; however, we believe that there is the potential for us to record an impairment charge in our statement of operations during the first quarter of 2008, or at a future time as a result of on-going collectability assessments.

We also agreed to pay Edison a total of $5.5 million to fund Edison's discovery and research activities over the initial 18 months of the research period following the signing of the Edison agreement. This funding is in the form of payments made in advance each quarter. We have paid $2.8 million of the $5.5 million to Edison as of December 31, 2007. We have the option to extend the term of the research period beyond 18 months for up to three consecutive six month periods, subject to payments to Edison in amounts to be agreed upon. A further description of the Edison agreement is included above under the caption "Collaborative Agreements".

Additional Product Candidates. We have two other product candidates in formulation development:

PW4153	Parkinson's disease
PW4110	Epilepsy

We are currently developing formulations and plan to conduct pilot scale Phase I clinical studies on these product candidates to obtain pharmacokinetic data. If the Phase I clinical studies of any of these product candidates show the desired plasma level profiles, we expect to advance the product candidate into further clinical trials after consideration of a number of factors, including our available resources, at such time, the regulatory pathway and the development status of our other product candidates. We will also determine how to advance the product, for example whether to develop the product on our own and, if not, when to seek a collaborator.

In the third quarter of 2007, we completed a scientific review of our development programs, which we conducted to align our efforts with our corporate strategy and internal resources. As a result of this review, we

determined to cease development of torsemide ER, a controlled release formulation of torsemide, that we were developing for the treatment of chronic edema resulting from congestive heart failure. In addition, we made the decision to cease efforts on two Phase I programs.

Under a collaboration agreement with Mylan, we developed Nifedipine XL, a generic version of Procardia XL, based on our TIMERx technology. In March 2000, Mylan announced that it had signed a supply and distribution agreement with Pfizer, to market Pfizer's generic versions of all three strengths (30 mg, 60 mg, 90 mg) of Procardia XL. In connection with that agreement, Mylan decided not to market Nifedipine XL, and agreed to pay us a royalty on all future net sales of the 30 mg strength of Pfizer's generic Procardia XL.

We have incurred net losses since 1994 including net losses of $34.5 million, $31.3 million and $22.9 million during 2007, 2006 and 2005, respectively. As of December 31, 2007, our accumulated deficit was approximately $207 million. We expect operating losses and negative cash flows to continue until substantial sales of Opana ER or other products that we develop occur. We currently generate revenues primarily from royalties received from Mylan. Our future profitability will depend on several factors,. including:

- the commercial success of Opana ER, and the timing and amount of royalties from Endo's sales of Opana ER which may be affected by any potential generic entry;
- the level of our investment in research and development activities;
- the level of our investment for acquisitions, or in-licensing of technologies or compounds intended to support our growth;
- the successful development and commercialization of product candidates in our portfolio;
- the timing and amounts of payments to Edison in connection with the Edison agreement, as well as our internal costs of development for drug candidates for which we acquire rights under this agreement; and
- royalties from Mylan's sales of Pfizer's generic version of Procardia XL 30 mg.

Our strategy includes developing drug candidates to treat disorders of the nervous system. We expect to leverage our expertise in drug formulation and drug development to advance these products. We also expect to expend resources on new technologies and product candidates obtained through in-licenses or acquisitions. Our spending in the area of new technology and product candidates, however, is discretionary and is subject to identifying appropriate opportunities, as well as the availability of funds from our operations, cash resources, collaborative research and development arrangements, and external financing.

Our results of operations may fluctuate from quarter to quarter depending on the amount and timing of royalties on Endo's sales of Opana ER, which we expect in 2008, Mylan's sales of Pfizer's generic version of Procardia XL 30 mg, the volume and timing of shipments of formulated bulk TIMERx material, including to Endo, the variations in payments under our collaborative agreements, and the amount and timing of our investment in research and development activities.

Critical Accounting Policies and Estimates

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

Revenue Recognition

Royalties and licensing fees — We recognize revenues from non-refundable up-front fees received under collaboration agreements ratably over the performance period of the related collaboration agreements. If the estimated performance period is subsequently modified, the period over which the up-front fee is recognized is modified accordingly on a prospective basis. Non-refundable 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. Upon termination of a collaboration agreement, any remaining non-refundable licensing fees we had received, which had been deferred, are generally recognized in full. Product royalty fees are recognized when earned, as reported by our collaborators, and are generally subject to review or audit.

Milestone payments — We recognize revenue from milestone payments received under collaboration agreements when earned, provided that the milestone event is substantive, its achievability was not reasonably assured at the inception of the agreement, we have no further performance obligations relating to the event, and collectibility is reasonably assured. If these criteria are not met, we recognize milestone payments ratably over the remaining period of our performance obligations under the collaboration agreement.

Product sales — We recognize revenues from product sales when title transfers and customer acceptance provisions have lapsed, provided that collections of the related accounts receivable are probable. Shipping and handling costs are included in the cost of product sales.

Research and development reimbursements — We recognize revenue from reimbursements received in connection with our research and development collaboration agreements as related research and development costs are incurred, and our contractual services are performed, provided collectibility is reasonably assured. Such revenue is included in research and development reimbursements revenue in our statements of operations. Amounts contractually owed us under these research and development collaboration agreements, including any earned but unbilled receivables, are included in trade accounts receivable in our balance sheets. Our principal costs under these agreements are generally for our personnel conducting research and development, as well as for research and development performed by outside contractors or consultants.

Research and Development Expenses

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

These estimates involve identifying services, which have been performed on our behalf, and estimating the level of service performed and associated cost incurred for such service as of each balance sheet date in our financial statements. In connection with such service fees, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual levels of service incurred by such service providers. The date on which services commence, the level of services performed on or before a given date, and the cost of such services are subject to our judgment. We make these judgments based upon the facts and circumstances known to us in accordance with generally accepted accounting principles.

Deferred Taxes — Valuation Allowance

Valuation allowances are established against the recorded deferred income tax assets to the extent that we believe it is more likely than not that a portion of the deferred income tax assets are not realizable. While we may consider any potential future taxable income and ongoing prudent and feasible tax planning strategies in

assessing the need for the valuation allowance, in the event we were to determine that we would be able to realize our deferred tax assets in the future in excess of our net recorded amount, an adjustment to the deferred tax asset would increase income in the period such determination was made. At December 31, 2007, we had recorded full valuation allowances totaling approximately $72.6 million against our net deferred tax assets, as we believe it more likely than not that our deferred income tax assets will not be realized due to our historical losses.

Impairment of Long-Lived Assets

For purposes of recognizing and measuring impairment of our long-lived assets, including intangible assets such as our patents, we assess the recoverability of the carrying amount of these assets whenever facts and circumstances indicate that the carrying amount may not be fully recoverable. We measure the impairment related to long-lived assets by the amount by which the carrying amount of the assets exceeds the fair value of the assets. In assessing the recoverability of our intangible assets, we must make assumptions and estimates regarding the amounts and timing of future cash flows and other factors to determine the fair value of the respective assets. Estimated cash flow assumptions include profitability and/or net sales projections provided by our marketing partners or developed internally, based upon historical revenues or projected market share for new products. If these estimates or their related assumptions change in the future, we may be required to record impairment charges for these assets.

Share-Based Compensation

Effective January 1, 2006, we adopted SFAS 123R, "Share-Based Payment" requiring the expense recognition of the estimated fair value of all share-based payments granted to employees and directors, including grants of stock options and grants under compensatory employee stock purchase plans. Prior to this, we did not record the estimated fair value associated with such awards as an expense, but rather, we disclosed the estimated fair value in the notes to our financial statements as was permitted prior to our adoption of SFAS 123R. For the year ended December 31, 2007, we recorded approximately $3.8 million of expense associated with share-based payments, primarily comprised of approximately $2.5 million attributable to employee and director stock options, and $1.1 million attributable to restricted stock awards. As of December 31, 2007, there was approximately $3.1 million and $953,000 of unrecognized compensation cost related to stock option awards and outstanding restricted stock awards, respectively, that we expect to recognize as expense over a weighted average period of 1.1 years and 3.2 years, respectively.

The valuation of employee stock options is an inherently subjective process, since market values are generally not available for long-term, non-transferable employee stock options. Accordingly, we utilize an option pricing model to derive an estimated fair value. In calculating the estimated fair value of our stock options, we used a Black-Scholes-Merton pricing model, which requires the consideration of the following variables for purposes of estimating fair value:

- the stock option exercise price;
- the expected term of the option;
- the grant date price of our common stock, which is issuable upon exercise of the option;
- the expected volatility of our common stock;
- expected dividends on our common stock (we do not anticipate paying dividends for the foreseeable future); and
- the risk free interest rate for the expected option term.

Of the variables above, we believe that the selection of an expected term and expected stock price volatility are the most subjective. We use historical employee exercise and option expiration data to estimate the expected term assumption for the Black-Scholes-Merton grant date valuation. We believe that this historical data is currently the best estimate of the expected term of a new option, and that generally, all groups of our employees exhibit similar exercise behavior. In general, the longer the expected term used in the

Black-Scholes-Merton pricing model, the higher the grant-date fair value of the option. For options granted prior to 2006, we used historical volatility to estimate the grant-date fair value of stock options. Historical volatility is calculated based on a period equal to the expected term of stock option awards, and actual stock prices during this period. Following a review of alternative methods of estimating expected volatility, we changed our method of estimating expected volatility for all stock options granted after 2005 from exclusively relying on historical volatility to using an average of implied volatility and historical volatility. In accordance with SFAS 123R, we selected the average of implied volatility and historical volatility as we believe neither of these measures is better than the other in estimating the expected volatility of our common stock. We believe that our estimates, both expected term and stock price volatility, are reasonable in light of the historical data we analyzed.

The valuation assumptions selected upon our adoption of SFAS 123R were applied to stock options that we granted subsequent to our adoption of SFAS 123R on January 1, 2006; however, stock option expense recorded in the years ended December 31, 2007 and 2006 also included amounts related to the continued vesting of stock options that were granted prior to January 1, 2006. In accordance with the transition provisions of SFAS 123R, the grant date estimates of fair value associated with prior awards, which were also calculated using a Black-Scholes-Merton option pricing model, have not been changed. The specific valuation assumptions that were utilized for purposes of deriving an estimate of fair value at the time that prior awards were issued are as disclosed in our prior annual reports on Form 10-K. We use the accelerated attribution method to recognize expense for all options granted.

Upon the adoption of SFAS 123R, we were also required to estimate the level of award forfeitures expected to occur, and record compensation cost only for those awards that are ultimately expected to vest. This requirement applies to all awards that are not yet vested, including awards granted prior to January 1, 2006. Accordingly, we periodically perform a historical analysis of option awards that were forfeited (such as by employee separation) prior to vesting, and ultimately record stock option expense that reflects this estimated forfeiture rate.

Results of Operations for Years Ended December 31, 2007, 2006 and 2005

Revenues

	2007	Percentage Increase (Decrease) from 2006	2006	Percentage Increase (Decrease) from 2005	2005
	(In thousands, except percentages)				
Royalty and Licensing Fees	$2,613	(16)%	$3,118	(50)%	$6,213
Product Sales	519	36	381	n/a	—
Research and Development Reimbursement	176	n/a	—	—	—
Total Revenues	$3,308	(5)%	$3,499	(44)%	$6,213

Substantially all of the royalty and licensing fees for 2007 and 2006 were generated from royalties received from Mylan. In 2005, royalties and licensing fees included $2.25 million in revenue recognized under our license agreement with Prism, which was terminated in the third quarter of 2005. Royalties from Mylan decreased in 2007 as compared to 2006, and in 2006 as compared to 2005, as a result of decreases in Mylan's net sales of Pfizer's 30 mg generic version of Procardia XL. We believe that the decreases in royalties from 2006 to 2007 and from 2005 to 2006 were due in part to two of Mylan's customers purchasing significantly less product in 2007 as compared to 2006, and in 2006 as compared to 2005. In addition, we believe royalties decreased in both 2007 and 2006 from the prior year due to generic competition which contributed toward lower pricing overall.

Product sales in 2007 and 2006 consisted of sales of formulated TIMERx material to collaborators, with no comparable product sales occurring in 2005. Product sales in 2006 exclude shipments of TIMERx material to Endo for use in Opana ER that occurred prior to FDA approval in June 2006. We recognized the sales price

and related costs of these pre-approval shipments as offsets to research and development expense in accordance with our policy for cost-sharing arrangements, such as with Endo in connection with Opana ER. Following the FDA approval of Opana ER, we recognize TIMERx material shipments to Endo for use in Opana ER as product sales. As a result, we expect product sales to increase modestly in future periods as a result of higher forecasted sales of Opana ER.

Revenue from research and development reimbursement consists of reimbursements of our expenses under a research and development collaboration agreement involving the development of a product candidate using our TIMERx technology.

Cost of Revenues

	2007	Percentage Increase (Decrease) from 2006	2006	Percentage Increase (Decrease) from 2005	2005
	(In thousands, except percentages)				
Cost of Product Sales	$438	90%	$231	492%	$39
Cost of Research and Development Reimbursements	167	n/a	—	—	—
Total Cost of Revenues	$605	162%	$231	492%	$39

Cost of product sales primarily consists of the costs related to sales of formulated TIMERx material to our collaborators, as well as amortization of related patent and deferred royalty costs. The cost of product sales increased from 2006 to 2007 and from 2005 to 2006 primarily as a result of increased shipments of TIMERx product to Endo for use in Opana ER.

Cost of research and development reimbursements consists of our expenses under a research and development collaboration agreement which commenced in August 2007 involving the development of a product candidate using our TIMERx technology.

Selling, General and Administrative Expenses

	2007	Percentage Increase (Decrease) from 2006	2006	Percentage Increase (Decrease) from 2005	2005
	(In thousands, except percentages)				
Selling, General and Administrative Expenses	$14,260	1%	$14,075	6%	$13,247

Selling, general and administrative expenses, or SG&A, for 2007 increased as compared to 2006 due to increased facility-related costs, and legal fees associated with the IMPAX litigation, business development activities and general corporate matters. These increased costs and fees were partially offset by decreased market research expenses, as market research expenses for 2006 included significant costs associated with an extensive review of the product candidates then in our pipeline.

The increases in our facility-related costs noted above were primarily attributable to our efforts in the first half of 2007 to explore alternative locations for our facilities. In June 2007, we extended the lease terms of our two facilities. We anticipate lower facility-related costs in 2008 as compared to 2007.

The increase in SG&A expenses in 2006 as compared to 2005, was primarily due to increased compensation expense, primarily relating to the $2.1 million recorded for employee stock options resulting from our adoption of SFAS 123R effective January 1, 2006, as well as increased market research expenses associated with our extensive review of the product candidates in our pipeline. In 2005, SG&A included a one-time charge of approximately $3.0 million that we recorded in connection with the agreement we entered into with Tod Hamachek, our former Chairman and Chief Executive Officer, upon his resignation in February 2005. This $3.0 million charge included a non-cash charge of approximately $2.4 million related to the accelerated vesting and extension of exercise periods of stock options held by Mr. Hamachek.

We expect that SG&A expenses in 2008 will decline as compared to 2007 as we seek SG&A expense reductions in employee headcount, market research expense and professional fees.

Research and Product Development Expenses

Research and product development expenses increased by $704,000 in 2007 as compared to 2006 due to spending on the Edison program and increased spending on the development of nalbuphine ER. These increases were partially offset by lower spending on our torsemide ER program, which we terminated in July 2007, lower expenses related to stock based compensation primarily as a result of stock option forfeitures and lower expenses associated with Opana ER, reflecting the higher expenses we incurred in 2006 in preparation for Endo's launch of Opana ER. We intend to carefully manage our research and development expenses in 2008 through reductions in headcount and consulting fees, and managing the timelines of our development programs. We do not expect, however, our overall investment in research and product development expenses to decrease significantly in 2008.

Research and product development expenses increased by $5.1 million or 28% in 2006 as compared to 2005, primarily due to increased spending in 2006 on the development of nalbuphine ER and torsemide ER, as well as increased compensation expense of $1.9 million related to stock based compensation resulting from our adoption of SFAS 123R effective January 1, 2006. These increases were partially offset by expense reductions in 2006 attributable to the discontinuation in the second quarter of 2005 of the development of PW2101, a drug that we were developing in 2004 and 2005 for the treatment of hypertension and angina.

In the table below, research and product development expenses are set forth in the following categories:

	2007	Percentage Increase (Decrease) from 2006	2006	Percentage Increase (Decrease) from 2005	2005
	(In thousands, except percentages)				
Nalbuphine ER	$ 6,618	57%	$ 4,211	256%	$ 1,184
Torsemide ER	413	(81)%	2,196	111%	1,043
Edison Program	3,797	n/a	—	—	—
PW2101	—	—	—	(100)%	1,817
Phase I and Internal Costs	12,733	(23)%	16,450	20%	13,753
Total Research and Product Development Expense	$23,561	3%	$22,857	28%	$17,797

Our quarterly reports filed in 2007 included separate categories for Phase I Products and Internal Costs and for Research and New Technology development which included costs related to research on drug delivery systems. Because of our increased focus on product development and minimal research being done on new technology, these costs are now all included in Phase I and Internal Costs.

- *Nalbuphine ER* — These expenses reflect our direct external expenses relating to the development of nalbuphine ER. These expenses approximated 28% of R&D expenses for 2007 and consisted primarily of payments to third parties in connection with clinical trials of nalbuphine ER, including payments for the drug active. The expenses for this program increased in 2007 from 2006, as we conducted a Phase I safety trial and a Phase IIa proof of concept efficacy and safety trial in 2007. During 2008, we expect our research and product development expenses relating to nalbuphine ER to decrease compared to 2007 as we do not plan to begin a Phase IIb trial until the second half of 2008 subject to the availability of capital resources to conduct this study. The costs, however, could be significantly impacted by the timing of when we start this trial; therefore, the timing of the trial will effect the level of our R&D expenses in 2008.
- *Torsemide ER* — These expenses reflect our direct external expenses relating to the development of torsemide ER. These expenses consisted primarily of payments to third parties in connection with clinical trials of torsemide ER. During the third quarter of 2007, we completed a review of all our

development programs, including torsemide ER. As a result of this review, we terminated our development efforts on this program. This decision was based upon our analysis of the expected level of effort required for this program compared to our internal resources and the program's lack of fit with our corporate strategy. We do not expect to incur any expenses for torsemide ER in future periods.

- *Edison Program* — These expenses reflect our funding of Edison's research activities under the Edison agreement as well as our direct external expense relating to the preclinical development work that we are conducting on A0001. The amounts included in 2007 include the initial upfront payment of $1.0 million and quarterly research and development payments that we began paying in the second half of 2007. We anticipate that these expenses will increase in 2008 as we continue to make quarterly research and development payments for the full year of 2008 and increase our activity with respect to the development of A0001, including a Phase I clinical trial we currently intend to commence in the second half of 2008.
- *Phase I and Internal Costs* — These expenses reflect internal and external expenses not separately reported under a product development program noted above, and include the areas of pharmaceutical development, clinical and regulatory. The types of expenses included in internal expenses primarily are salary and benefits, stock based compensation costs, depreciation on purchased equipment and the amortization or any write-downs of patent costs, other than product patent write-offs charged directly to a separately reported product development program or amortization of patent costs relating to commercialized products which are included in cost of revenues. The types of expenses included in external expenses are primarily payments to third parties for the drug active and proof-of-principle biostudies conducted on our Phase I product candidates.

These costs decreased in 2007 from the comparable periods in 2006, primarily as a result of a decrease in share-based compensation expense, as discussed above, as well as the termination of certain preclinical programs in 2007. We continually evaluate the Phase I product candidates we are developing, and may terminate or accelerate development of product candidates based on study results, product development risk, commercial opportunity, perceived time to market and other factors

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

Tax Rates

The effective tax rates for 2007, 2006 and 2005 were essentially zero. The effective tax rates differs than the federal statutory rate of a 34% benefit due primarily to valuation allowances recorded to offset net deferred tax assets relating to our net operating losses.

Liquidity and Capital Resources

Sources of Liquidity

Since 1998, when we became an independent, publicly owned company, we have funded our operations and capital expenditures from the proceeds of the sale and issuance of shares of common stock, sales of excipients, the sale of our excipients business, sales of formulated bulk TIMERx material, royalties and milestone payments from Mylan and other collaborators, and advances under credit facilities. As of December 31, 2007, we had cash, cash equivalents and short-term investments of $23.0 million.

Private Placement. On March 11, 2008, we sold units representing an aggregate of 8,140,600 shares of our common stock, $0.001 par value per share, together with warrants to purchase an aggregate of

4,070,301 shares of our common stock, in a private placement, for a total purchase price of approximately $25.1 million. We expect net proceeds to be approximately $23.2 million from this private placement, after deducting the placement agent's fees and other estimated expenses.

The warrants are exercisable on or prior to March 11, 2013, at an exercise price of $3.62 per share. The warrants may also be exercised pursuant to cashless exercise provisions under certain circumstances.

Pursuant to the securities purchase agreement entered into in connection with the private placement, we agreed to file a registration statement with the SEC by April 10, 2008, registering for resale the shares and shares issuable under the warrants. We also agreed to use our reasonable best efforts to have the registration statement declared effective as soon as practicable after the filing date of the registration statement, but in any event within 90 days after the filing date of the registration statement. The failure to file the registration statement on or prior to April 10, 2008, or the failure to have the registration statement declared effective by the SEC within 90 days after we file the registration statement will result in financial penalties to us. We has agreed to maintain the registration statement's effectiveness until the earlier of (i) the later of (A) the twelve month anniversary of March 11, 2008, the closing of the private placement or (B) the twelve month anniversary of the last date on which warrant shares are issued upon exercise of warrants and (ii) the date all of the shares and warrant shares have been resold by the original purchasers.

Senior Secured Credit Facility. On March 13, 2007, we entered into a $24.0 million senior secured credit facility with Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services Inc. The credit facility consists of: (i) a $12.0 million term loan advanced upon the closing of the credit facility and (ii) a $12.0 million term loan that we may access until September 15, 2008, subject to conditions specified in the agreement. Under the credit facility, we may not access this second amount unless our market capitalization at the time of the advance request is greater than $250 million and an additional patent relating to Opana ER has been issued and listed in the FDA's Orange Book. On October 2, 2007, a patent relating to Opana ER was issued and listed in the Orange Book. As a result, we may access the additional $12.0 million at any time that our market capitalization is greater than $250 million up until September 15, 2008, as noted above. As of March 11, 2008, our market capitalization was approximately $88.5 million.

In connection with this credit facility, we granted the lender a perfected first priority security interest in all existing and after-acquired assets, excluding our intellectual property which is subject to a negative pledge; royalty payments from Mylan on their sales of Pfizer's generic version of Procardia XL 30 mg, if we pledge such royalty payments to another lender; up to $3.0 million of equipment which we may, at our election, pledge to another lender in connection with an equipment-financing facility separate from the credit facility; and the assets of the trust described below under "Contractual Obligations". In addition, we are precluded from paying cash dividends to our shareholders during the term of the agreement. Each loan has a term of 42 months from the date of advance with interest-only payments for the first nine months, but in any event, not beyond September 30, 2008; interest plus monthly principal payments equal to 1.67% of the loan amount for the period from the end of the interest-only period through December 2008; and interest plus straight line amortization payments with respect to the remaining principal balance for the remainder of the term.

Amounts outstanding under the credit facility bear interest at an annual rate of one month LIBOR at the time of the advance plus 5%. The rate will be fixed for the term of the applicable loan. At the time of final payment of each loan under the credit facility, we will pay an exit fee of 3.0% of the original principal loan amount. Should any prepayment occur, we are also required to pay prepayment penalties of 3.0% of any prepaid amount in the first year, 2.0% of any prepaid amount in the second year and 1% of any prepaid amount thereafter. As of December 31, 2007, the interest rate on the credit facility was 10.32% and $12.0 million was outstanding. Beginning January 2008, we began making monthly principal payments on this loan, in addition to the monthly interest payments. Based on the terms of the credit facility, the loan amount currently outstanding will be fully paid by September 2010.

Cash Flows

In 2007, we had negative cash flow from operations of $29.6 million, primarily due to our net loss of $34.5 million for the year, which included depreciation and amortization of $1.5 million and a non-cash charge of $3.8 million for stock-based compensation. During 2007, we also expended approximately $1.5 million in cash in connection with the royalty termination agreements discussed below. Such costs were deferred and are being amortized.

In 2006, we had negative cash flow from operations of $23.6 million, primarily due to our net loss of $31.3 million for the year which included depreciation and amortization of $1.6 million and a non-cash charge of $5.0 million for stock-based compensation. In 2005, we had negative cash flow from operations of $20.1 million, primarily due to the net loss of $22.9 million we had for the year which included depreciation and amortization of $1.5 million, inventory and patent write-offs of $634,000 and a non-cash charge of $2.4 million relating to the accelerated vesting and extension of exercise periods of stock options held by Mr. Hamachek in connection with his resignation in February 2005. Operating cash flows in 2005 also included approximately $2.7 million in the net pay-down of accounts payable and accrued expenses.

In 2007, net cash provided by investing activities totaled $16.1 million, primarily reflecting purchases and maturities of marketable securities of $17.3 million. Net cash provided by investing activities also reflected $918,000 expended primarily for the acquisition of laboratory equipment for drug development activities and $319,000 expended to secure patents on technology. In 2006, net cash provided by investing activities totaled $13.1 million, primarily reflecting sales and maturities of marketable securities, net of purchases, of $15.1 million. Net cash provided by investing activities also reflected $1.8 million expended primarily for the acquisition of laboratory equipment for drug development activities and $619,000 expended to secure patents on technology we have developed, as well as proceeds from the withdrawal of $446,000 from the cash surrender value of a life insurance policy to reimburse us for retirement and deferred compensation benefits we directly paid to Mr. Hamachek. In 2005, net cash provided by investing activities totaled $20.3 million primarily reflecting sales and maturities of marketable securities, net of purchases, of $21.0 million. In addition, investing activities in 2005 reflected $276,000 in capital expenditures for the acquisitions of fixed assets primarily related to laboratory equipment for drug development activities as well as costs incurred for information technology. Funds expended for patents in 2005 totaled $479,000 and included costs to secure patents on technology and products developed by us.

Financing activities provided $13.0 million in cash in 2007, primarily from the proceeds of the term loan discussed above and net cash proceeds from stock option exercises. In 2006 and 2005, financing activities provided $10.8 million and $1.5 million, respectively, in cash, substantially all due to net cash proceeds from stock option exercises.

On February 1, 2007, we entered into a royalty termination agreement with Dr. Baichwal, our Senior Vice President, Licensing and Chief Scientific Officer, terminating certain provisions of the recognition and incentive agreement dated as of May 14, 1990, as amended, between Penwest and Dr. Baichwal. Under the recognition and incentive agreement, we were obligated to pay Dr. Baichwal on an annual basis in arrears (i) one-half of one percent of our net sales of TIMERx material to third parties, (ii) one-half of one percent of royalties received by us under licenses, collaborations or other exploitation agreements with third parties with respect to the sale, license, use or exploitation by such third parties of products based on or incorporating the TIMERx material, and (iii) one-half of one percent of payments made in lieu of the net sales or royalties as described above and received by us. Under the terms of the termination agreement, Penwest and Dr. Baichwal terminated this payment obligation and agreed that we would have no further obligation to make any payments to Dr. Baichwal under the recognition and incentive agreement except for amounts owed with respect to 2006. On February 1, 2007 we paid Dr. Baichwal $770,000 in cash and issued to him 19,696 shares of our common stock with a fair market value of approximately $287,000, for total consideration of $1,057,000. Dr. Baichwal remains an officer of Penwest.

On February 1, 2007, we entered into a royalty termination agreement with Dr. Staniforth, a director of and consultant to Penwest, terminating the royalty agreement dated as of September 25, 1992, as amended, between Penwest and Dr. Staniforth. Under the royalty agreement, we were obligated to pay Dr. Staniforth on

an annual basis in arrears one-half of one percent of our net revenue generated from the sales or licenses of products covered by the TIMERx patents. Under the terms of the termination agreement, Penwest and Dr. Staniforth terminated this payment obligation and agreed that we would have no further obligation to make any payments to Dr. Staniforth under the royalty agreement except for amounts owed with respect to 2006. On February 1, 2007 we paid Dr. Staniforth $770,000 in cash and issued to him 19,696 shares of our common stock with a fair market value of approximately $287,000, for total consideration of $1,057,000. Dr. Staniforth remains on the Board of Directors.

On February 5, 2008, we loaned Edison $1.0 million pursuant to the loan agreement provisions of the Edison agreement. The loan bears interest at an annual rate of one month LIBOR at the time of the loan, plus 5% , or a total of 8.14%, which rate is fixed for the term of the loan. The loan matures or the earlier of July 16, 2012 and the occurrence of an event of default, as defined the Edison agreement. All accrued and unpaid interest is payable on the maturity date; however, interest accruing on any outstanding loan amount after July 16, 2010 is due and payable monthly in arrears. As of March 11, 2008, $1.0 million is outstanding under this loan. We are currently assessing the collectability of the loan made to Edison. At the present time, we have not completed our initial assessment; however, we believe that there is the potential for us to record an impairment charge in our statement of operations during the first quarter of 2008, or at a future time as a result of on-going collectability assessments.

Funding Requirements

We anticipate that, based upon our current operating plan, our existing capital resources together with the expected net proceeds of $23.2 million from the private placement and expected royalties from third parties, will be sufficient to fund our operations on an ongoing basis through at least the first quarter of 2009.

We currently anticipate that we will begin to receive royalty payments related to Opana ER from Endo in the second half of 2008. In addition, we are currently taking measures to reduce our spending and manage our costs more closely. This may include adjusting the pace and timing of our clinical programs to match these costs with our financial resources. Finally, we plan to seek to enter into collaboration and licensing agreements for nalbuphine ER and other of our products and technologies. The goal with these efforts is to be able to fund our ongoing operations until at least the second half of 2009 without seeking additional funding from the capital market.

We currently do not meet the $250 million market capitalization requirement necessary to draw upon the second $12 million term loan under our credit facility with Merrill Lynch Capital. If we were able to borrow these funds, we believe our ability to operate on an ongoing basis without additional external financing would extend for at least one to two additional calendar quarters, depending on the timing of our clinical trials. We expect our capital expenditures to be lower in 2008 as compared to 2007 and to not exceed approximately $500,000 for 2008 as we closely manage our capital spending.

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

- the commercial success of Opana ER;
- the timing and amount of payments received under collaborative agreements, including in particular our agreement with Endo with respect to Opana ER and our agreement with Mylan with respect to Pfizer's generic Procardia XL 30 mg;
- our ability to access the second $12 million term loan under the credit facility and the timing of the availability of this $12 million;
- the timing and amount of payments to Edison in connection with the Edison agreement, as well as our internal costs of development for drug candidates for which we acquire rights under the Edison agreement;

- the progress of other collaborative and independent development projects, funding obligations with respect to the projects, and the related costs to us of clinical studies for our product candidates;
- the level of investment for the acquisition or in-licensing of technologies or compounds intended to support our growth;
- the structure and terms of any future collaborative agreements;
- the prosecution, defense and enforcement of our patents and other intellectual property rights, such as the Opana ER patents and the IMPAX matter;
- the prosecution, defense and enforcement of our patents and other intellectual property rights, such as our Orange Book listed patents for Opana ER including our costs associated with the IMPAX litigation and any other litigation which we become involved;
- the level of our investment in capital expenditures for facilities or equipment; and
- our success in reducing our spending and managing our costs.

If we determine to acquire additional product candidates or technologies, we may need to seek additional funding through collaborative agreements, or public financings of equity or debt securities.

We plan to meet our long-term cash requirements through our existing balances in cash and marketable securities, the second term loan of the credit facility noted above if we are able to meet the requirements necessary to borrow these funds and revenues from collaborative agreements, as well as through equity or debt financings. In July 2005, we filed a registration statement on Form S-3 with the SEC, which became effective on August 17, 2005. This shelf registration statement covers the issuance and sale by us of any combination of common stock, preferred stock, debt securities and warrants having an aggregate purchase price of up to $75 million as of March 11, 2008, no securities have been issued under this shelf registration statement.

If we raise additional funds by issuing equity securities, further dilution to our then-existing shareholders may result. Additional debt financing, such as the credit facility noted above, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt or equity financing may contain terms, such as liquidation and other preferences, that are not favorable to us or our shareholders. If we raise additional funds through collaboration and licensing arrangements or research and development with third parties, it may be necessary to relinquish valuable rights to our technologies, research programs or potential product, or grant licenses on terms that may not be favorable to us. We cannot be certain that additional financing will be available in amounts or on terms acceptable to us, if at all. If we are unable to obtain this additional financing, we may be required to delay, reduce the scope of, or eliminate one or more of our planned research, development and commercialization activities, including our planned clinical trials, which could harm our financial condition and operating results.

Contractual Obligations

Our outstanding contractual cash obligations include obligations under our operating leases primarily for facilities in Danbury, CT and Patterson, NY, purchase obligations primarily relating to clinical development, payments due under our credit facility relating to interest, principal and exit fees, obligations under deferred compensation plans as discussed below, and sponsored research and development payment obligations under our Edison agreement as described above. Following is a table summarizing our contractual obligations as of December 31, 2007 (in thousands).

	Total	Less than One Year	1-3 Years	4-5 Years	After 5 Years
Operating leases	$ 1,406	$ 806	$ 600	$ —	$ —
Purchase obligations	3,205	3,205	—	—	—
Deferred compensation, including current portion	2,878	294	587	587	1,410
Payments due under credit facility	14,423	3,548	10,875	—	—
Edison agreement	4,667	4,542	125	—	—
Total	$26,579	$12,395	$12,187	$587	$1,410

Deferred compensation, including current portion, reflects the commitments described below:

- We have a Supplemental Executive Retirement Plan, or SERP, a nonqualified plan which covers our former Chairman and Chief Executive Officer, Tod R. Hamachek. Under the SERP, effective in May 2005, we became obligated to pay Mr. Hamachek approximately $12,600 per month over the lives of Mr. Hamachek and his spouse.
- We also have a Deferred Compensation Plan, or DCP, a nonqualified plan which covers Mr. Hamachek. Under the DCP, effective in May 2005, we became obligated to pay Mr. Hamachek approximately $140,000 per year, including interest, in ten annual installments. However, these installments are recalculated annually based on market interest rates as provided for under the DCP.

We do not fund these liabilities, and no assets are held by the plans. However, we have two whole-life insurance policies in a rabbi trust, the cash surrender value or death benefits of which are held in trust for the SERP and DCP liabilities. In April 2006, we withdrew from the trust approximately $446,000 as reimbursement for all SERP and DCP benefit payments we previously made to Mr. Hamachek. Effective in June 2006, Mr. Hamachek's SERP and DCP benefit payments are being made directly from the assets in the trust. As of December 31, 2007, trust assets consisted of the cash surrender value of these life insurance polices totaling $2.5 million and $4,000 held in a money market account.

Under the terms of our Edison agreement, we are obligated to make milestone payments to Edison upon the achievement of certain clinical and regulatory events. We will not be responsible for the payment of future milestone and/or royalty payments in the event that the development program is discontinued and the agreement is terminated prior to the achievement of these events. Preclinical and clinical development of drug candidates is a long, expensive and uncertain process. At any stage of the preclinical or clinical development process, we may decide to discontinue the development of A0001 or other drug candidates under the Edison agreement. The contractual obligations listed in the table above do not include any such future potential milestone or royalty payments to Edison. In addition, as discussed above, under the terms of the Edison agreement, Edison had the right to draw upon a loan commitment we made to them of up to $1.0 million. On February 5, 2008, we loaned Edison $1.0 million pursuant to the loan agreement which is included in the "Edison agreement" in the table above.

Net Operating Loss Carryforwards

As of December 31, 2007, we had federal net operating loss, or NOL, carryforwards of approximately $191.4 million for income tax purposes, of which approximately $6.2 million, $8.4 million, $9.1 million, $17.7 million, $19.4 million, $13.5 million, $22.8 million, $21.8 million, $42.4 million and $30.1 million expire in 2018, 2019, 2020, 2021, 2022, 2023, 2024, 2025, 2026 and 2027, respectively. In addition, we had federal research and development tax credit carryforwards of approximately $6.3 million of which $67,000, $359,000, $341,000, $777,000, $828,000, $858,000, $760,000, $669,000, $926,000 and $695,000 expire in 2018, 2019, 2020, 2021, 2022, 2023, 2024, 2025, 2026 and 2027, respectively. The use of the NOL carryforwards, and research and development tax credit carryforwards are limited to our future taxable earnings. For financial reporting purposes, as of December 31, 2007, and 2006, respectively, valuation allowances of $72.6 million and $62.7 million have been recognized to offset net deferred tax assets, primarily attributable to the NOL carryforwards. The valuation allowance increased $9.9 million in 2007, $14.3 million in 2006 and $8.2 million in 2005. Utilization of the operating losses are subject to limitations due to the ownership change provisions of the Internal Revenue Code. In general, Section 382 of the Internal Revenue Code could limit our ability to use our NOL carryforwards for U.S. federal income tax purposes in the event of certain changes in ownership of our company, including as a result of trading activity in our common stock and offerings of common stock by us, such as our recent private placement. If such limitations were triggered as a result of future shifts in ownership of us, the use of our NOL carryforwards for U.S. federal income tax purposes would be limited.

Market Risk and Risk Management Policies

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

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

As of December 31, 2007, our marketable securities consisted primarily of corporate debt and U.S. Government-agency backed discounted notes, and approximated $7.3 million. These marketable securities had maturity dates of up to six months. Due to the relatively short-term maturities of these securities, management believes there is no significant market risk. As of December 31, 2007, market values approximated carrying values. As of December 31, 2007, we had approximately $23.0 million in cash, cash equivalents and short-term investments, and accordingly, a sustained decrease in the rate of interest earned of 1% would have caused a decrease in the annual amount of interest earned of up to approximately $230,000.

Recent Accounting Pronouncements

On January 1, 2007, we adopted the provisions of Financial Accounting Standards Board, or FASB, Interpretation No. 48, "Accounting for Uncertainty in Income Taxes — an interpretation of FASB Statement No. 109", or FIN 48, is an interpretation of Statement of Financial Accounting Standards, or SFAS, 109, which clarifies the accounting for uncertainty in income taxes. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 requires that we recognize in our financial statements the impact of a tax position if that position is more likely than not to be sustained on audit, based on the technical merits of the position. FIN 48 also provides guidance on derecognition of a previously recognized tax position, classification, interest and penalties, accounting in interim periods and disclosures. The provisions of FIN 48

were effective beginning January 1, 2007, with any cumulative effect of the change in accounting principle to be recorded as an adjustment to the opening balance of retained earnings.

We currently have a full valuation allowance against our net deferred tax assets and have not recognized any benefits from tax positions in our statements of operations. Accordingly, the adoption of the provisions of FIN 48 did not have a material impact on our financial statements.

We expect to recognize potential interest and penalties related to income tax positions as a component of income tax expense in our statements of operations in any future periods in which we must record a liability. Since we have not recorded a liability at December 31, 2007, there would be no impact to our effective tax rate. We do not anticipate that total unrecognized tax benefits will significantly change during the next twelve months.

We are subject to federal and state income tax examinations for all tax periods subsequent to our spin-off from our former parent company on August 31, 1998.

In February 2007, the FASB issued SFAS No. 159 "The Fair Value Option for Financial Assets and Financial Liabilities — Including an amendment of FASB Statement No. 115", or SFAS 159 . SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. SFAS 159 is effective for fiscal years beginning after November 15, 2007 and, as such, we plan to adopt the provisions of SFAS 159 as of January 1, 2008 and we do not expect a material impact from this adoption on our results of operations, financial position or cash flow.

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements", or SFAS 157. SFAS 157 provides a common definition of fair value to be applied to existing GAAP requiring the use of fair value measures, establishes a framework for measuring fair value and enhances disclosure about fair value measures under other accounting pronouncements, but does not change existing guidance as to whether or not an asset or liability is carried at fair value. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 for all financial assets and liabilities and any other assets and liabilities that are recognized or disclosed at fair value on a recurring basis. For nonfinancial assets and liabilities, SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2008. We plan to adopt the provisions of SFAS 157 as of January 1, 2008, and we do not expect a material impact on our results of operations, financial position or cash flow.

In June 2007, the FASB's Emerging Issues Task Force, or EITF, reached a consensus on EITF Issue No. 07-3, *"Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities"*, or EITF No. 07-3. The consensus reached on EITF No. 07-3, which was ratified by the FASB on June 27, 2007, requires companies that are involved in research and development activities, to defer nonrefundable advance payments for future research and development activities and to recognize those payments as goods and services are delivered. We will be required to assess on an ongoing basis whether or not the goods or services will be delivered, and to expense the nonrefundable advance payments immediately if it is determined that delivery is unlikely. EITF No. 07-3 is effective for fiscal years beginning after December 15, 2007. EITF 07-3 is to be applied prospectively for new contracts entered into on or after the effective date. The pronouncement is not expected to have a material effect on our results of operations, financial position or cash flows.

In December 2007, the EITF of the FASB reached a consensus on Issue No. 07-1, *"Accounting for Collaborative Arrangements"* or EITF 07-1. The EITF concluded on the definition of a collaborative arrangement and that revenues and costs incurred with third parties in connection with collaborative arrangements would be presented gross or net based on the criteria in EITF 99-19 and other accounting literature. Based on the nature of the arrangement, payments to or from collaborators would be evaluated and its terms, the nature of the entity's business, and whether those payments are within the scope of other accounting literature would be presented. Companies are also required to disclose the nature and purpose of collaborative arrangements along with the accounting policies and the classification and amounts of significant financial-statement amounts related to the arrangements. Activities in the arrangement conducted in a separate legal entity should be accounted for under other accounting literature; however required disclosure under

EITF 07-1 applies to the entire collaborative agreement. This issue is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, and is to be applied retrospectively to all periods presented for all collaborative arrangements existing as of the effective date. We are in the process of evaluating the effect the adoption of this pronouncement will have on our results of operations, financial position, cash flows and related disclosures.

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

ITEM 7A. *QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK*

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

ITEM 8. *FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA*

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

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

None.

ITEM 9A. *CONTROLS AND PROCEDURES*

(a) *Evaluation of Disclosure Controls and Procedures.* Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2007. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2007, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

(b) *Changes in Internal Control Over Financial Reporting.* No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act) occurred during the fiscal quarter ended December 31, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

(c) *Reports on Internal Control Over Financial Reporting*

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) and 15d-15(f) promulgated under the Securities Exchange Act of 1934 as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

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

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2007. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework. Based on this assessment, management believes that, as of December 31, 2007, our internal control over financial reporting is effective based on those criteria.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders of
Penwest Pharmaceuticals Co.

We have audited Penwest Pharmaceuticals Co.'s internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Penwest Pharmaceuticals Co.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

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

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

In our opinion, Penwest Pharmaceuticals Co. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of Penwest Pharmaceuticals Co. as of December 31, 2007 and 2006, and the related statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2007 of Penwest Pharmaceuticals Co. and our report dated March 12, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Stamford, CT
March 12, 2008

PART III

ITEM 10. *DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE*

The information required by this item will be contained in our definitive proxy statement for the 2008 annual meeting of shareholders under the captions "Discussion of Proposals," "Information About Corporate Governance" and "Other Information" and is incorporated herein by this reference.

We have adopted a code of business conduct and ethics applicable to all of our directors and employees. The code of business conduct and ethics is available on the corporate governance section of "Investor Relations" of our website, *www.penwest.com.*

Any waiver of the code of business conduct and ethics for directors or executive officers, or any amendment to the code that applies to directors or executive officers, may only be made by the board of directors. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of this code of ethics by posting such information on our website, at the address and location specified above. To date, no such waivers have been requested or granted.

Information regarding our executive officers is set forth in Part I of this annual report on Form 10-K under the caption "Executive Officers of the Registrant."

ITEM 11. *EXECUTIVE COMPENSATION*

The information required by this item will be contained in our 2008 proxy statement under the captions "Information About Corporate Governance" and "Information About Executive and Director Compensation" and is incorporated herein by this reference.

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

The information required by this item will be contained in our 2008 proxy statement under the captions "Information About Executive and Director Compensation" and "Other Information" and is incorporated herein by this reference.

ITEM 13. *CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE*

The information required by this item will be contained in our 2008 proxy statement under the caption "Information About Corporate Governance" and is incorporated herein by this reference.

ITEM 14. *PRINCIPAL ACCOUNTANT FEES AND SERVICES*

The information required by this item will be contained in our 2008 proxy statement under the caption "Discussion of Proposals" and is incorporated herein by this reference.

PART IV

ITEM 15. *EXHIBITS AND FINANCIAL STATEMENT SCHEDULES*

(a) (1), (2) 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 balance sheets as of December 31, 2007 and 2006 and the related statements of operations, cash flows and shareholders' equity for each of the three years in the period ended December 31, 2007.

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.

(3) 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.

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.

/s/ Jennifer L. Good

Jennifer L. Good
President and Chief Executive Officer

Date: March 12, 2008

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.

/s/ Jennifer L. Good Jennifer L. Good	President and Chief Executive Officer, Director (principal executive officer)	Date: March 12, 2008
/s/ Benjamin L. Palleiko Benjamin L. Palleiko	Senior Vice President, Corporate Development and Chief Financial Officer (principal financial officer)	Date: March 12, 2008
/s/ Frank P. Muscolo Frank P. Muscolo	Controller and Chief Accounting Officer (principal accounting officer)	Date: March 12, 2008
/s/ Paul E. Freiman Paul E. Freiman	Chairman of the Board	Date: March 12, 2008
/s/ Christophe Bianchi Christophe Bianchi, M.D.	Director	Date: March 12, 2008
/s/ Peter F. Drake Peter F. Drake, Ph.D.	Director	Date: March 12, 2008
/s/ Robert J. Hennessey Robert J. Hennessey	Director	Date: March 12, 2008
/s/ David P. Meeker David P. Meeker, M.D.	Director	Date: March 12, 2008
/s/ William J. O'Shea William J. O'Shea	Director	Date: March 12, 2008
 John N. Staniforth, Ph.D.	Director	Date:
/s/ Anne M. VanLent Anne M. VanLent	Director	Date: March 12, 2008

APPENDIX A

PENWEST PHARMACEUTICALS CO.

INDEX TO FINANCIAL STATEMENTS AND FINANCIAL STATEMENT SCHEDULE

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders
Penwest Pharmaceuticals Co.

We have audited the accompanying balance sheets of Penwest Pharmaceuticals Co. as of December 31, 2007 and 2006, and the related statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2007. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Penwest Pharmaceuticals Co. at December 31, 2007 and 2006, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

As discussed in Notes 2 and 3 to the financial statements, the Company adopted the provisions of the Financial Accounting Standards Board's Statement of Financial Accounting Standards No. 123(R) (revised 2004), "Share-Based Payment" and Statement of Financial Accounting Standards No. 158, "Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans" in 2006.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Penwest Pharmaceuticals Co.'s internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 12, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Stamford, Connecticut
March 12, 2008

PENWEST PHARMACEUTICALS CO.

BALANCE SHEETS

	December 31, 2007	December 31, 2006
	(In thousands, except share amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,680	$ 16,182
Marketable securities	7,293	24,408
Trade accounts receivable	781	683
Inventories	667	201
Prepaid expenses and other current assets	1,489	1,595
Total current assets	25,910	43,069
Fixed assets, net	3,582	3,787
Patents, net	2,539	3,184
Deferred charges	2,479	—
Other assets	2,472	2,702
Total assets	$ 36,982	$ 52,742
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,239	$ 1,324
Accrued expenses	1,602	2,096
Accrued development costs	1,483	1,105
Loan payable — current portion	2,405	—
Deferred compensation — current portion	290	290
Total current liabilities	8,019	4,815
Loan payable	9,595	—
Accrued financing fee	360	—
Deferred revenue	183	43
Deferred compensation	2,588	2,763
Total liabilities	20,745	7,621
Shareholders' equity:		
Preferred stock, par value $.001, authorized 1,000,000 shares, none outstanding	—	—
Common stock, par value $.001, authorized 60,000,000 shares, issued and outstanding 23,426,323 shares at December 31, 2007 and 23,132,815 shares at December 31, 2006	23	23
Additional paid in capital	222,927	217,427
Accumulated deficit	(206,893)	(172,428)
Accumulated other comprehensive income	180	99
Total shareholders' equity	16,237	45,121
Total liabilities and shareholders' equity	$ 36,982	$ 52,742

See accompanying notes

PENWEST PHARMACEUTICALS CO.

STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2007	2006	2005
	(In thousands, except per share data)		
Revenues:			
Royalties and licensing fees	$ 2,613	$ 3,118	$ 6,213
Product sales	519	381	—
Research and development reimbursements	176	—	—
Total revenues	3,308	3,499	6,213
Cost of revenues:			
Cost of product sales	438	231	39
Cost of research and development reimbursements	167	—	—
Total cost of revenues	605	231	39
Gross profit	2,703	3,268	6,174
Operating expenses:			
Selling, general and administrative	14,260	14,075	13,247
Research and product development	23,561	22,857	17,797
Total operating expenses	37,821	36,932	31,044
Loss from operations	(35,118)	(33,664)	(24,870)
Investment income	1,770	2,352	1,974
Interest expense	(1,117)	—	—
Loss before income tax expense	(34,465)	(31,312)	(22,896)
Income tax expense	—	—	2
Net loss	$(34,465)	$(31,312)	$(22,898)
Basic and diluted net loss per common share	$ (1.48)	$ (1.38)	$ (1.05)
Weighted average shares of common stock outstanding	23,216	22,751	21,711

See accompanying notes

PENWEST PHARMACEUTICALS CO.

STATEMENTS OF SHAREHOLDERS' EQUITY

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
	Shares	Amount				
				(In thousands)		
Balances, December 31, 2004	21,693	$22	$197,097	$(118,218)	$(100)	$ 78,801
Net loss	—	—	—	(22,898)	—	(22,898)
Changes in unrealized loss on marketable securities	—	—	—	—	(54)	(54)
Comprehensive loss	—	—	—	—	—	(22,952)
Proceeds from stock option and Employee Stock Purchase Plan exercises	151	—	1,479	—	—	1,479
Stock compensation charges in connection with stock incentive plans	46	—	685	—	—	685
Stock compensation charge in connection with modification of stock options	—	—	2,398	—	—	2,398
Balances, December 31, 2005	21,890	22	201,659	(141,116)	(154)	60,411
Net loss	—	—	—	(31,312)	—	(31,312)
Changes in unrealized loss on marketable securities	—	—	—	—	143	143
Comprehensive loss	—	—	—	—	—	(31,169)
Transition adjustment for funded status of post retirement plan	—	—	—	—	110	110
Proceeds from stock option and Employee Stock Purchase Plan exercises	1,213	1	10,790	—	—	10,791
Stock compensation charges in connection with stock incentive plans	30	—	4,978	—	—	4,978
Balances, December 31, 2006	23,133	23	217,427	(172,428)	99	45,121
Net loss	—	—	—	(34,465)	—	(34,465)
Changes in unrealized gain/loss on marketable securities	—	—	—	—	18	18
Adjustment for funded status of post retirement plan	—	—	—	—	63	63
Comprehensive loss	—	—	—	—	—	(34,384)
Proceeds from stock option and Employee Stock Purchase Plan exercises	113	—	1,135	—	—	1,135
Issuance of common stock pursuant to royalty termination agreements	39	—	573	—	—	573
Stock compensation charges in connection with stock incentive plans	141	—	3,792	—	—	3,792
Balances, December 31, 2007	23,426	$23	$222,927	$(206,893)	$ 180	$ 16,237

See accompanying notes

PENWEST PHARMACEUTICALS CO.

STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2007	2006	2005
		(In thousands)	
Operating activities:			
Net loss	$(34,465)	$(31,312)	$(22,898)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	1,107	1,001	987
Amortization of patents	379	565	464
Inventory reserves	18	—	497
Patent impairment losses	584	254	137
Deferred revenue	140	(14)	(14)
Deferred compensation	182	190	194
Deferred royalty termination costs	(1,541)	—	—
Stock compensation	3,792	4,978	3,083
Changes in operating assets and liabilities:			
Trade accounts receivable	(98)	259	184
Inventories	(483)	(61)	5
Accounts payable, accrued expenses and other	752	497	(2,700)
Net cash used in operating activities	(29,633)	(23,643)	(20,061)
Investing activities:			
Acquisitions of fixed assets, net	(918)	(1,818)	(276)
Patent costs	(319)	(619)	(479)
Purchases of marketable securities	(24,605)	(27,739)	(51,499)
Proceeds from maturities of marketable securities	41,950	41,248	47,054
Proceeds from sales of marketable securities	—	1,600	25,450
Proceeds from cash surrender value of life insurance policy withdrawal	—	446	—
Net cash provided by investing activities	16,108	13,118	20,250
Financing activities:			
Issuance of common stock	1,135	10,790	1,479
Proceeds from loan payable	12,000	—	—
Debt issuance costs	(112)	—	—
Net cash provided by financing activities	13,023	10,790	1,479
Net (decrease)/increase in cash and cash equivalents	(502)	265	1,668
Cash and cash equivalents at beginning of year	16,182	15,917	14,249
Cash and cash equivalents at end of year	$ 15,680	$ 16,182	$ 15,917

See accompanying notes

1. BUSINESS

Penwest Pharmaceuticals Co. (the "Company" or "Penwest") is a drug development company dedicated to bringing to the marketplace innovative products that help improve the lives of patients. The Company's goal is to identify, develop and commercialize products that address unmet medical needs, primarily for disorders of the nervous system. The Company is currently applying its drug development and drug delivery expertise to a pipeline of potential products that are in various stages of development, and intends to commercialize independently or through third party alliances.

On June 22, 2006, the United States Food and Drug Administration ("FDA") approved Opana® ER. Opana ER, an extended release formulation of oxymorphone hydrochloride, is a product that the Company developed with Endo Pharmaceuticals Inc. ("Endo") using its proprietary TIMERx® drug delivery technology. Opana ER is approved for twice-a-day dosing in patients with moderate to severe pain requiring continuous, around-the-clock opioid therapy for an extended period of time and being marketed by Endo in the United States.

The Company is currently developing product candidates designed for the treatment of pain, epilepsy, Parkinson's disease and diseases related to the mitochondrial respiratory chain. The Company is developing nalbuphine ER, a controlled release formulation of nalbuphine hydrochloride, for the treatment of moderate chronic pain. In addition, the Company is developing A0001, a product candidate designed for the treatment of diseases related to the mitochondrial respiratory chain, that it is developing under a collaboration and license agreement with Edison Pharmaceuticals, Inc. ("Edison"), that the Company entered into on July 16, 2007 (the "Edison Agreement"). Under the Edison Agreement, the Company has agreed with Edison to collaborate on the development of A0001 and up to one additional drug candidate of Edison's, initially for the treatment of inherited mitochondrial respiratory chain diseases. Finally, the Company has two other product candidates in formulation development for treatment of epilepsy and Parkinson's disease.

The Company's strategy includes developing drug candidates to treat disorders of the nervous system. The Company expects to leverage its expertise in drug formulation and drug development to advance these products. The Company also expects to expend resources on product candidates obtained through in-licenses or acquisitions. The Company's spending in this area, however, is discretionary and is subject to identifying appropriate opportunities, as well as the availability of funds from its operations, cash resources, collaborative research and development arrangements, and external financing.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The preparation of financial statements in conformity with U.S. generally accepted accounting principles 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 prior year amounts have been reclassified to conform to the current year presentation. These reclassifications had no impact on the Company's financial position or results of operations.

Cash and Cash Equivalents

All highly liquid investments with maturities of 90 days or less when purchased are considered cash equivalents.

Marketable Securities

The Company accounts for marketable securities in accordance with Statement of Financial Accounting Standards ("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 income (loss). The specific identification method is used to compute the realized gains and losses, if any, on marketable securities.

Credit Risk and Fair Value of Financial Instruments

The Company performs ongoing credit evaluations of its customers and generally does not require collateral. Revenues from product sales and licensing fees are primarily derived from major pharmaceutical companies that generally have significant cash resources. Allowances for doubtful accounts receivable are maintained based on historical payment patterns, aging of accounts receivable and actual write-off history. As of December 31, 2007 and 2006, no allowances for doubtful accounts were recorded by the Company. One customer of the Company accounted for approximately 77%, 89% and 63% of total revenues in 2007, 2006 and 2005, respectively. Another customer of the Company accounted for approximately 15% of total revenues for 2007, and another customer accounted for approximately 36% of total revenues for 2005.

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 certain restrictions on maturities and concentration by issuer.

The carrying value of financial instruments, which includes cash, cash equivalents, marketable securities, receivables and accounts payable, approximates fair value due to the short term nature of these instruments.

Inventories

Inventories, which consist primarily of manufactured bulk TIMERx, as well as raw materials, are stated at the lower of cost (first-in, first-out) or market. The costs of any bulk TIMERx and raw materials acquired for research and development activities that also have alternative future uses are capitalized when acquired. The Company periodically reviews and quality tests its inventory to identify obsolete, slow moving or otherwise unsaleable inventories and establishes allowances for situations in which the cost of the inventory is not expected to be recovered. Inventory allowances or write-offs associated with development projects are charged to research and product development expense prior to regulatory approval. The Company records pre-approval sales of its bulk TIMERx to its development project collaborators as an offset to research and product development expense in situations where cost-sharing arrangements exist. These pre-approval sales were not material in 2007, 2006 or 2005.

Long-Lived Assets

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

Machinery and equipment	5-10 years
Office furniture, equipment and software	3-10 years
Leasehold improvements	1-3 years

The Company reviews the recoverability of its long-lived assets, including definite-lived intangible assets, whenever facts and circumstances indicate that the carrying amount may not be fully recoverable. For purposes of recognizing and measuring impairment, the Company evaluates long-lived assets based upon the lowest level of independent cash flows ascertainable to evaluate impairment. If the sum of the undiscounted future

cash flows expected over the remaining asset life is less than the carrying value of the assets, the Company may recognize an impairment loss. The impairment related to long-lived assets is measured as the amount by which the carrying amount of the assets exceeds the fair value of the asset. When fair values are not readily available, the Company estimates fair values using expected discounted future cash flows.

Foreign Currencies

Realized gains and losses from foreign currency transactions are reflected in the statements of operations and were not significant in any year in the three year period ended December 31, 2007.

Accumulated Other Comprehensive Income (Loss)

Accumulated other comprehensive income (loss) at December 31, 2007 and 2006 consisted of adjustments for the funded status of the Company's Supplemental Executive Retirement Plan ("SERP") recorded in connection with SFAS No. 158 "Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans, an amendment of FASB Statements No. 87, 88, 106 and 132(R)" (see Note 14) and unrealized gains and losses on marketable securities. Accumulated other comprehensive loss at December 31, 2005 consisted of unrealized losses on marketable securities.

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 2007, 2006 and 2005, as such losses were fully offset by valuation allowances. Valuation allowances are established against the recorded deferred income tax assets to the extent that the Company believes it is more likely than not that a portion of the deferred income tax assets are not realizable.

On January 1, 2007, the Company adopted the provisions of Financial Accounting Standards Board ("FASB") Interpretation No. 48, "Accounting for Uncertainty in Income Taxes — an interpretation of FASB Statement No. 109" ("FIN 48"). FIN 48 is an interpretation of SFAS No. 109, which clarifies the accounting for uncertainty in income taxes. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 requires that the Company recognize in its financial statements the impact of a tax position if that position is more likely than not to be sustained on audit, based on the technical merits of the position. FIN 48 also provides guidance on derecognition of a previously recognized tax position, classification, interest and penalties, accounting in interim periods and disclosures. The provisions of FIN 48 were effective beginning January 1, 2007, with any cumulative effect of the change in accounting principle to be recorded as an adjustment to the opening balance of retained earnings.

The Company currently has a full valuation allowance against its net deferred tax assets and has not recognized any benefits from tax positions in its statements of operations. Accordingly, the adoption of the provisions of FIN 48 did not have a material impact on the Company's financial statements.

The Company expects to recognize potential interest and penalties related to income tax positions as a component of income tax expense in its statements of operations in any future periods in which the Company must record a liability. Since the Company has not recorded a liability at December 31, 2007, there is no impact to the Company's effective tax rate. The Company does not anticipate that total unrecognized tax benefits will significantly change during the next twelve months.

The Company is subject to federal and state income tax examinations for all tax periods subsequent to its spin-off from its former parent company on August 31, 1998.

Revenue Recognition

Royalties and licensing fees — The Company recognizes revenues from non-refundable up-front fees received under collaboration agreements ratably over the performance period of the related collaboration agreement. If the estimated performance period is subsequently modified, the period over which the up-front fee is recognized is modified accordingly on a prospective basis. Non-refundable 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. Upon termination of a collaboration agreement, any remaining non-refundable licensing fees received by the Company, which had been deferred, are generally recognized in full. Product royalty fees are recognized when earned, as reported by the Company's collaborators, and are generally subject to review or audit by the Company.

Milestone payments — The Company recognizes revenue from milestone payments received under collaboration agreements when earned, provided that the milestone event is substantive, its achievability was not reasonably assured at the inception of the agreement, the Company has no further performance obligations relating to the event, and collectability is reasonably assured. If these criteria are not met, the Company recognizes milestone payments ratably over the remaining period of the Company's performance obligations under the collaboration agreement.

Product sales — The Company recognizes revenues from product sales when title transfers and customer acceptance provisions have lapsed, provided that collections of the related accounts receivable are probable. Shipping and handling costs are included in the cost of product sales.

Research and development reimbursements — The Company recognizes revenue from reimbursements received in connection with its research and development collaboration agreements as related research and development costs are incurred, and the Company's contractual services are performed, provided collectability is reasonably assured. Such revenue is included in research and development reimbursements revenue in the Company's statements of operations. Amounts contractually owed to the Company under these research and development collaboration agreements, including any earned but unbilled receivables, are included in trade accounts receivable in the Company's balance sheets. The Company's principal costs under these agreements are generally for its personnel conducting research and development, as well as for research and development performed by outside contractors or consultants.

Research and Development Expenses

Research and development expenses consist of costs associated with products being developed internally as well as products being developed under collaboration agreements, and include related salaries, benefits and other personnel related expenses, costs of drug active, pre-clinical and clinical trial costs, and contract and other outside service fees including payments to collaborators for sponsored research activities. The Company expenses research and development costs as incurred. A significant portion of the Company's development activities are outsourced to third parties, including contract research organizations and contract manufacturers in connection with the production of clinical materials. These arrangements may require estimates to be made of related service fees or of our share of development costs. These arrangements may also require the Company to pay termination costs to the third parties for reimbursement of costs and expenses incurred in the orderly termination of contractual services.

Per Share Data

Loss per common share is computed based on the weighted average number of shares of common stock 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 stock equivalents is included in 2007, 2006 and 2005 as the effects would be antidilutive. Such securities, excluded due to their antidilutive effect, are as follows:

	December 31,		
	2007	2006	2005
	(In thousands of shares)		
Stock options outstanding	2,411	2,267	3,016
Restricted stock outstanding (unvested)	142	52	68
	2,553	2,319	3,084

Share-Based Compensation

Effective January 1, 2006, the Company accounts for its share-based compensation using SFAS No. 123 (revised 2004), "Share-Based Payment" ("SFAS No. 123R"). SFAS No. 123R requires all share-based payments to employees, including grants of employee stock options as well as compensatory employee stock purchase plans, to be recognized as an expense in the statement of operations based on their fair values as they are earned by the employees under the vesting terms.

The valuation of employee stock options is an inherently subjective process, since market values are generally not available for long-term, non-transferable employee stock options. Accordingly, the Company uses an option pricing model to derive an estimated fair value. In calculating the estimated fair value of stock options granted, the Company uses a Black-Scholes-Merton pricing model which requires the consideration of the following variables for purposes of estimating fair value:

- the stock option exercise price;
- the expected term of the option;
- the grant date price of the Company's common stock, which is issuable upon exercise of the option;
- the expected volatility of the Company's common stock;
- expected dividends on the Company's common stock (the Company does not anticipate paying dividends for the foreseeable future); and
- the risk-free interest rate for the expected option term.

Of the variables above, the Company believes that the selection of an expected term and expected stock price volatility are the most subjective. The Company uses historical employee exercise and option expiration data to estimate the expected term assumption for the Black-Scholes-Merton grant date valuation. The Company believes that this historical data is currently the best estimate of the expected term of a new option, and that generally, all groups of its employees exhibit similar exercise behavior. In general, the longer the expected term used in the Black-Scholes-Merton pricing model, the higher the grant-date fair value of the option. For options granted prior to 2006, the Company used historical volatility to estimate the grant-date fair value of stock options. Historical volatility is calculated based on a period equal to the expected term of stock option awards, and actual stock prices during such period. Effective January 1, 2006, following a review of alternative methods of estimating expected volatility, the Company changed its method of estimating expected volatility for all stock options granted, from exclusively relying on historical volatility, to using an average of implied volatility and historical volatility. In accordance with SFAS 123R, the Company selected the average

of implied volatility and historical volatility as it believes neither of these measures is better than the other in estimating the expected volatility of the Company's common stock. The Company believes that its estimates, both expected term and stock price volatility, are reasonable in light of the historical data analyzed.

The valuation assumptions selected upon the adoption of SFAS 123R were applied to stock options that the Company granted subsequent to its adoption of SFAS 123R; however, stock option expense recorded in 2007 and 2006 also included amounts related to the continued vesting of stock options that were granted prior to January 1, 2006. In accordance with the transition provisions of SFAS 123R, the grant date estimates of fair value associated with prior awards, which were also calculated using a Black-Scholes-Merton option pricing model, were not changed. The Company uses the accelerated attribution method to recognize expense for all options granted.

In accordance with SFAS 123R, the Company also estimates the level of award forfeitures expected to occur, and records compensation cost only for those awards that are ultimately expected to vest. This requirement applies to all awards that are not yet vested, including awards granted prior to January 1, 2006. Accordingly, the Company periodically performs a historical analysis of option awards that were forfeited (such as by employee separation) prior to vesting, and ultimately records stock option expense that reflects the estimated forfeiture rate.

3. RECENT ACCOUNTING PRONOUNCEMENTS

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities — Including an amendment of FASB Statement No. 115" ("SFAS No. 159"). SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007 and, as such, the Company plans to adopt the provisions of SFAS 159 as of January 1, 2008. The Company does not expect the adoption of this pronouncement to have a material effect on its results of operations, financial position or cash flows.

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements" ("SFAS No. 157"). SFAS No. 157 provides a common definition of fair value to be applied to existing generally accepted accounting principles ("GAAP") requiring the use of fair value measures, establishes a framework for measuring fair value and enhances disclosure about fair value measures under other accounting pronouncements, but does not change existing guidance as to whether or not an asset or liability is carried at fair value. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 for all financial assets and liabilities, and any other assets and liabilities that are recognized or disclosed at fair value on a recurring basis. For nonfinancial assets and liabilities, SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2008. The Company plans to adopt the provisions of SFAS No. 157 as of January 1, 2008 and does not expect the adoption to have a material effect on its results of operations, financial position or cash flows.

In June 2007, the FASB's Emerging Issues Task Force ("EITF") reached a consensus on EITF Issue No. 07-3, *"Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities"* ("EITF No. 07-3"). The consensus reached on EITF No. 07-3, which was ratified by the FASB on June 27, 2007, requires companies that are involved in research and development activities to defer nonrefundable advance payments for future research and development activities, and to recognize those payments as goods and services are delivered. The Company will be required to assess on an ongoing basis whether or not the goods or services will be delivered, and to expense the nonrefundable advance payments immediately if it determines that delivery is unlikely. EITF No. 07-3 is effective for fiscal years beginning after December 15, 2007 and, as such, the Company plans to adopt the provisions of EITF No. 07-3 as of January 1, 2008. EITF No. 07-3 is to be applied prospectively for new contracts entered into on or after the effective date. The Company does not expect the adoption of this pronouncement to have a material effect on its results of operations, financial position or cash flows.

In December 2007, the EITF of the FASB reached a consensus on Issue No. 07-1, *"Accounting for Collaborative Arrangements"* ("EITF No. 07-1"). The EITF concluded on the definition of a collaborative arrangement and that revenues and costs incurred with third parties in connection with collaborative arrangements would be presented gross or net based on the criteria in EITF No. 99-19 and other accounting literature. Based on the nature of the arrangement, payments to or from collaborators would be evaluated and its terms, the nature of the entity's business, and whether those payments are within the scope of other accounting literature would be presented. Companies are also required to disclose the nature and purpose of collaborative arrangements, along with the accounting policies, and the classification and amounts of significant financial-statement amounts related to the arrangements. Activities in the arrangement conducted in a separate legal entity should be accounted for under other accounting literature; however required disclosure under EITF No. 07-1 applies to the entire collaborative agreement. EITF No. No. 07-3 is effective for fiscal years beginning after December 15, 2008 and is to be applied retrospectively to all periods presented for all collaborative arrangements existing as of the effective date. The Company is in the process of evaluating the effect the adoption of this pronouncement will have on its results of operations, financial position, cash flows and related disclosures.

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.

4. MARKETABLE SECURITIES

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

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
		(In thousands)		
December 31, 2007:				
Corporate debt securities	$ 6,785	$ 7	$—	$ 6,792
U.S. government agency-backed discounted notes	501	—	—	501
Total marketable securities	$ 7,286	$ 7	$—	$ 7,293
December 31, 2006:				
Corporate debt securities	$21,381	$ 3	$10	$21,374
U.S. government agency-backed discounted notes	3,038	—	4	3,034
Total marketable securities	$24,419	$ 3	$14	$24,408

Maturities of marketable securities at fair value as of December 31, 2007, are as follows (in thousands):

Contractual maturity — maturing in one year or less	$7,293

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 certain restrictions on maturities and concentration by issuer (see Note 2, "Credit Risk and Fair Value of Financial Instruments").

A decline in the market value of any security below cost that is deemed to be other than temporary results in a reduction in carrying amount to fair value. Such impairments are charged to the results of operations and a new cost basis for the security is established. Unrealized losses on marketable securities held at December 31, 2006 were not deemed other than temporary, as all such securities were investment grade, and management believed the impairments were attributable to increased market rates.

5. INVENTORIES

Inventories are summarized as follows:

	December 31,	
	2007	2006
	(In thousands)	
Raw materials	$ 37	$ 64
Finished products	630	137
Total inventories	$667	$201

Inventories primarily consist of bulk TIMERx product. Inventories at December 31, 2007 are net of allowances of $18,000. There were no inventory allowances as of December 31, 2006.

The Company currently has no internal commercial scale manufacturing capabilities. Generally, the Company's collaborators manufacture the pharmaceutical products, and the Company is responsible for supplying them with bulk TIMERx. The Company outsources the commercial manufacture of its bulk TIMERx to a third-party pharmaceutical company, Draxis Specialty Pharmaceuticals Inc. ("Draxis"), under a manufacturing and supply agreement with an initial term that expires in November 2009. The agreement automatically renews for successive one-year periods, unless either party gives notice of its intent not to renew the agreement at least 180 days prior to the end of the then-current term. Under the terms of the agreement, the Company may be obligated, under certain conditions, to purchase finished bulk TIMERx and certain raw materials used in manufacturing TIMERx upon termination or expiration of the agreement.

The Company's TIMERx technology is based on a hydrophilic matrix combining a heterodispersed mixture primarily composed of two polysaccharides, xanthan and locust bean gums, in the presence of dextrose. The Company and Draxis purchase these gums from a primary supplier. Although the Company has qualified alternate suppliers with respect to these gums and to date has not experienced difficulty acquiring these materials, there can be no assurance that interruptions in supplies will not occur in the future or that the Company will not have to obtain substitute suppliers.

6. FIXED ASSETS

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

	December 31,	
	2007	2006
	(In thousands)	
Equipment and leasehold improvements	$6,777	$6,382
Software	2,442	1,998
Projects in progress	25	308
	9,244	8,688
Less: accumulated depreciation and amortization	5,662	4,901
	$3,582	$3,787

The Company capitalizes certain costs associated with developing or obtaining internal-use software. These costs include external direct costs of materials and services used in developing or obtaining the software, and payroll and payroll-related costs for employees directly associated with the software development project. The Company did not capitalize any software development costs in 2007, 2006 or 2005. The Company includes software development costs within equipment and software, and generally amortizes the software development costs over a period of five years, once the systems are placed in service. Amortization

expense related to software development costs totaled $324,000 for 2007 and $323,000 for 2006 and 2005, respectively. Unamortized software development costs totaled $183,000 and $507,000 as of December 31, 2007 and 2006, respectively.

7. PATENTS

	December 31,	
	2007	2006
	(In thousands)	
Patents, net of accumulated amortization of $1,947 and $2,101, respectively:	$2,539	$3,184

Patents include costs to secure patents on technology and products developed by the Company. Patents are amortized on a straight-line basis over their estimated useful lives of 17 to 20 years. Amortization expense of approximately $379,000, $565,000 and $464,000 was recorded in the years ended December 31, 2007, 2006, and 2005, respectively.

The approximate amortization expense expected to be recognized related to existing patent costs is as follows (in thousands):

Year	Amount
2008	$ 295
2009	293
2010	278
2011	235
2012	171
Thereafter	1,267
Total	$2,539

Patents are evaluated for potential impairment whenever events or circumstances indicate that future undiscounted cash flows may not be sufficient to recover their carrying amounts. An impairment loss is recorded to the extent the asset's carrying value is in excess of the fair value of the asset. When fair values are not readily available, the Company estimates fair values using expected discounted future cash flows. During the years ended December 31, 2007, 2006 and 2005, the Company recorded impairment losses of approximately $584,000, $254,000 and $137,000, respectively, relating to its patents. The impairment losses recorded in 2007 and 2006 related to the write-off of patent costs primarily in connection with early stage development programs discontinued by the Company, and it determined no longer had value. The impairment losses recorded in 2005 primarily related to the write-off of patents in connection with the termination of the PW2101 development program, which patents the Company determined no longer had value. Such impairment losses are reflected in research and product development expense in the statements of operations.

8. LOAN PAYABLE

Credit Facility

On March 13, 2007, the Company entered into a $24.0 million senior secured credit facility (the "Credit Facility") with Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services Inc. The Credit Facility consists of: (i) a $12.0 million term loan advanced upon the closing of the Credit Facility and (ii) a $12.0 million term loan that the Company may access until September 15, 2008, subject to conditions specified in the Credit Facility. Under the Credit Facility, the Company may not access this second amount unless the Company's market capitalization at the time of the advance request is greater than $250 million and an additional patent relating to Opana ER has been issued and listed in the FDA's list of Approved Drug

Products with Therapeutic Equivalence Evaluations (the "Orange Book"). On October 2, 2007, an additional patent relating to Opana ER was issued and listed in the Orange Book. As a result, the Company may access the additional $12.0 million at any time that the Company's market capitalization is greater than $250 million, up until September 15, 2008, as noted above. As of March 11, 2008, the Company's market capitalization was approximately $88.5 million.

In connection with the Credit Facility, the Company granted the lender a perfected first priority security interest in all existing and after-acquired assets of the Company, excluding: its intellectual property, which is subject to a negative pledge; royalty payments from Mylan Pharmaceuticals, Inc. ("Mylan") on their sales of Pfizer Inc.'s ("Pfizer") generic version of Procardia XL 30 mg, if the Company pledges such royalty payments to another lender; up to $3.0 million of equipment which the Company may, at its election, pledge to another lender in connection with an equipment financing facility separate from the Credit Facility; and the assets of the Company's trust described in Note 14. In addition, the Company is precluded from paying cash dividends to its shareholders during the term of the Credit Facility. Each loan has a term of 42 months from the date of advance with interest-only payments for the first nine months, but in any event, not beyond September 30, 2008; interest plus monthly principal payments equal to 1.67% of the loan amount for the period from the end of the interest-only period through December 2008; and interest plus straight-line amortization payments with respect to the remaining principal balance for the remainder of the term.

Amounts outstanding under the Credit Facility bear interest at an annual rate of one-month LIBOR at the time of the advance plus 5%. The rate will be fixed for the term of the applicable loan. At the time of final payment of each loan under the Credit Facility, the Company will pay an exit fee of 3.0% of the original principal loan amount. Should any prepayment occur, the Company is also required to pay prepayment penalties of 3.0% of any prepaid amount in the first year, 2.0% of any prepaid amount in the second year and 1% of any prepaid amount thereafter. As of December 31, 2007, the interest rate on the Credit Facility was 10.32% and $12.0 million was outstanding.

As of December 31, 2007, principal payments due on the $12.0 million in principal outstanding under the Credit Facility are as follows:

	(In thousands)
Less than one year	$ 2,405
One to two years	5,483
Two to three years	4,112
	$12,000

The Company accrued an exit fee as noted above of $360,000 in connection with the $12.0 million term loan advanced upon the closing of the Credit Facility. These costs, as well as other debt issuance costs incurred by the Company in securing the Credit Facility, were deferred and are included in deferred charges in the Company's balance sheet as of December 31, 2007. These costs are being amortized over the term of the loan with such amortization included in interest expense in the Company's statements of operations. The Company paid $905,000 of interest in 2007.

9. SHAREHOLDERS' EQUITY

On July 27, 2005, the Company filed a registration statement on Form S-3 with the Securities and Exchange Commission (the "SEC"), which became effective on August 17, 2005. This shelf registration statement covers the issuance and sale by the Company of any combination of common stock, preferred stock, debt securities and warrants having an aggregate purchase price of up to $75 million. As of March 11, 2008, no securities have been issued under this shelf registration statement.

Share-Based Compensation

The Company recognized share-based compensation in its statements of operations for 2007 and 2006 as follows:

	2007	2006
Selling, general and administrative	$3,194	$3,071
Research and product development	598	1,907
Total	$3,792	$4,978

The decrease in share-based compensation expense in 2007 as compared to 2006, is primarily attributable to actual forfeitures and an increase in the Company's forfeiture rate assumptions for employee stock options.

The Company adopted SFAS No. 123R using the modified prospective transition method. Under this method, prior periods are not restated for the effect of SFAS No. 123R. Had the Company accounted for stock-based compensation plans using the fair value based accounting method proscribed by SFAS No. 123R for the periods prior to 2006, the Company's net loss and net loss per share would have approximated the pro forma amounts indicated below:

	2005 (In thousands, except per share data)
Net loss — as reported	$(22,898)
Stock-based compensation expense included in reported net loss	2,939
Stock-based compensation under fair value method	(3,652)
Net loss — pro forma after stock-based compensation under fair value method	$(23,611)
Net loss per share, basic and diluted — as reported	$ (1.05)
Net loss per share, basic and diluted — pro forma after stock-based compensation under fair value method	$ (1.09)

Penwest Stock Incentive Plans

As of December 31, 2007, the Company had three stock option plans: the 2005 Stock Incentive Plan (the "2005 Plan"), the 1998 Spin-off Option Plan (the "Spin-off Plan") and the 1997 Equity Incentive Plan (the "1997 Plan"). The 2005 Plan and the 1997 Plan provide for the grants of incentive stock options, nonstatutory stock options, restricted and unrestricted 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"). Since the 2005 Plan was approved, the Company has granted options and issued other securities to employees, directors and consultants under the 2005 Plan, and no additional Awards have been made under the Spin-off Plan or the 1997 Plan. A total of 1,650,000 shares of common stock may be issued pursuant to Awards granted under the 2005 Plan. Such Awards generally may not be granted at an exercise price that is less than the fair market value of the common stock on the date of grant, as determined by the Company's Board of Directors. Stock option awards generally vest over a one to four year period and expire no later than ten years from the date of grant. 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. Restricted stock awards currently vest over a one to four year period and are recorded at fair value, which is based on the fair market value of the common stock on the date of grant.

Under the terms of executive retention agreements entered into with each executive officer, if, within 12 months following a change in control of the Company, the executive's employment is terminated by the Company other than for cause, death or disability, or by the executive for good reason, as such terms are defined, the vesting of all stock options and restricted stock held by the executive will be accelerated in full, to the extent not already vested, and all shares of stock underlying stock options and all shares of restricted stock will be free of any right of repurchase by the Company. The retention agreements terminate if a change in control of the Company does not occur prior to December 31, 2008.

The following table presents a summary of the Company's stock option activity and related information for the year ended December 31, 2007:

	Shares	Weighted Average Exercise Price	Weighted-Average Remaining Contractual Terms in Years	Aggregate Intrinsic Value
Balance at December 31, 2006	2,266,660	$14.23		
Granted	497,250	$12.88		
Exercised	(95,024)	$10.60		
Forfeited	(249,676)	$15.41		
Expired	(8,250)	$15.54		
Balance at December 31, 2007	2,410,960	$13.97	5.8	$2,421
Options Exercisable	1,487,305	$13.00	4.1	$2,421

The weighted average fair values of options granted during 2007, 2006 and 2005 were $5.55, $11.18 and $6.82, per share, respectively. Total cash received by the Company from the exercise of stock options during 2007 was approximately $1.0 million. The total intrinsic values of options exercised during 2007, 2006 and 2005 were approximately $247,000, $14.8 million and $827,000, respectively. The total fair value of options which vested during 2007, 2006 and 2005 were approximately $2.8 million, $2.7 million and $3.8 million, respectively. As of December 31, 2007, there was approximately $3.1 million of unrecognized compensation cost related to stock option awards that the Company expects to recognize as expense over a weighted average period of 1.1 years.

The fair values of each option grant in 2007, 2006 and 2005 were estimated using the Black-Scholes-Merton option pricing model with the following weighted average assumptions:

	2007	2006	2005
Expected dividend yield	None	None	None
Risk free interest rate	4.7%	4.7%	4.1%
Expected volatility	56%	58%	48%
Expected life of options	5.5 years	5.6 years	7.5 years

The following table presents a summary of restricted stock activity for 2007:

	Shares	Weighted-Average Grant-Date Fair Value	Aggregate Intrinsic Value
Restricted stock outstanding at December 31, 2006	51,500	$15.24	$853,355
Granted	144,000	$13.66	
Vested	(41,500)	$15.77	
Cancelled	(12,000)	$14.86	
Restricted stock outstanding at December 31, 2007	142,000	$14.77	$827,860

Total compensation cost recognized for restricted stock awards during 2007, 2006 and 2005 was approximately $1.1 million, $771,000 and $436,000, respectively. The total fair value of restricted stock which vested during 2007, 2006 and 2005 was approximately $655,000, $452,000 and $233,000, respectively. As of December 31, 2007, there was approximately $953,000 of unrecognized compensation cost related to outstanding restricted stock awards that the Company expects to recognize as expense over a weighted average period of approximately 3.2 years.

Employee Stock Purchase Plan

The Employee Stock Purchase Plan was approved in October 1997 and enables all employees to subscribe "during specified offering periods" to purchase shares of the Company's 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 18,398 shares, 10,404 shares and 13,779 shares issued under the Plan during 2007, 2006 and 2005, 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.

On March 5, 2008, in connection with a private placement referenced under the caption "Subsequent Events", we entered into an amendment (the "Amendment") to the Rights Agreement (the "Rights Agreement"), dated as of July 27, 1998, between the Company and Mellon Investor Services LLC, as Rights Agent, that sets out the terms and conditions of the rights. The Amendment modifies the definition of Exempted Person under the Rights Agreement to provide that Perceptive Life Sciences Master Fund Ltd., together with its affiliates and associates ("Perceptive"), will be an Exempted Person under the Rights Agreement until the earlier of the date on which Perceptive beneficially owns more than 19.9% of the outstanding Common Stock or such date when Perceptive beneficially owns less than 10% of the outstanding Common Stock, at which time Perceptive shall cease to be an Exempted Person.

10. COMMITMENTS

Leases

The Company leases approximately 15,500 square feet of office and research and development space in Patterson, New York. In November 2006, the Company exercised its one year renewal option, extending the then-current term to February 26, 2008. In June 2007, the Company signed an additional amendment to the lease extending the term through February 28, 2009 and providing for monthly rent payments of approximately $21,000 plus operating expenses, plus a 10 month renewal option for the Company to December 31, 2009.

The Company leases its corporate offices in Danbury, Connecticut, comprising approximately 21,500 square feet of office space. In 2006, the Company exercised its first of two one year renewal options extending this lease through December 31, 2007. In June 2007, the Company signed an additional amendment to the lease, extending the term through December 31, 2009, plus two six month renewal options to December 31, 2010. Pursuant to the lease, monthly rent payments, including utilities, approximate $49,000 for 2008 and 2009.

As of December 31, 2007, certain of the Company's property and equipment are leased under operating leases ranging from one to two years. Rental expense under operating leases was $931,000, $873,000 and $848,000 , for the years ended December 31, 2007, 2006 and 2005, respectively. Of such amounts, approximately $195,000, $171,000 and $198,000 in 2007, 2006 and 2005, respectively, related to contingent rents including allocated operating expenses of the Company's leased facility in Patterson, New York.

Future minimum lease payments as of December 31, 2007 for noncancellable operating leases having initial lease terms of more than one year are as follows:

	Operating Leases
	(In thousands)
2008	$ 806
2009	600
Thereafter	—
Total minimum lease payments	$1,406

Other Contracts

A significant portion of the Company's development activities are outsourced to third parties, including contract research organizations and contract manufacturers in connection with the production of clinical materials. The Company was contractually obligated for approximately $3.2 million of future services under these agreements as of December 31, 2007. These arrangements may also require the Company to pay termination costs to the third parties for reimbursement of costs and expenses incurred in the orderly termination of contractual services.

11. INCOME TAXES

There was no provision for income taxes for 2007 and 2006. The provision for income taxes for 2005 consisted of current foreign income taxes and totaled $2,000.

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

	2007	2006	2005
Statutory tax rate	(34)%	(34)%	(34)%
Valuation allowance	34	34	34
	—%	—%	—%

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

	2007	2006
	(In thousands)	
Deferred compensation and SERP liability	$ (1,190)	$ (1,266)
Deferred revenue	(71)	(17)
Stock-based compensation	(2,782)	(1,830)
Tax credit carryforwards	(6,427)	(5,363)
Net operating loss carryforwards	(63,391)	(56,156)
Other	(359)	(13)
Total deferred tax assets	(74,220)	(64,645)
Depreciation and amortization	1,373	1,608
Other	257	337
Total deferred tax liabilities	1,630	1,945
Net deferred tax asset before valuation allowance	(72,590)	(62,700)
Valuation allowance	72,590	62,700
Net deferred tax liability	$ —	$ —

The Company made no income tax payments in 2007 and 2006. The Company's income tax payments for 2005, consisting solely of foreign income taxes, approximated $2,000.

At December 31, 2007, the Company had federal net operating loss ("NOL") carryforwards of approximately $191.4 million for income tax purposes, of which approximately $6.2 million, $8.4 million, $9.1 million, $17.7 million, $19.4 million, $13.5 million, $22.8 million, $21.8 million, $42.4 million and $30.1 million expire in 2018, 2019, 2020, 2021, 2022, 2023, 2024, 2025, 2026 and 2027, respectively. In addition, the Company had federal research and development tax credit carryforwards of approximately $6.3 million of which $67,000, $359,000, $341,000, $777,000, $828,000, $858,000, $760,000, $669,000, $926,000 and $695,000 expire in 2018, 2019, 2020, 2021, 2022, 2023, 2024, 2025, 2026 and 2027, respectively. The use of the NOL carryforwards and research and development tax credit carryforwards are limited to future taxable earnings of the Company.

The exercise of non-qualified stock options and the vesting of restricted stock give rise to compensation that is included in the taxable income of the applicable employees and directors, and deducted by the Company for federal and state income tax purposes. As a result of the exercise of non-qualified stock options and the vesting of restricted stock, the Company's net operating loss carryforwards include approximately $20.6 million attributable to excess tax benefits from stock compensation deductions, which can be used to

offset future taxable income, if any. If and when realized, the related tax benefits of these net operating loss carryforwards will be credited directly to paid-in capital.

For financial reporting purposes, at December 31, 2007 and 2006, respectively, valuation allowances of $72.6 million and $62.7 million have been recognized to offset net deferred tax assets, primarily attributable to the Company's NOL carryforward. The valuation allowance increased $9.9 million in 2007, $14.3 million in 2006 and $8.2 million in 2005. Utilization of the operating losses are subject to limitations in the event of an ownership change under the provisions of the Internal Revenue Code.

12. COMPENSATION CHARGE

On February 14, 2005, Tod R. Hamachek resigned from his positions as the Company's Chief Executive Officer and Chairman of the Board of Directors, and as a member of the Board, and entered into a Severance and Settlement Agreement and Release with the Company (the "Agreement"). Under the Agreement, the Company agreed that, in consideration of Mr. Hamachek's release and other agreements under the Agreement, it would pay Mr. Hamachek eighteen months base salary ($594,000) as severance pay, pay all premium costs relating to medical insurance continuation coverage for eighteen months and provide certain other benefits. The Company also agreed to accelerate in full the vesting of all unvested stock options (146,000 shares) held by Mr. Hamachek, and to extend the period during which he could exercise his stock options to the earlier of two years or their original expiration date. In connection with the Agreement, the Company recorded a charge to its statement of operations totaling approximately $3.0 million in 2005. This charge, included in selling, general and administrative expense in 2005, includes a non-cash charge of approximately $2.4 million relating to the stock options noted above.

13. ROYALTY TERMINATION AGREEMENT

On February 1, 2007, the Company entered into a royalty termination agreement with Anand Baichwal, the Company's Senior Vice President of Licensing and Chief Scientific Officer, which terminated specified provisions of the Recognition and Incentive Agreement dated as of May 14, 1990, as amended, between the Company and Dr. Baichwal (the "Baichwal Termination Agreement"). Pursuant to the Baichwal Termination Agreement, the Company and Dr. Baichwal agreed that the Company would have no further obligation to make any payments to Dr. Baichwal under the Recognition and Incentive Agreement, except for amounts owed with respect to 2006. In consideration for such agreement, the Company paid Dr. Baichwal $770,000 in cash and issued to him 19,696 shares of the Company's common stock with a fair market value of approximately $287,000, for total consideration of $1,057,000. Dr. Baichwal remains an officer of Penwest.

On February 1, 2007, the Company entered into a royalty termination agreement with John N. Staniforth, a director of the Company, which terminated the Royalty Agreement dated as of September 25, 1992, as amended, between the Company and Dr. Staniforth (the "Staniforth Termination Agreement"). Pursuant to the Staniforth Termination Agreement, the Company and Dr. Staniforth agreed that the Company would have no further obligation to make any payments to Dr. Staniforth under the Royalty Agreement except for amounts owed with respect to 2006. In consideration for such agreement, the Company paid Dr. Staniforth $770,000 in cash and issued to him 19,696 shares of the Company's common stock with a fair market value of approximately $287,000, for total consideration of $1,057,000. Dr. Staniforth remains a member of the Board of Directors of Penwest.

Consideration paid and other costs incurred in connection with the termination agreements noted above totaled approximately $2.1 million and were deferred by the Company. These costs are being amortized based on certain estimated future royalty revenues, primarily from Endo in connection with Opana ER, and are included in deferred charges in the balance sheet as of December 31, 2007. Such amortization approximated $17,000 for 2007 and is included in cost of product sales in the Company's statements of operations.

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 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 $164,000, $244,000 and $229,000 for 2007, 2006 and 2005, 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 2007, 2006, or 2005.

Supplemental Executive Retirement Plan

The Company has a Supplemental Executive Retirement Plan ("SERP" or the "Plan"), a nonqualified plan, which covers the former Chairman and Chief Executive Officer of Penwest, Mr. Hamachek. For 2007, 2006 and 2005, the net expense for the SERP was $120,000, $122,000 and $124,000, respectively. The Plan is unfunded and has no assets. The Company uses a measurement date of December 31 for its SERP.

On December 31, 2006, the Company adopted the recognition and disclosure provisions of SFAS No. 158, "Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans, an amendment of FASB Statements No. 87, 88, 106 and 132(R)". SFAS No. 158 requires employers to recognize the funded status (i.e. the difference between the fair value of plan assets and the projected benefit obligations) of defined benefit pension and other postretirement benefit plans as an asset or liability in its statement of financial position and to recognize changes in the funded status in the year in which the changes occur as a component of comprehensive income. In addition, SFAS No. 158 requires employers to measure the funded status of its plans as of the date of its year-end statement of financial position and also requires additional disclosures regarding amounts included in accumulated other comprehensive income. The adjustment to accumulated other comprehensive income (loss) at adoption represents the net unrecognized actuarial gains remaining from the initial adoption of SFAS No. 87, "Employers' Accounting for Pensions", all of which were previously netted against the plan's funded status in our statement of financial position pursuant to the provisions of SFAS No. 87. These amounts will be subsequently recognized as net periodic pension cost pursuant to our historical accounting policy for amortizing such amounts. Further, actuarial gains and losses that arise in subsequent periods, and are not recognized as net periodic pension cost in the same periods, will be recognized as a component of accumulated other comprehensive income (loss). Those amounts will be subsequently recognized as a component of net periodic pension cost on the same basis as the amounts recognized in accumulated other comprehensive income (loss) at the adoption of SFAS No. 158.

The incremental effects of adopting the provisions of SFAS No. 158 for the Plan on the Company's statement of financial position at December 31, 2006 are presented in the following table. The adoption of SFAS No. 158 had no effect on the Company's statements of operations for the year ended December 31, 2006, or for any prior period presented, and it will have no effect on the Company's future operating results.

Had the Company not been required to adopt SFAS No. 158 at December 31, 2006, it would have recognized a minimum pension liability pursuant to the provisions of SFAS No. 87 of $2,297,000.

The effect of recognizing the funded status and adjusting the liability of the Plan is included in the table below under the column labeled "Effect of adopting SFAS No. 158" (in thousands):

	December 31, 2006		
	Prior to Adopting SFAS No. 158	Effect of Adopting SFAS No. 158	As Reported at December 31, 2006
Intangible asset (retirement plan)	$ —	$ —	$ —
Liability for plan benefits	$2,297	$(110)	$2,187
Accumulated other comprehensive income	$ —	$ 110	$ 110

The following disclosures summarize information relating to the Plan:

Change in benefit obligation:

	2007	2006
	(In thousands)	
Benefit obligation at beginning of period	$2,187	$2,168
Interest cost	118	120
Actuarial (gain) loss	(62)	50
Benefits paid	(151)	(151)
Benefit obligation at December 31,	$2,092	$2,187

Change in plan assets:

	2007	2006
	(In thousands)	
Fair value of plan assets at beginning of year	$ —	$ —
Employer contributions	151	151
Benefit payments	(151)	(151)
Fair value of plan assets at end of year	$ —	$ —

Amounts recognized in the statement of financial position consist of:

	2007	2006
	(In thousands)	
Current liabilities	$ (147)	$ (147)
Noncurrent liabilities	(1,945)	(2,040)
Net amount recognized at December 31, (included in deferred compensation)	$(2,092)	$(2,187)

Amounts recognized in accumulated other comprehensive income consist of:

	2007	2006
	(In thousands)	
Net gain	$(184)	$(122)
Prior service cost	11	12
Total	$(173)	$(110)

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

	2007	2006
	(In thousands)	
Projected benefit obligation	$2,092	$2,187
Accumulated benefit obligation	$2,092	$2,187
Plan assets at fair value	$ —	$ —

Components of net periodic benefit cost:

	2007	2006
	(In thousands)	
Interest cost	$118	$120
Amortization of prior service cost	2	2
Amortization of gains	—	—
Net periodic benefit cost	$120	$122

The amortization of prior service cost is determined using straight-line amortization of the cost over the average remaining service period of the employee expected to receive benefits under the Plan. The estimated prior service costs that will be amortized from accumulated other comprehensive income into net periodic benefit cost during 2008 is approximately $2,000.

Other changes in benefit obligations recognized in other comprehensive income:

	2007	2006
	(In thousands)	
Net gain	$(62)	N/A
Amortization of prior service cost	(1)	N/A
Total recognized in other comprehensive income	$(63)	N/A

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

	2007	2006
Discount rate	5.90%	5.60%
Rate of compensation increase	N/A	N/A

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

	2007	2006
Discount rate	5.60%	5.75%
Rate of compensation increase	N/A	N/A

Plan contributions are equal to benefits paid to the Plan participant during the year. The Company expects to make contributions to the Plan of approximately $151,000 in 2008. Effective February 14, 2005, Mr. Hamachek resigned from his positions as Chairman and Chief Executive Officer (see Note 12). Under the SERP, effective in May 2005, the Company became obligated to pay Mr. Hamachek approximately $12,600 per month over the lives of Mr. Hamachek and his spouse. The following benefit payments are expected to be paid over the next ten years (in thousands):

2008	$151
2009	151
2010	151
2011	151
2012	151
Years 2013-2017	752

Deferred Compensation Plan

The Company has a Deferred Compensation Plan ("DCP"), a nonqualified plan which covers Mr. Hamachek. No amounts were contributed to the DCP during 2007, 2006 and 2005. Under the DCP, the Company recognized interest expense of $62,000, $68,000 and $70,000 for 2007, 2006 and 2005, respectively. The liability for the DCP was approximately $786,000 and $867,000 as of December 31, 2007 and 2006, respectively, and is included in deferred compensation on the Company's balance sheets, including the current portion of approximately $143,000 at December 31, 2007. The Company has not funded this liability and no assets are held by the DCP. In connection with the resignation and retirement of Mr. Hamachek in February 2005 (see Note 12) under the DCP, effective in May 2005, the Company became obligated to pay Mr. Hamachek approximately $143,000 per year, including interest, in ten annual installments. These installments are recalculated annually based on market interest rates as provided for under the DCP. The following benefit payments, including interest, are expected to be paid under the DCP over the seven remaining annual installments (in thousands):

2008	$143
2009	143
2010	143
2011	143
2012	143
Years 2013-2014	286

The Company has two whole-life insurance policies held in a rabbi trust (the "Trust"), the cash surrender value or death benefits of which are held in trust for the SERP and DCP liabilities. The Company is entitled to borrow against or withdraw from these policies to fund the liabilities under the SERP and the DCP as provided by the terms of the Trust. In April 2006, the Company withdrew from the Trust approximately $446,000 as reimbursement for all SERP and DCP benefit payments previously made by the Company to Mr. Hamachek. In addition, effective in June 2006, Mr. Hamachek's SERP and DCP benefit payments are being made directly from the assets in the Trust. The cash surrender value of these life insurance polices totaled $2,472,000 and $2,702,000 as of December 31, 2007 and 2006, respectively. Trust assets, including $4,000 and $2,000 held in a money market account at December 31, 2007 and 2006, respectively, are included in Other Assets in the Company's balance sheets.

Health Care and Life Insurance Benefits

The Company offers health care and life insurance benefits to its active employees. Costs incurred for these benefits were $710,000, $685,000 and $603,000 in 2007, 2006 and 2005, respectively.

15. COLLABORATION AND LICENSING AGREEMENTS

The Company enters into collaborative and licensing agreements with pharmaceutical companies to in-license, develop, manufacture and/or market products that fit within its business strategy. The Company also licenses its proprietary drug delivery technologies to other companies for their use in products outside the Company's focus areas.

Endo Pharmaceuticals Inc.

In September 1997, the Company entered into a strategic alliance agreement with Endo with respect to the development of Opana ER, an extended release formulation of oxymorphone hydrochloride using the Company's TIMERx technology. This agreement was amended and restated in April 2002, and was further amended in January 2007 (the "2007 Amendment"). Endo is a specialty pharmaceutical company with a market leadership position in pain management. Endo has a product line that includes established brands such as Lidoderm®, Percodan®, Percocet® and Frova® as well as Opana ER and Opana®.

During the development of the product, the Company formulated Opana ER, and Endo conducted all clinical studies and prepared and filed all regulatory applications. The Company agreed to supply bulk TIMERx material to Endo, and Endo agreed to manufacture and market Opana ER in the United States. The Company also agreed with Endo that any development and commercialization of Opana ER outside the United States would be accomplished through licensing to third parties approved by both Endo and the Company, and that the Company and Endo would divide equally any fees, royalties, payments or other revenue received by the parties in connection with such licensing activities. Endo is currently seeking a collaborator for Europe.

Prior to April 17, 2003, the Company shared with Endo the costs involved in the development of Opana ER. On April 17, 2003, the Company exercised its option under the terms of the agreement and discontinued its participation in the funding of the development of Opana ER. As a result of this termination of funding, Endo completed the development of Opana ER and has the right to recoup the portion of development costs incurred by Endo that otherwise would have been funded by the Company, in accordance with the terms described below.

The Company entered into the 2007 Amendment as part of the resolution of a dispute between the parties with regard to the sharing of marketing expenses during the period prior to when Opana ER reaches profitability. Under the terms of the 2007 Amendment, the Company and Endo agreed that royalties payable to the Company for U.S. sales of Opana ER would be calculated based on net sales of the product rather than on operating profit. In connection with this change, the Company and Endo agreed:

- Endo will pay the Company royalties on U.S. sales of Opana ER calculated based on a royalty rate starting at 22% of annual net sales of the product up to $150 million of annual net sales, with the royalty rate then increasing, based on agreed-upon levels of annual net sales achieved, from 25% up to a maximum of 30%.
- No royalty payments will be due to the Company for the first $41 million of royalties that would otherwise have been payable beginning from the time of the product launch in July 2006 (the "Royalty Holiday"). If the Company was not subject to the $41 million Royalty Holiday, the Company believes that it would have received royalties from Endo of approximately $18.6 million for the year ended December 31, 2007. Cumulatively, through December 31, 2007, the Company believes that approximately $19.7 million has been applied against the Royalty Holiday. We expect that Endo will initiate the payment of royalties to the Company on U.S. sales of Opana ER commencing in the second half of 2008.

- Endo will pay the Company a percentage of any sublicense income it receives and milestone payments of up to $90 million based upon the achievement of agreed-upon annual net sales thresholds.
- The Company's share of the development costs for Opana ER that it opted out of funding in April 2003 will be fixed at $28 million and will be recouped by Endo through a temporary 50% reduction in royalties. This temporary reduction in royalties will not apply until the threshold for the $41 million Royalty Holiday has been met.

The Company and Endo are currently in litigation with IMPAX Laboratories, Inc. ("IMPAX") in connection with IMPAX's Abbreviated New Drug Application ("ANDA") for Opana ER (see Note 16).

Edison Pharmaceuticals, Inc.

On July 16, 2007, the Company entered into a collaboration and license agreement with Edison. Under the Edison Agreement, the Company and Edison have agreed to collaborate on the development of one of Edison's drug candidates, A0001, and up to one additional Edison drug candidate, initially directed to the treatment of inherited mitochondrial respiratory chain diseases.

During the initial 18 months of the Edison Agreement, Edison is obligated to present to the Company at least one compound identified by Edison that satisfies agreed-upon criteria for consideration as a development candidate under the collaboration, in addition to A0001. The Company has the option, exercisable upon payment of a one-time fee, to select any such compound for development. If A0001, or any compound as to which the Company has exercised its option, fails in toxicology studies during this 18 month research period or any extended research period (the "Research Period"), the Company has the right to select a replacement compound, without any additional fee, which may be identified by Edison during the remainder of the Research Period.

Under the Edison Agreement, the Company has exclusive, worldwide rights to develop and commercialize A0001 and any other compound as to which the Company has exercised its option, or any replacement compound, for the treatment of all indications, subject to other terms and conditions in the Edison Agreement.

In consideration for the rights granted to the Company under the Edison Agreement, the Company paid Edison an upfront cash payment of $1.0 million upon entering into the Edison Agreement and agreed to loan Edison up to an aggregate principal amount of $1.0 million, with the right to draw upon such loan commitment in one or more installments at any time prior to the earliest of July 16, 2012, the occurrence of an event of default, a change in control of Edison or the termination of the Edison Agreement, solely to fund Edison's research and development. The Company is also required to make payments to Edison upon achievement of specified milestones set forth in the Edison Agreement and royalty payments based on net sales of products containing A0001, any other compound as to which the Company has exercised its option, or any replacement compound.

On February 5, 2008, the Company loaned Edison $1.0 million pursuant to the loan provisions of the Edison Agreement noted above. The loan bears interest at an annual rate of one month LIBOR at the time of the loan, plus 5% , or a total of 8.14%, which rate is fixed for the term of the loan. The loan has a maturity date of the earlier of July 16, 2012 and the occurrence of an event of default, as defined in the Edison Agreement. All accrued and unpaid interest is payable on the maturity date; however, interest accruing on any outstanding loan amount after July 16, 2010 is due and payable monthly in arrears. As of March 11, 2008, $1.0 million is outstanding under this loan. The Company is currently assessing the collectability of the loan made to Edison. At the present time, the Company has not completed its initial assessment; however, it believes that there is the potential for the Company to record an impairment charge in its statement of operations during the first quarter of 2008, or at a future time as a result of on-going collectability assessments.

The Company also agreed to pay Edison a total of $5.5 million over the initial 18 months of the Research Period to fund Edison's discovery and research activities during the period, with such payments to be made in quarterly installments. As of December 31, 2007, the Company has paid approximately $2.8 million of the $5.5 million to Edison. The Company has the option to extend the term of the Research Period for up to three consecutive six month periods, subject to the Company's funding of Edison's activities in amounts to be agreed upon. During the initial 18 months of the Research Period and during any extension of the Research Period in which the Company's funding exceeds a specified amount, Edison has agreed not to develop or commercialize any compounds, by itself, or with or on behalf of any third party, for the treatment of certain inherited mitochondrial diseases, other than under the collaboration with the Company, or under specified circumstances. In addition, until 60 days after the later of the presentation of a development candidate by Edison, or the expiration of the Research Period, and in other specified circumstances, Edison has agreed not to disclose or provide to another party, or enter into any agreement with another party granting any options or rights to, any compound believed to have activity in the treatment of certain inherited mitochondrial diseases.

Following the end of the Research Period, the license of any compound under the Edison Agreement ends, on a country-by-country, product-by-product basis, when neither Edison nor the Company has any remaining royalty payment obligations to each other with respect to such compound. Each party's royalty payment obligation ends upon the later of expiration of the last-to-expire claim of all licensed patents covering such party's product or expiration of the FDA's designation of such product as an orphan drug. The Edison Agreement may be terminated by the Company with 120 days prior written notice to Edison; provided that Penwest pays Edison a termination fee equal to 25% of the amount remaining to be paid over the initial 18 months of the Research Period as of the effective date of such termination. The Edison Agreement may also be terminated by either party in the event of the other party's uncured material breach or bankruptcy.

Mylan Pharmaceuticals Inc.

On March 2, 2000, Mylan announced that it had signed a supply and distribution agreement with Pfizer to market generic versions of all three strengths (30 mg, 60 mg, 90 mg) of Pfizer's generic Procardia XL. In connection with that agreement, Mylan decided not to market Nifedipine XL, a generic version of Procardia XL that the Company had developed in collaboration with Mylan. As a result, Mylan entered into a letter agreement with the Company whereby Mylan agreed to pay Penwest a royalty on all future net sales of Pfizer's generic version of Procardia XL 30 mg. The royalty percentage was comparable to the percentage called for in Penwest's original agreement with Mylan for Nifedipine XL 30 mg. Mylan has retained the marketing rights to Nifedipine XL 30 mg. Mylan's sales in the United States in 2007 of Pfizer's generic version of Procardia XL 30 mg totaled approximately $21.3 million. The term of the letter agreement continues until such time as Mylan permanently ceases to market Pfizer's generic version of Procardia XL 30 mg. In 2007, 2006 and 2005, royalties from Mylan were approximately $2.6 million, $3.1 million and $3.9 million, respectively, or 77%, 89% and 63%, respectively, of the Company's total revenue.

Otsuka Pharmaceutical Co., Ltd.

The Company signed a research and development agreement with Otsuka Pharmaceutical Co., Ltd. ("Otsuka") of Japan effective August 14, 2007 to develop a formulation of an Otsuka compound utilizing Penwest's TIMERx drug delivery technology. In connection with the agreement, the Company received an initial nonrefundable up-front payment which was recorded as deferred revenue upon receipt and will be recognized as revenue over the contractual performance period. The Company will also be reimbursed for development costs incurred in the formulation of the compound, up to specified amounts. Additionally, under the agreement, the Company may receive milestone payments upon the achievement of specified events.

Prism Pharmaceuticals, Inc.

On April 26, 2005, the Company entered into a licensing agreement (the "License Agreement") with Prism Pharmaceuticals, Inc. ("Prism") granting Prism exclusive rights to market Penwest's PW2101 product in the United States and Canada. Under the terms of the License Agreement, the Company granted Prism an exclusive license under certain Penwest intellectual property to develop, make, use and commercialize PW2101 in the United States and Canada for all indications except the treatment and/or prophylaxis of migraine. Prism made a non-refundable $4.0 million payment to the Company upon signing the License Agreement and had agreed to pay the Company milestone payments upon achievement of milestones related to FDA approval and launch of PW2101, and royalties on net sales. Upon receipt, the Company deferred the $4.0 million received from Prism.

In June 2005, the FDA issued a non approvable letter for the Company's NDA for PW2101. Given the FDA's concerns expressed in the non approvable letter, the time and resources the Company expected it would take to address them, and the commercial window for this product opportunity, the Company decided not to undertake the additional activities on PW2101 that it believed would be required to address the FDA's concerns. On July 7, 2005, the Company was notified by Prism that Prism also did not intend to proceed with development activities on PW2101 under the License Agreement. As a result, the License Agreement terminated effective July 20, 2005. In connection with the termination, the Company and Prism signed a settlement agreement in September 2005, and Penwest repaid Prism $1.75 million of the $4.0 million payment the Company received from Prism, and recognized the remaining $2.25 million as licensing fee revenue in the third quarter of 2005.

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 involving the Company could cause the Company to pay substantial damages, alter its products or processes, obtain additional licenses and/or cease certain activities. Even if the outcome is favorable to the Company, the Company could incur substantial litigation costs.

On October 3, 2007, the Company received a letter from IMPAX notifying the Company of its filing of an ANDA containing a Paragraph IV Certification under 21 U.S.C. § 355(j) for Opana ER in four strengths, 5 mg, 10 mg, 20 mg and 40 mg. This Paragraph IV Certification notice referred to the Company's patent, U.S. Patent No. 7,276,250, which covers the formulation of Opana ER and was listed in the Orange Book as of October 2, 2007. On October 4, 2007, IMPAX announced in a press release that the FDA had rescinded the acceptance of IMPAX's ANDA filing. On November 5, 2007, the Company received a letter from IMPAX notifying it of additional Paragraph IV Certifications relating to the Company's patents, U.S. Patent Nos. 5,622,933 and 5,958,456, which were listed in the Orange Book as of October 19, 2007. On November 15, 2007, Endo and the Company filed a lawsuit against IMPAX in the United States District Court for the District of Delaware (U.S. Dist. Delaware). The lawsuit against IMPAX not only alleged infringement of certain of these Orange Book-listed U.S. patents but also sought declaratory judgment that, among other things, IMPAX had no legitimate basis to trigger the Hatch-Waxman ANDA patent litigation process because the FDA, according to IMPAX, had rescinded its acceptance of IMPAX's ANDA. It further asked the court to declare that the Paragraph IV Certification notices that IMPAX served on Endo and the Company are null, void and of no legal effect. On December 14, 2007, the Company received a letter from IMPAX notifying it of a refiling of its ANDA for Opana ER that was accepted by the FDA as of November 23, 2007. The notice letter states that IMPAX's ANDA contains Paragraph IV Certifications for the three patents above and the FDA had required IMPAX to notify Endo and the Company of these certifications. In this notice, IMPAX also stated that it would not withdraw its prior Paragraph IV Certification notices because it believed they were properly provided and because IMPAX was continuing to seek to convince the FDA to assign an earlier filing date to

its ANDA. As a result of the FDA's determination of IMPAX's ANDA filing date and the receipt of the new Paragraph IV Certification notice, on December 20, 2007, the Company and Endo filed a notice of dismissal of the portion of its November 15, 2007 complaint seeking declaratory judgment that, among other things, IMPAX had no basis to trigger the Hatch-Waxman ANDA patent litigation process and that any Paragraph IV Certification notices served prior to November 23, 2007 were null, void and of no legal effect. The Company and Endo did not dismiss the patent infringement claims because IMPAX refused to withdraw its prior Paragraph IV Certification notices. On January 25, 2008, Endo and the Company filed a lawsuit against IMPAX in U.S. Dist. Delaware, alleging infringement of certain Orange Book-listed patents in response to IMPAX's December notices. Endo and the Company intend to pursue all available legal and regulatory avenues defending Opana ER.

The Company is also a party from time to time to certain other types of claims and proceedings in the ordinary course of business. The Company does not believe any of these matters will result, individually or in the aggregate, in a material adverse effect upon its financial condition or future results of operations.

17. SUBSEQUENT EVENTS

Actavis Paragraph IV Certification Notice. On February 14, 2008, the Company received a notice from Actavis South Atlantic LLC, ("Actavis") advising of the filing by Actavis of an ANDA containing a Paragraph IV certification under 21 U.S.C. Section 355(j) for Opana ER in four strengths, 5 mg, 10 mg, 20 mg and 40 mg. The Actavis Paragraph IV certification notice refers to the Company's Orange Book listed patents, U.S. Patent Nos. 5,128,143, 5,662,933, 5,958,456 and 7,276,250, which cover the formulation of Opana ER. These patents expire in 2008, 2013, 2013 and 2023, respectively. The Company is currently reviewing the details of this notice from Actavis.

Private Placement. On March 11, 2008, the Company sold units representing an aggregate of 8,140,600 shares of its Common Stock, together with warrants to purchase an aggregate of 4,070,301 shares of its Common Stock, in a private placement, for a total purchase price of approximately $25.1 million. The Company expects net proceeds to be approximately $23.2 million from this private placement, after deducting the placement agent's fees and other estimated expenses.

The warrants are exercisable on or prior to March 11, 2013 at an exercise price of $3.62 per share. The warrants may also be exercised pursuant to cashless exercise provisions under certain circumstances.

Pursuant to the securities purchase agreement entered into in connection with the private placement, the Company agreed to file a registration statement with the Securities and Exchange Commission ("SEC") by April 10, 2008, registering for resale the shares and shares issuable under the warrants. The Company also agreed to use its reasonable best efforts to have the registration statement declared effective as soon as practicable after the filing date of the registration statement, but in any event within 90 days after the filing date of the registration statement. The failure to file the registration statement on or prior to April 10, 2008, or the failure to have the registration statement declared effective by the SEC within 90 days after the Company files the registration statement will result in financial penalties to the Company. The Company has agreed to maintain the registration statement's effectiveness until the earlier of (i) the later of (A) the twelve month anniversary of March 11, 2008, the closing date of the private placement or (B) the twelve month anniversary of the last date on which warrant shares are issued upon exercise of warrants and (ii) the date all of the shares and warrant shares have been resold by the original purchasers.

18. QUARTERLY FINANCIAL DATA (UNAUDITED)

Summarized quarterly financial data for the years ended December 31, 2007 and 2006 is as follows:

	Quarter Ended			
	Mar. 31, 2007	June 30, 2007	Sept. 30, 2007	Dec. 31, 2007 (a)
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Total revenues	$ 842	$ 712	$ 882	$ 872
Gross profit	732	568	739	664
Net loss	$(6,954)	$(8,958)	$(9,251)	$(9,302)
Net loss per share	$ (0.30)	$ (0.39)	$ (0.40)	$ (0.40)

	Quarter Ended			
	Mar. 31, 2006	June 30, 2006	Sept. 30, 2006	Dec. 31, 2006
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
	(In thousands, except per share data)			
Total revenues	$ 965	$ 1,075	$ 720	$ 739
Gross profit	943	1,042	671	612
Net loss	$(6,303)	$(7,416)	$(8,741)	$(8,852)
Net loss per share	$ (0.28)	$ (0.33)	$ (0.38)	$ (0.38)

(a) During the fourth quarter of 2007, the Company recognized an impairment loss of $414,000 related to patents primarily in connection with early stage development programs discontinued by the Company, and that it determined no longer had value. Such charge was reflected in research and product development expense. In addition, the Company recorded a net credit of $327,000 in the fourth quarter of 2007 as an adjustment to incentive compensation expense to reflect a reduction in expected payouts in 2008, of which a credit of $188,000 and a credit of $139,000 were recorded to selling, general and administrative expense and research and product development expense, respectively.

SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS

PENWEST PHARMACEUTICALS CO.
DECEMBER 31, 2007

	Balance at Beginning of Period	Additions: Charged to Costs and Expenses	Additions: Charged to Other Accounts-Describe	Deductions-Describe	Balance at End of Period
			(In thousands)		
Year ended December 31, 2007					
Inventory Allowances	$ —	$ 18	$—	$ —	$ 18
Year ended December 31, 2006					
Inventory Allowances	$208	$ —	$—	$208(a)	$ —
Year ended December 31, 2005					
Inventory Allowances	$ 85	$497	$—	$374(a)	$208

(a) Disposals of unrecoverable inventory costs.

Corporate Directory and Shareholder Information

Officers

Jennifer L. Good
President and
Chief Executive Officer

Benjamin L. Palleiko
Senior Vice President, Corporate Development and
Chief Financial Officer

Anand R. Baichwal, Ph.D.
Senior Vice President, Licensing and
Chief Scientific Officer

Amale Hawi, Ph.D.
Senior Vice President,
Pharmaceutical Development

Paul F. Hayes
Vice President,
Strategic Marketing

Frank P. Muscolo
Controller and
Chief Accounting Officer

Thomas R. Sciascia, M.D.
Senior Vice President and
Chief Medical Officer

Board Committees

Audit Committee
Anne M. VanLent, Chair
Peter F. Drake, Ph.D.
David P. Meeker, M.D.

Compensation Committee
Robert J. Hennessey, Chair
Peter F. Drake, Ph.D.
Paul E. Freiman
W. James O'Shea

Nominating and Governance Committee
Paul E. Freiman, Chair
Robert J. Hennessey
David P. Meeker, M.D.
Anne M. VanLent

Scientific Review Committee
David P. Meeker, M.D., Chair
Christophe Bianchi, M.D.
John N. Staniforth, Ph.D.

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(845) 878-8400
Fax: (845) 878-3420

Website
www.penwest.com

Shareholder Information
Our common stock, $.001 par value, is listed with and trades on the Nasdaq Global Market under the symbol "PPCO." The high and low sale prices of our common stock during 2007 and 2006 are set forth below. These prices reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

Periods in 2007	**High**	**Low**
Quarter Ended March 31	$17.50	$9.43
Quarter Ended June 30	$13.99	$9.92
Quarter Ended September 30	$14.60	$10.57
Quarter Ended December 31	$11.64	$4.68

Periods in 2006	**High**	**Low**
Quarter Ended March 31	$23.70	$19.00
Quarter Ended June 30	$23.10	$15.73
Quarter Ended September 30	$22.74	$16.20
Quarter Ended December 31	$19.35	$15.67

On April 23, 2008, there were 640 shareholders of record.

We have never paid cash dividends on our common stock. We presently intend to retain earnings, if any, for use in the operation of our business, and are precluded from paying

any cash dividends under the terms of our senior secured credit facility. See "Sources of Liquidity" under the caption "Liquidity and Capital Resources" in "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Form 10-K for the fiscal year ended December 31, 2007.

Annual Meeting
11:00 a.m., June 11, 2008
39 Old Ridgebury Road, Suite 11
Danbury, Connecticut

Form 10-K
We filed our annual report on Form 10-K for the fiscal year ended December 31, 2007 with the SEC on March 17, 2008, pursuant to the Securities Exchange Act of 1934. Shareholders may obtain a copy of this report without charge by written request to Penwest Pharmaceuticals Co., Attention: Corporate Secretary, 39 Old Ridgebury Road, Suite 11, Danbury, Connecticut 06810-5120, or view the 10-K in its entirety on our website www.penwest.com. The 10-K is included with this annual report.

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Boston, MA 02109

Independent Registered Public Accounting Firm
Ernst & Young LLP
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Stamford, CT 06905

Investor Relations
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Transfer Agent and Registrar
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Jersey City, NJ 07310-1900
Website: www.melloninvestor.com

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TTD for Hearing Impaired:
1-800-231-5469
Foreign Shareholders:
(201) 680-6578
TTD Foreign Shareholders:
(201) 680-6610

Forward-Looking Statements

This Annual Report contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. For this purpose, any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words "believes", "anticipates", "plans", "expects", "intends", "may", and other similar expressions are intended to identify forward-looking statements. There are a number of important factors that could cause our actual results to differ materially from those indicated by forward-looking statements contained in this report and presented elsewhere by management from time to time. These factors include the factors discussed in "Item 1-A-Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007 included in this annual report to shareholders.

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