2008 Annual Report

Dear Penwest Shareholder:

2008 was a very active and productive year for Penwest on many fronts. We received our first royalties on sales of Opana ER® from our partner Endo Pharmaceuticals, advanced our lead drug candidate A0001 into clinical trials, entered into two drug delivery technology collaborations, completed an equity financing resulting in net proceeds of $23 million, and took steps to reduce our operating expenses, including a significant decrease in overhead costs.

These developments were reflected in our much-improved financial performance for both the fourth quarter and full year ended December 31, 2008. Compared with the fourth quarter of 2007, our revenues increased sharply, our operating expenses decreased by 30%, and our net loss was substantially reduced. In fact, we see our improved financial results in 2008 continuing into 2009, with significantly increased royalties from Opana ER and 30% lower projected operating expenses compared with 2008 levels. As a result, we expect that for 2009, our net loss will decrease to a range of $1 million to $3 million for the full year compared with a net loss of $26.7 million in 2008.

We are excited about what we can achieve in 2009, building on our 2008 accomplishments. After a thorough review by the Board of Directors of the Company's business and strategy, we have established a highly-focused business plan for 2009, with well-defined goals and clear value milestones for our shareholders. The four goals of our plan are to:

- Maximize the value of Opana ER with our partner Endo Pharmaceuticals through additional intellectual property protection and the licensing of Opana ER in territories outside the United States.
- Advance the development of A0001, our compound for the treatment of mitochondrial diseases, to establish proof of concept.
- Monetize the value of the Company's proven drug delivery technologies and drug formulation expertise through additional drug delivery collaborations.
- Aggressively manage the Company's overhead and other costs to ensure that our spending is commensurate with our narrowed priorities.

We are intensely focused on implementing our plan and are excited about what we can achieve this year. At the same time, we and our Board will be monitoring our progress on each of these goals throughout this year, and are ready to revisit our strategic course and take decisive actions as appropriate.

Opana ER

We are pleased that our collaboration with Endo for Opana ER produced strong sales growth in 2008. For the year ended December 31, 2008, Endo's net sales of Opana ER increased 69% to $143.0 million. Endo's net sales for Opana ER for the fourth quarter of 2008 were $40.3 million, representing an increase of 76% over the fourth quarter of 2007. Endo pays us a tiered royalty based on its net sales of this product. We believe that Opana ER has strong prospects for continued growth. Managed care coverage for the product is broad and largely in place, which we believe may translate into meaningful volume increases in 2009.

Protecting the intellectual property around Opana ER is also a top priority for both Endo and Penwest, and we both are taking the steps necessary to defend it from the threat of generics.

With respect to licensing opportunities for Opana ER, we have taken the business development lead on identifying partners outside the United States to develop and market the product. We own these rights jointly with Endo, and the economics of any deal will be split evenly. The licensing of this asset in territories outside the United States is a high priority for us in 2009. Our efforts are progressing well, and we expect to sign an agreement for at least one territory by the end of the first half of this year.

Progress on Internal Drug Development

We also took significant steps on our lead internal drug development program – A0001 – in 2008 and early 2009. During 2008, we completed Investigational New Drug (IND)-enabling toxicology studies, submitted an IND for A0001 to the FDA and completed a Phase 1a single ascending dose safety study of the drug in healthy volunteers. In late February 2009, we began dosing a Phase Ib multiple ascending dose safety study of A0001 in healthy volunteers, and we are in the process of designing a Phase IIa clinical trial to establish proof of concept of biological activity, which we plan to commence in the second half of this year.

Given the potential value to shareholders of A0001, and the limited time and cost it will require for us to gain a better understanding of proof of concept on both safety and efficacy through the Phase 1b and Phase IIa trials, we believe that it is important to advance A0001 through this next phase of development. If our findings do not support further development of the drug, we will discontinue this program.

Drug Delivery Collaborations

In 2008, we entered into two additional drug delivery technology collaborations, one with Cobalt Laboratories and another with Otsuka Pharmaceutical. This is our second collaboration with Otsuka.

Under these agreements, we receive up-front fees, R&D cost reimbursements, and potential milestone and royalty payments. With two new agreements per year, we believe the up-front fees and R&D reimbursements can allow us to operate this aspect of our business on a breakeven basis while providing Penwest with the upside potential in products should they advance in development and commercialization and achieve the related milestone and royalty payments.

Further Expense Reductions

We continue to significantly reduce expenses and closely manage our cash burn. Since early 2008, we have reduced our staff level by 27 employees or 36%. The responsibilities of our current staff center on activities related to supporting and maximizing the value of Opana ER, advancing the development of A0001, carrying out our responsibilities under our existing drug delivery technology collaborations as well as signing new collaborations, and performing functions related to Penwest's operation as a public company.

Having decreased our staff and taken other significant cost-reduction actions, we believe we have optimized our infrastructure and overhead to execute on our current business plan in a cost effective manner. We expect that these efforts, together with the royalties we expect from Endo, will enable us to achieve quarterly profitability by the fourth quarter of 2009, and

profitability for the full year in 2010. Moreover, we do not anticipate requiring additional capital to implement our current business plan.

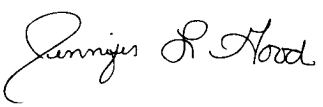
Closing

In closing, I want to thank my colleagues at Penwest for their tremendous efforts, and for their dedication to the Company and our mission. In the current economy, companies are scrutinizing every aspect of their business and downsizing their operations. Penwest is no exception. As a result, our employees are working very hard and doing whatever needs to be done, which often extends well beyond the job for which they were hired. Our entire team is positive, focused and highly motivated to succeed in carrying out our plan, building value for our shareholders and making a difference in the lives of patients and their families.

I look forward to keeping you informed of our progress in 2009. The Board is unanimous in its belief that we are following the right path for Penwest to build value for shareholders, both in 2009 and over the long-term. Our business plan is focused and executable, and we will continue to be accountable to you as we implement it.

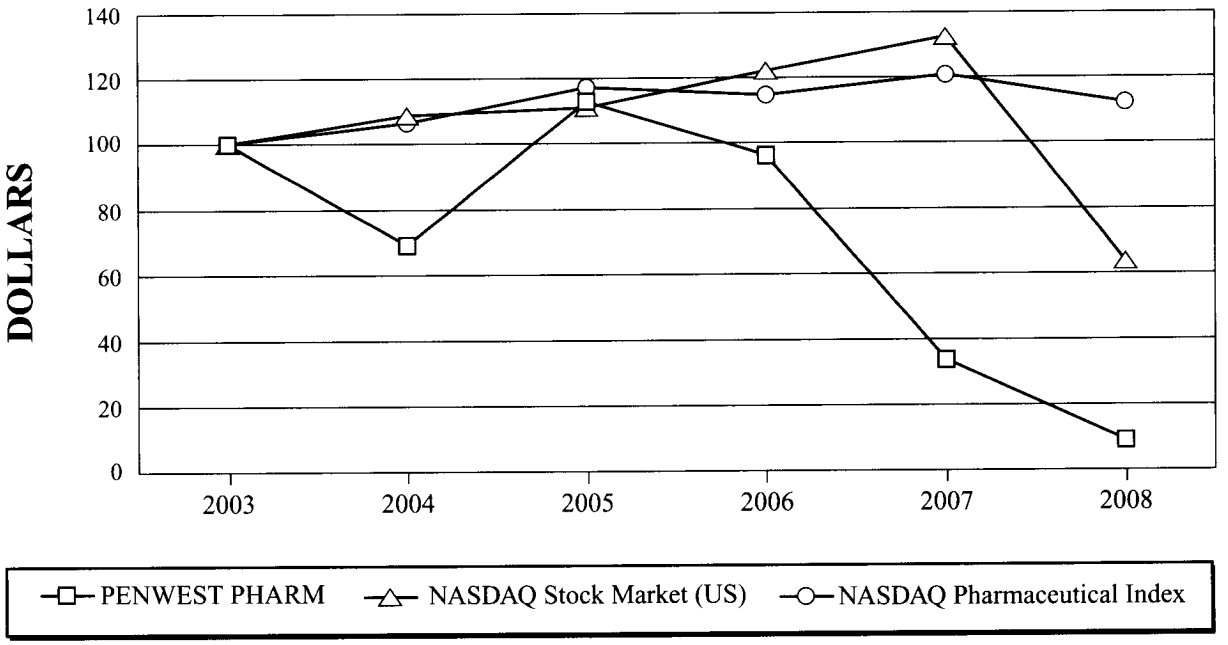
Thank you for your continued support.

Sincerely,



Jennifer L. Good
President and Chief Executive Officer

Comparison of 5 Year Cumulative Total Return



ASSUMES $100 INVESTED ON DECEMBER 31, 2003
ASSUMES DIVIDENDS REINVESTED
MEASUREMENT POINTS ARE ON THE LAST TRADING DAYS OF DECEMBER 31, 2004, DECEMBER 31, 2005, DECEMBER 31, 2006, DECEMBER 31, 2007 AND DECEMBER 31, 2008

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, 2008

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~~ 1-34267

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 ☐ (Do not check if a smaller reporting company) 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 30, 2008 was approximately $84,418,000 based on the last sale price of the Registrant's Common Stock on the Nasdaq National Market on June 30, 2008. The number of shares of the Registrant's Common Stock outstanding as of March 10, 2009 was 31,719,442.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of our definitive Proxy Statement relating to the 2008 Annual Meeting of Shareholders to be held on June 10, 2009 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 focused on identifying and developing products that address unmet medical needs, primarily for rare disorders of the nervous system. We are currently developing A0001, a coenzyme Q analog drug candidate that we licensed from Edison Pharmaceuticals, Inc., or Edison, for inherited mitochondrial respiratory chain diseases. We are also applying our drug delivery technologies and drug formulation expertise to the formulation of product candidates under licensing collaborations, which we refer to as drug delivery technology collaborations.

Opana® ER is an extended release formulation of oxymorphone hydrochloride that we developed with Endo Pharmaceuticals Inc., or Endo, using our proprietary TIMERx® drug delivery technology. Opana ER was approved by the United States Food and Drug Administration, or FDA, in June 2006 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. In 2008, we recognized $5.0 million in royalties from Endo related to sales of Opana ER. We are currently seeking to license Opana ER for development and commercialization outside the United States. Under our agreement with Endo, we and Endo share the rights to Opana ER outside the United States, and any economics from a related collaboration with a third party, equally.

We are currently developing A0001, a drug candidate that we are initially targeting for the treatment of inherited mitochondrial respiratory chain diseases, under a collaboration and license agreement with Edison that we entered into in July 2007. We are currently conducting a Phase Ib multiple ascending dose safety study of A0001 in healthy volunteers. If A0001 demonstrates an acceptable safety profile and tolerability in this Phase Ib study, we plan to commence a Phase IIa trial in patients with inherited mitochondrial respiratory chain diseases in the second half of 2009. The goal of this trial will be to determine if A0001 has biological activity. Under the Edison agreement, we have agreed to collaborate with Edison on the development of A0001 and up to one additional drug candidate of Edison's.

We are party to a number of collaborations involving the use of our extended release drug delivery technologies as well as our formulation development expertise. Under these collaborations, we are responsible for completing the formulation work on a product specified by our collaborator. If we are successful in-vitro, we transfer the formulation to our collaborator, who is then responsible for the completion of the clinical development, and ultimately, the commercialization of the product. Under the terms of these agreements, we generally receive up-front fees, reimbursement of research and development costs, and potential milestone and royalty payments. We are seeking to enter into additional drug delivery technology collaborations.

Our strategy is to identify and develop products that address unmet medical needs, primarily for rare disorders of the nervous system. In support of this strategy, we have set four clearly defined goals for 2009:

- *Maximizing the value of Opana ER, working closely with Endo.* We plan to continue to take steps to protect and prosecute the intellectual property around Opana ER and explore licensing opportunities for Opana ER outside the United States.
- *Advancing the development of A0001 drug candidate.* Through the planned Phase Ib and IIa trials, we are seeking to establish proof of concept with respect to both safety and efficacy.
- *Monetizing the value of our proven drug delivery technologies and drug formulation expertise by executing additional deals.* We are seeking to enter into at least two new collaborations in 2009. We believe that, with two agreements, this aspect of our business can operate on a breakeven basis, fund a portion of our overhead and provide us with a financial stake in products, should they advance in development and commercialization.
- *Managing overhead and other costs to ensure that our infrastructure is sized appropriately to our priorities.* We continue to significantly reduce expenses and closely manage our cash expenditures. In January 2009, we reduced our personnel by 18%.

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, and in March 2008 in 7.5 mg, 15 mg and 30 mg tablets. For the year ended December 31, 2008, Endo recorded net sales of Opana ER of $143.0 million, compared with $84.0 million for 2007, representing an increase in net sales of approximately 69%.

Under the terms of our collaboration with Endo, Endo pays us royalties based on U.S. net sales of Opana ER. No payments were due to us for the first $41 million of royalties otherwise payable to us beginning from the time of the product launch in July 2006, a period we refer to as the royalty holiday . In the third quarter of 2008, the royalty holiday ended and we began earning royalties from Endo on sales of Opana ER. Endo has the right under our agreement to recoup the $28 million in development costs that Endo funded on our behalf prior to the approval of Opana ER, through a temporary 50% reduction in royalties. For the year ended December 31, 2008, we recognized $5.0 million in royalties from Endo on sales of Opana ER. This royalty amount reflects this temporary reduction. As of December 31, 2008, $5.0 million of the $28 million has been recouped by Endo.

Opana ER is not approved for marketing outside the United States. We are currently seeking collaborators to develop and commercialize Opana ER in various territories outside the United States. Under the terms of our agreement with Endo, any fees, royalties, payments or other revenues received by the parties in connection with any collaborator outside the United States will be divided equally between Endo and us. A description of our agreement with Endo is included below under the caption "Collaborative and Licensing 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 Actavis' Kadian®, as well as generic versions of some of these products. We believe that products in the long acting, strong opioids market had aggregate sales in the United States in 2008 of approximately $4.7 billion.

IMPAX Laboratories, Inc., or IMPAX, Actavis South Atlantic LLC, or Actavis, and Sandoz, Inc., or Sandoz, have each filed abbreviated new drug applications, or ANDA's, that, together with their respective amendments, cover all seven strengths of Opana ER. Barr Laboratories, Inc., or Barr, has also filed an ANDA that covers the Opana ER 5 mg, 10 mg, 20 mg and 40 mg strengths. These ANDA filings each contained paragraph IV certifications under 21 U.S.C. Section 355(j). We and Endo have filed patent infringement lawsuits against each of IMPAX , Actavis, Sandoz and Barr in connection with their respective ANDA's.

We intend to pursue all available legal and regulatory avenues to defend Opana ER. We believe that we are entitled to a 30-month stay under the Hatch Waxman Act against IMPAX's ANDA, Actavis' ANDA, Sandoz's ANDA and Barr's ANDA. IMPAX has announced that it is seeking to reinstate an earlier filing date of its ANDA covering Opana ER 5mg, 10 mg, 20 mg and 40 mg. If this occurs, or if we and Endo are unsuccessful in these legal proceedings, Opana ER could be subject to generic competition as early as June 2009 when the new dosage form exclusivity expires.

On February 20, 2009, we and Endo settled all of the Actavis litigation. Both sides agreed to dismiss their respective claims and counterclaims with prejudice. Under the terms of the settlement, Actavis agreed not to challenge the validity or enforceability of our four Orange Book-listed patents. We and Endo agreed to grant Actavis a license under US Patent No. 5,958,456 and a covenant not to sue for its generic formulation of Opana ER under our four Orange Book-listed patents. The license and covenant not to sue will take effect on July 15, 2011, and earlier under certain circumstances.

The settlement is subject to the review of the U.S. Federal Trade Commission and Department of Justice.

A description of the legal proceedings related to Opana ER and the settlement with Actavis are included in "Part I. Item 3 — Legal Proceedings."

A0001. A0001 is a coenzyme Q analog that we are developing under our collaboration and licensing agreement with Edison. Coenzyme Q is a molecule intrinsic to mitochondria and its production of energy in the body. We are developing A0001 for the treatment of inherited mitochondrial respiratory chain diseases. We believe that impairment of mitochondrial function is a significant factor in a number of inherited mitochondrial respiratory chain diseases. As such, we believe that enhancing mitochondrial function may provide substantial clinical benefit to patients suffering from mitochondrial respiratory chain disease. A0001 has shown strong biological activity in cell assays developed by Edison to test the ability of the class to rescue cells from death caused by inherited mitochondrial diseases.

Mitochondrial diseases are devastating, potentially life-threatening illnesses for which there are no FDA-approved treatments. Mitochondrial diseases are diseases in which the mitochondria in the body is damaged, or not functioning properly, which results in a variety of diseases and disorders. We are currently focusing our development efforts on inherited mitochondrial respiratory chain diseases, which are a subset of mitochondrial disease and include, among other diseases, MELAS, (mitochondrial myopathy, encephalopathy, lactic acidosis, and stroke), Friedreich's Ataxia, Leber's Hereditary Optic Neuropathy and COQ10 deficiency. Drugs for the treatment of these diseases may receive orphan drug designation from the FDA. 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, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a product for this type of disease or condition will be recovered from sales in the United States for the product. A0001 has received orphan drug designation from the FDA for the treatment of inherited mitochondrial respiratory chain diseases, and we plan to file for orphan drug status for A0001 in the European Union. Orphan drug exclusivity, if granted, generally provides seven years of marketing exclusivity in the United States and ten years in Europe.

In May 2008, we submitted an Investigational New Drug application, or IND, for A0001 for the treatment of symptoms associated with inherited mitochondrial respiratory chain diseases. In July 2008, we initiated a Phase Ia placebo-controlled, single ascending dose trial designed to evaluate the safety and tolerability of A0001 in healthy subjects, and to collect pharmacokinetic data. A0001 was well tolerated by all subjects across all dose groups and there were no drug-related serious adverse events that occurred in the study. In February 2009, we initiated a Phase Ib multiple ascending dose clinical study in healthy volunteers. The study is a single-blind, placebo-controlled, multiple ascending dose clinical trial in healthy subjects, designed to assess the safety, tolerability, and pharmacokinetics of A0001 following repeat dosing in healthy male and female subjects. We plan to enroll a total of 30 healthy volunteers in the trial. We expect that results from this study will be available in the second quarter of 2009. If A0001 demonstrates an acceptable safety profile and tolerability in this Phase Ib study, we plan to commence a Phase IIa trial in patients with inherited mitochondrial respiratory chain diseases in the second half of 2009. We are currently working on the study design for the Phase IIa program. In parallel with the Phase Ib trial, we have initiated long-term animal toxicology studies to support the clinical program.

At least two companies have announced that they are pursuing programs based upon mitochondrial disease pathways. Santhera Pharmaceuticals, or Santhera, is currently conducting clinical trials of the coenzyme Q analog, idebenone, for the diseases of Friedreich's Ataxia, Duchenne's muscular dystrophy and Leber's Hereditary Optic Neuropathy. Santhera recently received regulatory approval in Canada for idebenone to be sold as a treatment for Friedreich's Ataxia under the brand name Catena®. GlaxoSmithKline plc., or GlaxoSmithKline, through its acquisition of Sirtris Pharmaceuticals, or Sirtris, is planning to study Sirtris' drug candidate resveratrol in MELAS. We believe A0001 is chemically distinct from Santheras's idebenone and Sirtris' resveratrol. As a result, we do not believe that the approval of these drug candidates will impact our ability to obtain FDA approval of A0001 and orphan drug exclusivity.

Under the terms of the Edison agreement, we have exclusive, worldwide rights to develop and commercialize A0001 and up to one additional compound of Edison's, which we may exercise our option to select, for all indications, subject to the terms and conditions in the agreement. Edison has not yet presented us with a compound for selection under the agreement.

In connection with the dosing in the Phase Ia trial noted above, we made a milestone payment to Edison in August 2008. A description of the Edison agreement is included below under the caption "Collaborative and Licensing Agreements."

Nifedipine XL. 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, that was approved by the FDA in December 1999. In March 2000, Mylan 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. Since the inception of our collaboration with Mylan, we have received revenue from Mylan of approximately $39 million, comprised primarily of royalties, as well as milestone payments and sales of bulk TIMERx material.

Nalbuphine ER. Nalbuphine ER is a controlled release formulation of nalbuphine hydrochloride, for the treatment of moderate chronic pain that we have developed through Phase IIa. 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 potential for abuse as compared to other opioids. We believe the profile of nalbuphine ER may be attractive in the treatment of moderate chronic pain compared to current options because we believe it should provide a better balance of good efficacy, low abuse potential and low side effects. We have conducted multiple Phase I and II studies of various formulations of nalbuphine ER.

In June 2007, we initiated a Phase IIa trial that was designed to determine the safety and efficacy of nalbuphine ER compared to placebo for the 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.

During 2008, we determined that due to the cost of the Phase IIb trial that would need to be conducted to advance the development of nalbuphine ER, and our limited financial resources, we would actively seek a collaborator. To date, we have not entered into a collaboration for nalbuphine ER. We plan to continue our licensing effort in 2009. We expect that upon completion of all the clinical trials required by the FDA for nalbuphine ER, our collaborator would seek FDA approval of nalbuphine ER through the filing of a 505 (b)(2) New Drug Application, or NDA.

Additional Product Candidate. We were developing PW4153, a drug candidate for the treatment of symptoms of Parkinson's disease, designed to be an extended release formulation containing carbidopa and levodopa. In July 2008, we conducted a Phase I clinical trial for PW4153 to assess the pharmacokinetics of our formulation in healthy volunteers. The goal of the formulation was to minimize the peak to trough fluctuation at steady state as compared to the currently marketed immediate release and extended release formulations. Our formulation did not meet this target and, as a result, we terminated this program in the third quarter of 2008.

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. Our TIMERx technologies have been used in four products that have received regulatory approval, two in the United States, including Opana ER, 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.

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. Several other drug formulations utilizing our TIMERx technology have received regulatory approval in the United States, United Kingdom, Italy, Finland and Brazil.

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 and Licensing Agreements

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 and July 2008.

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 are currently seeking collaborators outside the United States to develop and commercialize Opana ER.

Prior to April 17, 2003, we shared with Endo the funding of 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. In the third quarter of 2008, the royalty holiday was completed and we began to recognize royalties from Endo.
- Our share of the development costs for Opana ER that we opted out of funding in April 2003 would be fixed at $28 million and would be recouped by Endo through a temporary 50% reduction in royalties following the completion of the royalty holiday. As of December 31, 2008, $5.0 million of the $28 million had been recouped by Endo.
- 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.

We recognized royalties from Endo related to sales of Opana ER in the amount of $5.0 million for 2008.

In July 2008, we entered into a Second Amendment to the Amended and Restated Strategic Alliance Agreement with respect to Opana ER. Under the terms of this amendment, Endo agreed to directly reimburse us for costs and expenses incurred by us in connection with patent enforcement litigation related to Opana ER. If any of such costs and expenses are not reimbursed to us by Endo, we may bill Endo for these costs and expenses through adjustments to the pricing of TIMERx material that we supply to Endo for use in Opana ER. In connection with the amendment, in July 2008, Endo reimbursed us for such costs and expenses incurred prior to June 30, 2008, totaling approximately $470,000. We credited this reimbursement to selling, general and administrative expense. The costs we incurred subsequent to June 30, 2008 were not significant and have been reimbursed to us by Endo.

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 of Edison's. We have exclusive worldwide rights to develop and commercialize A0001 and the additional drug candidate of Edison's, which we may exercise our option to select, for all indications, subject to the terms and conditions in the Edison agreement.

Edison has agreed to present to us at least one compound that satisfies agreed upon criteria for consideration by us 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 with Edison to identify this compound, but to date no compound has completed the agreed upon criteria.

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 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 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 December 31, 2008, $1.1 million, which included accrued interest, is outstanding under this loan.

We also agreed to pay Edison a total of $5.5 million over the 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, 2008, we have paid $5.4 million of the $5.5 million to Edison. We had the option to extend the term of the research period for up to three consecutive six month periods; however, we did not exercise this option. During the 18 month research period, Edison 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 presentation of a development candidate by Edison, 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. Edison has not yet presented us with a development candidate and has the option to continue their work at their own expense. Until Edison presents us with an additional compound, it is not able to present compounds to any other parties, or develop or commercialize any compounds by itself or on behalf of a third party. If Edison does not present us with an additional compound, then the agreement provides for credits that we may apply against future potential royalties to Edison on A0001.

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. 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 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 had 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 2008 of Pfizer's generic version of Procardia XL 30 mg totaled approximately $14.9 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 2008, 2007 and 2006, royalties from Mylan were approximately $1.8 million, $2.6 million and $3.1 million, respectively, or 21%, 77% and 89%, respectively, of our total revenue.

Drug Delivery Technology Collaborations

We enter into development and licensing agreements with third parties under which we develop formulations of compounds utilizing our TIMERx drug delivery technologies. In connection with these agreements, we generally receive nonrefundable up-front fees, reimbursement for research and development costs incurred up to amounts specified in each agreement, and receive potential milestone payments upon the achievement of specified events. Finally, these agreements provide for us to receive payments from the sale of bulk TIMERx material and royalties on product sales upon commercialization of the product. As of December 31, 2008, we are a party to three such drug delivery technology collaborations, and for 2008, we recorded collaborative licensing and development revenue of $1.0 million.

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. Our research and product development expenses in 2008, 2007 and 2006 were $21.0 million, $23.6 million and $22.9 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., or Draxis. 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. 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. Endo currently markets Opana ER, and pursuant to our drug delivery technology agreements, our collaborators have responsibility for the marketing and distribution of any pharmaceutical products developed.

If we successfully develop one or more products for rare disorders of the nervous system, and determine to retain the rights to market or co-promote, we may build or acquire a relatively small specialty sales force that targets specialty physicians to market these products. We believe that high-prescribing neurologists 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 technologies 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, 2008, we owned a total of 32 U.S. patents and 96 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 2009 and 2024.

We own four issued U.S. patents listed in the FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations,* commonly referred to as the Orange Book for Opana ER. U.S. Patent No. 5,128,143 expired in September 2008, two patents expire in 2013 and one expires in 2023. They cover the formulation of Opana ER. 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, Actavis, Sandoz and Barr in connection with their respective ANDA's. We have agreed to settle our patent infringement litigation with Actavis. A description of the litigation and the Actavis settlement 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, the Food and Drug Administration Amendments Act of 2007, or FDAAA, granted significant new powers to the FDA, many of which are aimed at improving the safety of drug products before and after approval. In particular, FDAAA 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 FDAAA, companies that violate these and other provisions of the law are subject to substantial civil monetary penalties, as well as other civil and criminal 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" and "bioequivalent" to a drug which the FDA has previously approved as safe and effective.

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 and proposed labeling, 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, it will issue a "complete response" letter, which outlines the deficiencies in the NDA and, when possible, recommends actions that the applicant might take to place the application in condition for approval. Such actions may include, among other things, conducting additional safety or efficacy studies after which the sponsor may resubmit the application for further review. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

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 or, in some cases, a "section viii" statement. 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 may 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 the notice of the Paragraph IV 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 pre-clinical and clinical safety and effectiveness data. Instead, they must submit studies showing that the product is bioequivalent to the already approved drug (although, in some cases, even the submission of bioequivalence data may be waived). Drugs are bioequivalent if the rate and extent of absorption of the proposed generic 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 ANDA. 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 the notice of the Paragraph IV 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, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a product for this type of disease or condition will be recovered from sales in the United States for the product. 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 or obtain approval for the same product but for a different indication 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. Opana ER may also be subject to competition from generic versions of the product, such as the generic versions being developed by IMPAX, Actavis, Sandoz and Barr. We are also aware of tamper resistant formulations of oxycodone and morphine that have been submitted to the FDA for review and approval, which, if approved, would compete with Opana ER.

We believe A0001 and the Edison drug candidate we may acquire in the future may face competition from products that are under development by other companies for the same indications, such as Santhera and Sirtris, which was acquired by GlaxoSmithKline. Santhera's molecule, idebenone, is in active clinical development for the diseases of Friedreich's Ataxia, Duchennes muscular dystrophy, and Leber's Hereditary Optic Neuropathy. Santhera recently received regulatory approval in Canada for idebenone to be sold as a treatment for Friedreich's Ataxia under the brand name Catena®. GlaxoSmithKline, through its acquisition of Sirtris, is planning to study Sirtris' drug candidate resveratrol in MELAS.

We are seeking to enter into drug delivery technology collaborations. In seeking these collaborations, we are competing on the basis of our drug delivery technologies and drug formulation expertise with other companies that offer drug delivery technologies and formulation services, and the in-house drug delivery technologies and formulation expertise of our potential collaborators.

Employees

As of March 10, 2009, we employed approximately 48 people, of whom 34 were primarily involved in research and development activities, and 14 were primarily involved in selling, general and administrative

activities. As of March 10, 2009, 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 a history of net losses and may not be able to achieve or maintain profitability on an annual basis

We have incurred net losses since 1994, including net losses of $26.7 million, $34.5 million and $31.3 million during 2008, 2007 and 2006, respectively. As of December 31, 2008, our accumulated deficit was approximately $234 million.

We anticipate that, based upon our current operating plan, which contemplates a significant reduction in our operating expenses, and expected royalties from third parties, we will achieve quarterly profitability in the fourth quarter of 2009. If we do not receive royalties from Endo for Opana ER in such amounts as forecasted and provided to us by Endo, or if we are unable to significantly reduce our operating expenses, we may not be able to achieve quarterly profitability in the fourth quarter of 2009. However, even if we are able to achieve profitability on a quarterly basis, we may not be able to maintain it, or we may not be able to achieve profitability on an annual basis.

Developing drug candidates to treat rare disorders of the nervous system will require us to incur substantial costs and expenses associated with clinical trials, regulatory approvals and commercialization. For instance, if we determine to advance A0001 into later stage clinical trials in 2010, such costs and expenses are likely to increase. As a result, we may continue to incur net losses until such time as we can generate significant revenue from Opana ER or other products that we develop. 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 numerous factors, including:

- the commercial success of Opana ER, and the amount of royalties from Endo's sales of Opana ER, which may be adversely affected by any potential generic competition;
- our ability to successfully defend our intellectual property protecting our products;
- our ability to access funding support for development programs from third party collaborators;
- the level of our investment in research and development activities, including the timing and costs of conducting clinical trials of our products;
- the level of our general and administrative expenses;
- the successful development and commercialization of product candidates in our portfolio; and
- royalties from Mylan's sales of Pfizer's generic version of Procardia XL 30 mg.

We may require additional funding which may be difficult to obtain

As of December 31, 2008, we had cash, cash equivalents and marketable securities of approximately $16.7 million. We anticipate that, based upon our current operating plan, our existing capital resources, together with expected royalties from third parties, will be sufficient to fund our operations on an ongoing basis through at least the first half of 2010. If we do not receive royalties from Endo for Opana ER in such amounts as we anticipate, we may not be able to fund our ongoing operations through the first half of 2010 without seeking additional funding from the capital markets.

We have taken measures to reduce our spending and to manage our costs more closely, including staff reductions that we implemented in January 2009 and establishing a narrowed set of priorities for 2009, which recognize our limited financial resources and the challenging environment in which we operate. We are also seeking to enter into collaboration and licensing agreements for the development and marketing of Opana ER in territories outside the United States and for nalbuphine ER, and to enter into drug delivery technology collaborations. These collaborations may provide additional funding for our operations.

Requirements for capital in our business may be substantial. Our potential need to seek additional funding will depend on many factors, including:

- the commercial success of Opana ER, and the amount of royalties from Endo's sales of Opana ER, which may be adversely affected by any potential generic competition;
- the prosecution, defense and enforcement of our patents and other intellectual property rights, such as our Orange Book listed patents for Opana ER;
- the timing and amount of payments received under collaborative agreements including our agreement with Mylan with respect to Pfizer's generic version of Procardia XL 30 mg;
- 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 any development projects we may undertake and funding obligations with respect to these projects;
- our ability to enter into collaborations for Opana ER outside the United States, our drug delivery technologies and nalbuphine ER, and the structure and terms of any such agreements;
- our ability to access funding support for development programs from third party collaborators;
- the level of our investment in capital expenditures for facilities and equipment; and
- our success in reducing our spending and managing our costs.

Under the current economic environment, market conditions have made it very difficult for companies like ours to obtain equity or debt financing. We believe that any such financing that we could obtain would be on significantly unfavorable terms. 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 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. If we seek but are unable to obtain additional financing, we may be required to delay, reduce the scope of, or eliminate our planned development activities, including our planned clinical trials, which could harm our 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 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, Actavis and Sandoz have each filed an ANDA that, together with their respective amendments, cover all seven strengths of Opana ER. Barr has also filed an ANDA that covers the Opana ER 5 mg, 10 mg, 20 mg and 40 mg strengths. We and Endo have filed patent infringement lawsuits against each of IMPAX , Sandoz and Barr in connection with their respective ANDAs and have settled our litigation with Actavis. Descriptions of these lawsuits are included in "Part I. Item 3. — Legal Proceedings."

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 against IMPAX's ANDA , Actavis' ANDA, Sandoz's ANDA and Barr's ANDA. IMPAX has announced that it is seeking to reinstate an earlier filing date of its ANDA covering Opana ER 5 mg, 10 mg, 20 mg and 40 mg. If this occurs or if we and Endo are unsuccessful in our Hatch-Waxman patent lawsuits, Opana ER could be subject to generic competition as early as June 2009 when the new dosage form exclusivity expires. We expect that competition from one or more of these generic companies could cause significant erosion to the pricing of Opana ER, which in turn would adversely affect the royalties that we 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, or our collaborator's ability, to protect our patents and other intellectual property rights

Our success depends in significant part on our ability, or our collaborator's ability, to obtain patent protection for our products, both in the United States and in other countries, or on our collaborator's ability to obtain patents with respect to products on which we are collaborating with them. Our success also depends on our and our collaborator's 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, the earliest of which patents expired in September 2008 and the other of which patents expire in 2013, 2013 and 2023, respectively. As the owner of the patents listed in the Orange Book for Opana ER, we have become a party to ongoing Hatch-Waxman patent litigation. We and Endo filed patent infringement suits against IMPAX, Sandoz and Barr in connection with their respective ANDAs for Opana ER and settled our litigation with Actavis. We believe that we are entitled to the "30-month stay" available under the Hatch-Waxman Act against each of IMPAX, Actavis, Sandoz and Barr because we initiated the suit within 45 days of our receipt of their respective notice letters. However, IMPAX has publicly disclosed that it is seeking to reinstate an earlier filing date of its ANDA covering Opana ER 5 mg, 10 mg, 20 mg and 40 mg. If IMPAX is successful, we will not be entitled to the 30-month stay against IMPAX in these four strengths. 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 the 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 expect that generic competition would adversely affect the pricing of Opana ER, the royalties that we receive from Endo and the 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 version of 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, which 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, which we subsequently resolved. 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. Under our collaboration with Edison, we are responsible for pharmaceutical and clinical development, seeking regulatory approvals, manufacturing, and marketing of the products. Accordingly, we will have to continue to develop our own capabilities in these areas, or seek a collaborator.

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.

Misuse and/or abuse of Opana ER , which contains a narcotic ingredient, could subject us to additional regulations, including compliance with risk management programs, which may prove difficult or expensive for us 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 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 protection. 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.

Opana ER faces competition from products with the same indications. 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 versions being developed by IMPAX, Actavis, Sandoz and Barr. We are also aware of tamper resistant formulations of oxycodone and morphine that have been submitted to the FDA for review and approval, which, if approved, would compete with Opana ER.

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 currently conducting clinical trials of the coenzyme Q analog, idebenone for the diseases of Friedreich's Ataxia, Duchenne's muscular dystrophy, and Leber's Hereditary Optic Neuropathy. Santhera recently received regulatory approval in Canada for idebenone to be sold as a treatment for Friedreich's Ataxia under the brand name Catena®. GlaxoSmithKline plc., through its acquisition of Sirtris is planning to study Sirtris' drug candidate resveratrol for MELAS. If these companies are able to receive regulatory approvals for their products before we do, it may negatively impact our ability to receive regulatory approvals for our products if these products have orphan drug exclusivity or to achieve market acceptance of our products. If their products are more effective, safer or more affordable, our products may not be competitive.

Our drug delivery technologies and our efforts to enter into drug delivery technology collaborations, 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.

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 such as A0001

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 may 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, PW2101, 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 may develop will be in the early stages of development. There will be 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 Institutional Review Board or the FDA may suspend clinical trials at any time if the healthy subjects or patients participating in such trials are being exposed to unacceptable health risks or for other reasons. In the third quarter of 2008, we terminated the development of PW4153 after the results of a Phase I study did not meet our target profile.

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. In the United States, orphan drug designation is generally for drugs intended to treat a disease or condition that affects fewer than 200,000 or more than 200,000 individuals and for which there is no reasonable expectation that the cost of developing and making available in the

United States a product for this type of disease or condition will be recovered from sales in the United States for the product. In the European Union, orphan drug designation is for drugs intended to treat diseases affecting fewer than five in 10,000 individuals.

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 product candidate that we develop, 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, 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.

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 on commercially acceptable terms, or at all.

The cost of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. We could incur significant costs in participating or assisting in the litigation. In the case of the generic litigation involving Opana ER, our collaborator Endo is bearing all litigation costs. However, on other products we develop, we may be required to incur these costs to defend our patents. 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 Specialty Pharmaceuticals Inc. 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 primary product liability insurance in the 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 amounts of $5 million per occurrence and $5 million annually in the aggregate. 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 $5.41 per share and $0.37 per share, respectively, for the twelve months ended December 31, 2008. On March 10, 2009, the closing market price of our common stock was $1.46. The market is currently experiencing and 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, Articles of Incorporation and Bylaws and the laws of Washington State make a takeover of Penwest or a change in control or management of our Company 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 Articles 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. We may in the future adopt measures that may have the effect of deterring hostile takeovers or delaying or preventing changes in control or management of our company.

Proxy contests pursued by dissident shareholders may be costly and disruptive to our business operations

Campaigns by significant investors to effect changes at publicly traded companies have increased in recent years. Perceptive Life Sciences Master Fund Ltd., or Perceptive, and Tang Capital Partners, LP, or Tang, which currently beneficially own in excess of 40% of our outstanding common stock, in the aggregate, have sent a letter to our Nominating and Governance Committee for the purpose of nominating their own slate of directors for election at the 2009 annual meeting of shareholders. They have also issued a letter indicating that they plan to propose for a vote by our shareholders at the 2009 annual meeting a referendum on our strategy and certain amendments to our bylaws and threatening to sue our board of directors and officers.

If a proxy contest is pursued by Perceptive and Tang, or any other shareholder, it could result in substantial expense to us and consume significant attention of our management and Board of Directors. Moreover, if the proxy contest is intended to effect changes in our management and strategic direction, it could disrupt our operations and our ability to achieve our strategic goals by creating uncertainty for our employees and current and prospective suppliers, manufacturers and collaborators.

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 a research facility, 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. We lease this facility under a lease that expires on December 31, 2009.

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

ITEM 3. *LEGAL PROCEEDINGS*

Item 1. *Legal Proceedings*

Impax ANDA Litigation

On October 3, 2007, we received a letter from IMPAX notifying us of the filing by IMPAX 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 our 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, we received a letter from IMPAX notifying us of additional Paragraph IV certifications relating to our 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 us filed a lawsuit against IMPAX in the U.S. District Court of Delaware, or U.S. Dist. Delaware. The lawsuit against IMPAX not only alleged infringement of U.S. Patent Nos. 5,662,933 and 5,958,456 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 states that IMPAX's ANDA contains 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 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, we 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. We and Endo did not dismiss the patent infringement claims 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 U.S. Patent Nos. 5,662,933 and 5,958,456 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.

On June 14, 2008, we and Endo each received a notice from IMPAX advising us and Endo that IMPAX had amended its ANDA for Opana ER to include three additional strengths, 7.5 mg, 15 mg and 30 mg. This ANDA amendment contained a Paragraph IV certification against our Orange Book listed patents, U.S. Patent Nos. 5,662,933, 5,958,456 and 7,276,250. On July 25, 2008, we and Endo filed a lawsuit against IMPAX in U.S. Dist. Delaware, alleging infringement of U.S. Patent Nos. 5,662,933 and 5,958,456 in response to the notice. We believe that we are entitled to a 30-month stay under the Hatch-Waxman Act beginning on June 14, 2008 with respect to IMPAX's amended ANDA for 7.5 mg, 15 mg and 30 mg.

In January 2009, the cases against IMPAX were reassigned to the U.S. District Court of New Jersey, or U.S. Dist. NJ.

Actavis ANDA Litigation.

On February 14, 2008, we 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 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. On March 28, 2008, we and Endo and filed a lawsuit against Actavis in the U.S. Dist. NJ, alleging infringement of U.S. Patent No. 5,958,456. On June 2, 2008, we and Endo each received a notice from Actavis advising us and Endo that Actavis had amended its ANDA for Opana ER to include two additional strengths, 7.5 mg and 15 mg. On July 2, 2008, we and Endo each received a third notice from Actavis advising that Actavis had further amended its ANDA to include the 30 mg strength. Each ANDA amendment contained a Paragraph IV certification against our Orange Book listed patents, U.S. Patent Nos. 5,128,143, 5,662,933, 5,958,456 and 7,276,250. On July 11, 2008, we and Endo filed a lawsuit against Actavis in the U.S. Dist. NJ alleging infringement of U.S. Patent No. 5,958,456 based on these two additional Paragraph IV certification notices from Actavis. We believe we are entitled to a 30-month stay with respect to Actavis' ANDA covering Opana ER 5 mg, 10 mg, 20 mg and 40 mg beginning February 14, 2008, with respect to Actavis' amended ANDA covering Opana ER 7.5 mg and 15 mg beginning June 2, 2008 and against its amended ANDA covering Opana ER 30 mg beginning July 2, 2008.

On February 20, 2009, we and Endo settled all of the Actavis litigation. Both sides agreed to dismiss their respective claims and counterclaims with prejudice. Under the terms of the settlement, Actavis agreed not to challenge the validity or enforceability of our four Orange Book-listed patents. We and Endo agreed to grant Actavis a license under US Patent No. 5,958,456 and a covenant not to sue for its generic formulation of Opana ER under our four Orange Book-listed patents. The license and covenant not to sue will take effect on July 15, 2011, and earlier under certain circumstances.

The settlement is subject to the review of the U.S. Federal Trade Commission and Department of Justice.

Sandoz ANDA Litigation.

On July 10, 2008, we and Endo each received a notice from Sandoz advising us and Endo that Sandoz had filed with the FDA an ANDA for Opana ER in four strengths, 5 mg, 10 mg, 20 mg and 40 mg. This ANDA contained a Paragraph IV certification against our Orange Book listed patents, U.S. Patent Nos. 5,662,933, 5,958,456 and 7,276,250. On August 22, 2008, we and Endo filed a lawsuit against Sandoz in the U.S. Dist. Delaware, alleging infringement of U.S. Patent No. 5,958,456 in response to this notice. In January 2009, the cases against Sandoz were reassigned to the U.S. Dist. NJ.

Barr ANDA Litigation.

On September 12, 2008, we and Endo each received a notice from Barr advising us and Endo that Barr had filed with the FDA an ANDA for Opana ER in 40 mg. On September 13, 2008, we and Endo received an additional notice that Barr's ANDA was amended to include the strengths of 5 mg, 10 mg and 20 mg. Barr's ANDA as amended contained a Paragraph IV certification against our Orange Book listed patents, U.S. Patent Nos. 5,662,933, 5,958,456 and 7,276,250. On October 20, 2008, we and Endo filed a lawsuit against Barr in the U.S. Dist. Delaware, alleging infringement of U.S. Patent Nos. 5,662,933 and 5,958,456. In January 2009, the cases against Barr were reassigned to the U.S. Dist. NJ.

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 as of March 12, 2009.

Name	Age	Title	Dates
Jennifer L. Good	44	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.	54	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.	55	Senior Vice President, Pharmaceutical Development	2007 — current
		President, A. Hawi Consulting Ltd.	2002 — 2007
Paul F. Hayes	53	Vice President, Strategic Marketing	2005 — current
		Senior Director, Marketing, Oscient Pharmaceuticals	2002 — 2005
		Deputy Director, Marketing, Bayer Healthcare Pharmaceuticals	1999 — 2002
Frank P. Muscolo	52	Controller and Chief Accounting Officer	2007 — current
		Controller	1997 — 2007
Thomas Sciascia, M.D.	55	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 2008 and 2007 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 2008		
Quarter Ended March 31	$ 6.02	$ 2.40
Quarter Ended June 30	$ 3.72	$ 2.56
Quarter Ended September 30	$ 4.22	$ 1.60
Quarter Ended December 31	$ 2.11	$ 0.34
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

On March 10, 2009, we had 616 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 GE Business Financial Services Inc.

ITEM 6. *SELECTED FINANCIAL DATA*

The following selected financial data are derived from our 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,				
	2008	2007	2006	2005	2004
	(In thousands, except for per share data)				
STATEMENT OF OPERATIONS DATA:					
Revenues	$ 8,534	$ 3,308	$ 3,499	$ 6,213	$ 5,108
Cost of revenues	1,438	605	231	39	104
Selling, general and administrative	12,052	14,260	14,075	13,247	9,485
Research and product development	21,041	23,561	22,857	17,797	20,205
Investment income	541	1,770	2,352	1,974	906
Interest expense	(1,278)	(1,117)	—	—	—
Net loss	$(26,734)	$(34,465)	$(31,312)	$(22,898)	$(23,785)
Basic and diluted net loss per share	$ (0.89)	$ (1.48)	$ (1.38)	$ (1.05)	$ (1.28)
Weighted average shares of common stock outstanding — basic and diluted	29,923	23,216	22,751	21,711	18,627

	December 31,				
	2008	2007	2006	2005	2004
			(In thousands)		
BALANCE SHEET DATA:					
Cash and cash equivalents	$ 16,692	$ 15,680	$ 16,182	$ 15,917	$ 14,249
Marketable securities	—	7,293	24,408	39,377	60,121
Working capital	14,792	17,891	38,254	53,912	71,946
Total assets	31,854	36,982	52,742	67,021	87,522
Long term obligations-deferred compensation	2,384	2,588	2,763	2,977	3,314
Long term debt	4,112	9,595	—	—	—
Accumulated deficit	(233,627)	(206,893)	(172,428)	(141,116)	(118,218)
Shareholders' equity	$ 15,926	$ 16,237	$ 45,121	$ 60,411	$ 78,801

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

Overview

We are a drug development company focused on identifying and developing products that address unmet medical needs, primarily for rare disorders of the nervous system. We are currently developing A0001, a coenzyme Q analog drug candidate that we licensed from Edison, for inherited mitochondrial respiratory chain diseases. We also are applying our drug delivery technologies and drug formulation expertise to the formulation of product candidates under licensing collaborations, which we refer to as drug delivery technology collaborations.

Opana® ER is an extended release formulation of oxymorphone hydrochloride that we developed with Endo using our proprietary TIMERx® drug delivery technology. Opana ER was approved by the FDA in June 2006 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. In 2008, we recognized $5.0 million in royalties from Endo related to sales of Opana ER. We are currently seeking to license Opana ER for development and commercialization outside the United States. Under our agreement with Endo, we and Endo share the rights to Opana ER outside the United States, and any economics from a related collaboration with a third party, equally.

We are currently developing A0001, a product candidate that will be initially targeted for the treatment of inherited mitochondrial respiratory chain diseases, under a collaboration and license agreement with Edison that we entered into in July 2007. We are currently conducting a Phase Ib multiple ascending dose safety study of A0001 in healthy volunteers. If A0001 demonstrates an acceptable safety profile and tolerability in this Phase Ib study, we plan to commence a Phase IIa trial in patients with inherited mitochondrial respiratory chain diseases in the second half of 2009. The goal of this trial will be to determine if A0001 has biological activity. Under the Edison agreement, we have agreed to collaborate with Edison on the development of A0001 and up to one additional drug candidate of Edison's.

We are party to a number of collaborations involving the use of our extended release drug delivery technologies as well as our formulation development expertise. Under these collaborations, we are responsible for completing the formulation work on a product specified by our collaborator. If we are successful in-vitro, we transfer the formulation to our collaborator, who is then responsible for the completion of the clinical development, and ultimately, the commercialization of the product. Under the terms of these agreements, we generally receive up-front fees, reimbursement of research and development costs, and potential milestone and royalty payments. We are seeking to enter into additional drug delivery technology collaborations.

Endo. Under the terms of our collaboration with Endo, Endo pays us royalties based on U.S. net sales of Opana ER. No payments were due to us for the first $41 million of royalties otherwise payable to us beginning from the time of the product launch in July 2006, a period we refer to as the royalty holiday. In the third quarter of 2008, the royalty holiday ended and we began earning royalties from Endo on sales of Opana ER. Endo has the right under our agreement to recoup the $28 million in development costs that Endo funded on our behalf prior to the approval of Opana ER through a temporary 50% reduction in royalties. The royalty amount we recognized in 2008 reflects this temporary reduction. As of December 31, 2008, $5.0 million of the $28 million has been recouped by Endo.

Under the terms of our agreement with Endo, any fees, royalties, payments or other revenues received by the parties in connection with any collaborator outside the United States will be divided equally between Endo and us. We and Endo are currently seeking a collaborator to develop and commercialize Opana ER in territories outside the United States. A description of our agreement with Endo is included under the caption "Collaborative and Licensing Agreements" in "Part I. Item 1. Business".

We and Endo entered into a Second Amendment to the Amended and Restated Strategic Alliance Agreement with respect to Opana ER, in July 2008. Under the terms of this amendment, Endo agreed to directly reimburse us for costs and expenses incurred by us in connection with patent enforcement litigation related to Opana ER. If any of such costs and expenses are not reimbursed to us by Endo, we may bill Endo

for these costs and expenses through adjustments to the pricing of TIMERx material that we supply to Endo for use in Opana ER. In connection with the amendment, in July 2008, Endo reimbursed us for such costs and expenses incurred prior to June 30, 2008, totaling approximately $470,000. We credited this reimbursement to selling, general and administrative expense in the third quarter of 2008. Our costs incurred subsequent to June 30, 2008 were not significant and have been reimbursed to us by Endo.

Edison. Under the terms of the Edison agreement, we have exclusive, worldwide rights to develop and commercialize A0001 and up to one additional compound of Edison's, which we may exercise our option to select, for all indications, subject to the terms and conditions in the agreement. Edison has not yet presented us with the additional compound for selection under the agreement. In connection with the dosing in the Phase Ia trial noted above, we made a milestone payment to Edison in August 2008. A description of the Edison agreement is included under the caption "Collaborative and Licensing Agreements" in "Part I. Item 1. Business."

Mylan. Under a collaboration agreement with Mylan, we developed Nifedipine XL, a generic version of Procardia XL, based on our TIMERx technology that was approved by the FDA. In March 2000, Mylan 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.

Net loss and profitability. We have incurred net losses since 1994 including net losses of $26.7 million, $34.5 million and $31.3 million during 2008, 2007 and 2006, respectively. As of December 31, 2008, our accumulated deficit was approximately $234 million. We currently generate revenues primarily from royalties received from Endo on Endo's net sales of Opana ER and from Mylan on Mylan's net sales of Pfizer's generic version of Procardia XL 30 mg and, to a lesser extent, from bulk sales of TIMERx to Endo for use in Opana ER. We anticipate that, based upon our current operating plan, which contemplates a significant reduction in our operating expenses, and expected royalties from third parties, we will achieve quarterly profitability in the fourth quarter of 2009. If we do not receive royalties from Endo for Opana ER in such amounts as forecasted and provided to us by Endo, or if we are unable to significantly reduce our operating expenses, we may not be able to achieve quarterly profitability in the fourth quarter of 2009. Our future profitability will depend on numerous factors, including:

- the commercial success of Opana ER, and the amount of royalties from Endo's sales of Opana ER, which may be adversely affected by any potential generic competition;
- our ability to successfully defend our intellectual property protecting our products;
- our ability to access funding support for our development programs from third party collaborators;
- the level of our investment in research and development activities, including the timing and costs of conducting clinical trials of our products;
- the level of our general and administrative expenses;
- the successful development and commercialization of product candidates in our portfolio; and
- royalties from Mylan's sales of Pfizer's generic version of Procardia XL 30 mg.

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, 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 — We recognize revenue from royalties based on our collaborators' sales of products using our technologies, or their sales of other products as contractually provided for, as is the case with Mylan. We recognize royalties as earned in accordance with contract terms when royalties from collaborators can be reasonably estimated and collectability is reasonably assured.

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 revenues.

Collaborative licensing and development revenue — We recognize revenue from reimbursements received in connection with our drug delivery technology collaborations as related research and development costs are incurred, and our contractual services are performed, provided collectability is reasonably assured. We include such revenue in collaborative licensing and development revenue in our statements of operations. Amounts contractually owed to us under these collaboration agreements, including any earned but unbilled receivables, are included in trade accounts receivable in our balance sheets. Our principal costs under these agreements, which are generally reimbursed to us as provided by these agreements, include our personnel conducting research and development and our allocated overhead, as well as research and development performed by outside contractors or consultants.

We recognize revenues from non-refundable up-front fees received under collaboration agreements ratably over the performance period as determined under the related collaboration agreement. If the estimated performance period is subsequently modified, we will modify the period over which the up-front fee is recognized accordingly on a prospective basis. Upon termination of a collaboration agreement, any remaining non-refundable licensing fees we had received, which we deferred, are generally recognized in full. We include all such recognized revenues in collaborative licensing and development revenue in our statements of operations.

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 collectability 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.

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, preclinical 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. In such cases, we may be required to make estimates 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

We establish valuation allowances against our 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, 2008, we had recorded full valuation allowances totaling approximately $40.6 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

We account for our share-based compensation using SFAS 123R, "Share-Based Payment," or SFAS 123R. SFAS 123R requires us to recognize in expense all share-based payments granted to employees and directors, including grants of stock options and grants under compensatory employee stock purchase plans, in our statement of operations based on their fair values as they are earned by the employees and directors under the vesting terms. For the year ended December 31, 2008, we recorded approximately $3.1 million of expense associated with share-based payments, primarily comprised of approximately $2.2 million attributable to employee and director stock options, and approximately $791,000 attributable to restricted stock awards. As of December 31, 2008, there was approximately $1.6 million and $422,000 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 0.9 years and 2.2 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 granted, we use 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. We use an 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, 2008, 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.

As required under SFAS 123R, we 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 prior to vesting (such as by employee separation) and ultimately record stock option expense for the fair values of awards that actually vest.

Recent Accounting Pronouncements

In February 2007, the Financial Accounting Standards Board or FASB, issued Statement of Financial Accounting Standards or SFAS, No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities — Including an amendment of FASB Statement No. 115" or 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, we adopted the provisions of SFAS 159 as of January 1, 2008. We chose not to elect the fair value option to measure its financial assets and liabilities existing at January 1, 2008 that had not been previously carried at fair value, or of financial assets and liabilities it transacted in the year ended December 31, 2008. Therefore, the adoption of SFAS No. 159 had no effect on our financial statements. We continue to carry its marketable securities at fair value in accordance with SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities", as amended.

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements" or 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. Our adoption of the provisions of SFAS No. 157 as of January 1, 2008 did not have a material effect on our results of operations, financial position or cash flows.

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 are 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, we adopted the provisions of EITF No. 07-3 as of January 1, 2008. EITF No. 07-3 is applied prospectively for new contracts entered into on or after the effective date. Our adoption of this pronouncement did not have a material effect on our results of operations, financial position or cash flows.

In December 2007, the EITF reached a consensus on Issue No. 07-1, "Accounting for Collaborative Arrangements" or 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. 07-1 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. We plan to adopt the provisions of EITF No. 07-1 as of January 1, 2009 and we do not expect the adoption to have a material effect on our results of operations, financial position or cash flows.

In April 2008, the FASB issued FSP No. SFAS 142-3, "Determination of the Useful Life of Intangible Assets" or SFAS 142-3. In determining the useful life of intangible assets, SFAS 142-3 removes the requirement to consider whether an intangible asset can be renewed without substantial cost or material modifications to the existing terms and conditions and, instead, requires an entity to consider its own historical experience in renewing similar arrangements. SFAS 142-3 also requires expanded disclosure related to the determination of intangible asset useful lives. SFAS 142-3 is effective for financial statements issued for fiscal years beginning after December 15, 2008. We are currently evaluating the effect, if any, the adoption of SFAS 142-3 will have on our results of operations, financial position or cash flows.

In June 2008, the EITF reached a consensus Issue No. 07-5, "Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock or EITF No. 07-5. EITF No. 07-5 was issued to clarify how to determine whether certain instruments or features are indexed to an entity's own stock under EITF Issue No. 01-6, "The Meaning of Indexed to a Company's Own Stock" or EITF No. 01-6. The consensus in EITF No. 07-5 applies to any freestanding financial instrument or embedded feature that has the characteristics of a derivative as defined in FSP No. SFAS 133, "Accounting for Derivative Instruments and Hedging Activities" or SFAS 133. The consensus in EITF No. 07-5 supersedes EITF No. 01-6 and is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. We are currently evaluating the effect, if any, the adoption of EITF No. 07-5 will have on our results of operations, financial position or cash flows.

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.

Changes in Presentation

The changes in presentation described below were made to more closely align the presentation of our operating results with our peers.

Effective with our year-end reporting for 2008, we reclassified our licensing revenue from what was previously presented in royalties and licensing fees, and our research and development reimbursements revenue to their current presentation as collaborative licensing and development revenue in our statements of operations. The reclassification of licensing fees totaled $210,000, $60,000 and $14,000 for 2008, 2007 and 2006, respectively. The reclassifications of research and development reimbursements revenue totaled $834,000, $176,000 and $0 for 2008, 2007 and 2006, respectively. Total revenue was not impacted by this change in presentation.

Effective with our year-end reporting for 2008, we present our cost of revenues on a single line item within the operating expense section in our statements of operations. This change in presentation had no impact on our loss from operations; however, total operating expenses as presented increased by $1,438,000, $605,000 and $231,000 for 2008, 2007 and 2006, respectively, as a result of our including cost of revenues in operating expenses.

Results of Operations for Years Ended December 31, 2008, 2007 and 2006

Revenues

	2008	Percentage Increase (Decrease) from 2007	2007	Percentage Increase (Decrease) from 2006	2006
	(In thousands, except percentages)				
Royalties	$6,805	167%	$2,553	(18)%	$3,104
Product Sales	685	32	519	36	381
Collaborative Licensing and Development Revenue	1,044	342	236	1586	14
Total Revenues	$8,534	158%	$3,308	(5)%	$3,499

Royalties increased in 2008 because beginning in the third quarter of 2008, we began to recognize royalties from Endo on their net sales of Opana ER, following completion of the royalty holiday. For 2008, we recognized $5.0 million of royalties from Endo. All of our royalty revenues for 2007 and 2006 were generated from royalties received from Mylan. Royalties from Mylan decreased in 2008 as compared to 2007, and in 2007 as compared to 2006, 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 Mylan from 2007 to 2008 and from 2006 to 2007 were primarily due to increased generic competition which contributed toward lower pricing overall. In addition, we believe the decrease in royalties from 2006 to 2007 was due in part to two of Mylan's customers purchasing significantly less product in 2007 as compared to 2006.

Product sales in 2008, 2007 and 2006 consisted of sales of formulated TIMERx material, primarily to Endo. Product sales increased in 2008 in comparison with 2007 as a result of an increase in the selling price of TIMERx material to Endo, which increase was in effect for the first half of 2008, as provided for under our agreement with Endo. In connection with the amendment to the Endo agreement we entered into with Endo in July 2008, we reduced the selling price of TIMERx material to Endo in the second half of 2008 to approximately the levels which were in effect for 2007. Partially offsetting the increased revenue resulting from the higher selling prices in the first half of 2008, was a decrease in the volume of TIMERx material sold to Endo in 2008 as compared to 2007. We expect the average selling price of TIMERx material in 2009 to approximate pricing levels in effect in the second half of 2008 and in 2007, and the volume of TIMERx material to be sold to Endo to increase in 2009 as compared to 2008.

Revenue from collaborative licensing and development consists of reimbursements of our expenses under our drug delivery technology collaborations and the recognition of revenue relating to upfront payments from these collaborations. The increase in revenue from 2007 to 2008 and from 2006 to 2007 was due to the increased level of development activity resulting from the execution of one such collaboration agreement in 2007 and two such collaboration agreements in 2008.

Cost of Revenues

	2008	Percentage Increase (Decrease) from 2007	2007	Percentage Increase (Decrease) from 2006	2006
	(In thousands, except percentages)				
Cost of Royalties	$ 214	398%	$ 43	—%	$ 43
Cost of Product Sales	305	(23)	395	110	188
Cost of Collaborative Licensing and Development Revenue	919	450	167	n/a	—
Total Cost of Revenues	$1,438	138%	$605	162%	$231

Cost of royalties consists of the amortization of deferred royalty termination costs associated with the Baichwal and Staniforth royalty termination agreements discussed below, and the amortization of certain patent costs associated with our TIMERx technology. The cost of royalties increased from 2007 to 2008 primarily as a result of increased amortization of the deferred royalty termination costs as a result of increased royalty revenues recognized in 2008.

Cost of product sales consists of the costs related to sales of formulated TIMERx material, primarily to Endo. Cost of product sales decreased from 2007 to 2008 primarily as a result of a decrease in the volume of TIMERx material sold to Endo in 2008 for use in Opana ER. The cost of product sales increased from 2006 to 2007 primarily as a result of increased shipments of TIMERx product to Endo in 2008 for use in Opana ER.

Cost of collaborative licensing and development revenue consists of our expenses under our drug delivery technology collaborations. These costs increased from 2007 to 2008 and from 2006 to 2007 due to the increased level of development activity resulting from the execution of the collaboration agreements.

Selling, General and Administrative Expenses

	2008	Percentage Increase (Decrease) from 2007	2007	Percentage Increase (Decrease) from 2006	2006
	(In thousands, except percentages)				
Selling, General and Administrative Expenses	$12,052	(15)%	$14,260	1%	$14,075

Selling, general and administrative, or SG&A, expenses for 2008 decreased as compared to 2007 primarily due to lower share-based compensation expense, legal expense, facility related costs and lower business insurance costs. The lower share-based compensation expense is primarily attributable to lower average fair values associated with outstanding stock options and restricted stock in 2008 as compared to 2007, primarily as a result of decreases in the market price of our common stock. The decrease in legal fees was primarily attributable to a credit we recorded in 2008 for the reimbursement of legal expenses by Endo pursuant to the amendment we entered into with Endo in July 2008 and the direct payment of costs relating to the Opana ER litigation by Endo in the second half of 2008. The decrease in our facility-related costs was primarily attributable to our efforts in 2007 to explore alternative locations for our facilities. In June 2007, we terminated these efforts and extended the lease terms of our two facilities. These decreased expenses were partially offset by an impairment charge we recorded in the first quarter of 2008 in the amount of $1.0 million

to establish a reserve against the collectability of the loan that we made to Edison in February 2008 under the Edison agreement.

SG&A expenses 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.

In January 2009, we announced staff reductions of approximately 18% of our workforce as part of our efforts to aggressively manage our overhead cost structure. In connection with these staff reductions, we expect to record a severance charge in our statement of operations in the first quarter of 2009 in the amount of approximately $550,000, primarily to SG&A expense. In addition, as a result of these terminations, in the first quarter of 2009, we expect to record a non-cash credit of approximately $885,000, primarily to SG&A expense, under SFAS No. 123R associated with the forfeiture of stock options held by these former employees. As a result of these staff reductions as well as other efforts to closely manage our cost structure, we expect that SG&A expense will decline in 2009 as compared to 2008.

Research and Product Development Expenses

Research and product development, or R&D, expenses were $21.0 million for 2008, a decrease of $2.5 million as compared to $23.5 million for 2007. This decrease was primarily due to lower expenses related to the development of nalbuphine ER, reflecting the expenses incurred in 2007 for the Phase IIa proof of concept trial of nalbuphine ER that we completed in January 2008, lower costs associated with the development of other early stage product candidates, lower expenses due to staff reductions implemented in March 2008 and allocations of internal R&D costs related to our drug delivery technology collaborations, as noted above, to cost of collaborative licensing and development. Partially offsetting these lower expenses were increased expenses related to preclinical and clinical work we conducted on A0001, and increased contractual payments to Edison under the terms of the Edison agreement.

R&D 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.

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

	2008	Percentage Increase (Decrease) from 2007	2007	Percentage Increase (Decrease) from 2006	2006
	(In thousands, except percentages)				
A0001 and Edison Payments	$ 7,403	95%	$ 3,797	n/a	$ —
Nalbuphine ER	2,238	(66)	6,618	57%	4,211
PW4153	882	385	182	n/a	—
Other Phase I Products and Internal Costs	10,518	(19)	12,964	(30)	18,646
Total Research and Product Development Expense	$21,041	11%	$23,561	3%	$22,857

- *A0001 and Edison Payments* — These expenses reflect our funding of Edison's research activities under the Edison agreement as well as our direct external expenses relating to the development of A0001. These expenses approximated 35% of our R&D expenses for 2008 and included quarterly research and development payments to Edison totaling $3.5 million in 2008, a milestone payment made to Edison in 2008 for the commencement of dosing in a Phase Ia clinical trial of A0001, and costs related to preclinical studies and the Phase Ia study of A0001 we conducted in 2008. As of December 31, 2008,

we have incurred $11.2 million in total expenses for the A0001 program and for contract research payments to Edison. Of this amount, approximately $5.4 million consisted of the quarterly contract research payments to Edison. In May 2008, we submitted an IND for A0001 for certain indications. In July 2008, we initiated a Phase Ia placebo-controlled, single ascending dose trial designed to evaluate the safety and tolerability of A0001 in healthy subjects, and to collect pharmacokinetic data.

In February 2009, we initiated a Phase Ib multiple ascending dose clinical study in healthy volunteers. The study is a single-blind, placebo-controlled, multiple ascending dose clinical trial in healthy subjects, designed to assess the safety, tolerability and pharmacokinetics of A0001 following repeat dosing in healthy male and female subjects. We expect that results from this study will be available in the second quarter of 2009. If A0001 demonstrates an acceptable safety profile and tolerability in this Phase Ib study, we plan to commence a Phase IIa trial in patients with inherited mitochondrial respiratory chain diseases in the second half of 2009. We are currently working on the study design for the Phase IIa program. In parallel with the Phase Ib trial, we have initiated long-term animal toxicology studies to support the clinical program. We expect our A0001 costs to decline in 2008 as the quarterly contract research payments to Edison were substantially complete by the end of 2008. We cannot reasonably estimate or know the nature, timing and estimated costs of the efforts necessary to complete the development of A0001 due to the numerous risks and uncertainties associated with developing and commercializing drugs.

- *Nalbuphine ER* — These expenses reflect our direct external expenses relating to the development of nalbuphine ER. These expenses approximated 11% of our R&D expenses for 2008 and consisted primarily of payments to third parties in connection with clinical trials of nalbuphine ER. The expenses for this program decreased in 2008 as compared to 2007, as 2007 included costs we incurred in connection with a Phase I safety trial that we completed in 2007, a Phase IIa trial that we completed in January 2008 and costs for the purchase of drug active. In 2006, we advanced nalbuphine ER from Phase I through Phase IIa clinical trials and completed additional preparation for further clinical trials in 2007. We determined in 2008 to seek a collaborator for the further development and commercialization of nalbuphine ER, and not to conduct any additional development work until we enter into such a collaboration.

- *PW4153* — These expenses reflect our direct external expenses relating to the development of PW4153. These expenses approximated 4% of our R&D expenses for 2008 and consisted primarily of payments to third parties in connection with clinical trials and other development work. In July 2008, we conducted a Phase I clinical trial for PW4153 to assess the pharmacokinetics of our formulation in healthy volunteers. Based on the results of this study, we determined to terminate this development program. We do not anticipate any significant additional costs for this program in the future.

- *Other Phase I Products 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 related to preclinical studies, proof-of-principle biostudies conducted on our Phase I product candidates and payments to third parties for drug active.

  These costs decreased in 2008 from 2007 primarily as a result of the termination of certain programs in 2007, the termination of our program for PW4110 in the first quarter of 2008, lower expenses due to staff reductions implemented in March 2008 and allocations of internal costs related to our drug delivery technology collaborations to cost of collaborative licensing and development revenues. We evaluate product candidates on an on-going basis 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.

As discussed above, our development efforts in 2009 will focus on advancing the development of A0001. In addition, in January 2009, we announced staff reductions of approximately 18% of our workforce as part of our efforts to aggressively manage our overhead cost structure. As a result of these measures, the staff reduction we implemented in March 2008 as noted above, as well as other efforts to closely manage our cost structure, we expect R&D expense to decline significantly in 2009 as compared to 2008.

Tax Rates

The effective tax rates for 2008, 2007 and 2006 were zero. The effective tax rates differ from the federal statutory rate of a 35% benefit for 2008, and a 34% benefit for 2007 and 2006 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 Endo, Mylan and other collaborators, and advances under credit facilities. As of December 31, 2008, we had cash, cash equivalents and short-term investments of $16.7 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 received net proceeds of approximately $23.1 million from this private placement, after deducting the placement agent's fees and other 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 filed a registration statement with the Securities and Exchange Commission, or SEC, on April 10, 2008, registering for resale the shares sold in the private placement and the shares issuable under the warrants. This registration statement was declared effective by the SEC on April 28, 2008. We have agreed to use our reasonable best efforts to maintain the registration statement's effectiveness until the earlier of (i) the later of (a) March 11, 2009, 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., which was acquired by GE Capital in February 2008, and is now known as GE 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 had the right to access until September 15, 2008, subject to conditions specified in the credit agreement. We did not access the second $12.0 million term loan prior to September 15, 2008, at which time it expired in accordance with the terms of the agreement.

Our outstanding term loan has a term of 42 months from the date of advance, with interest-only payments for the first nine months; 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, through its maturity date in September 2010.

The interest rate on our outstanding term loan is fixed at 10.32%. At the time of final payment of the loan, 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 1.0% of any prepaid amount thereafter. As of December 31, 2008, $9.6 million of the term loan was outstanding. Beginning January 2008, we began making monthly principal payments on this loan, in addition to the monthly interest payments. Beginning January 2009, the principal portion of our payments increased from their 2008 level to reflect the straight line amortization of the remaining principal amount outstanding, as noted above. These principal payments are expected to total approximately $5.5 million for 2009. Under the terms of the credit facility, the loan amount is required to be fully paid by September 2010.

Cash Flows

In 2008, we had negative cash flow from operations of $26.0 million, primarily due to our net loss of $26.7 million for the year, which included non-cash charges of $3.1 million for share-based compensation, $1.4 million for depreciation and amortization, $1.0 million for the establishment of a loan reserve for the Edison loan discussed below and $702,000 of patent impairment charges. In addition, cash flow from operating activities reflected increased receivables of $4.1 million as of December 31, 2008 as compared to December 31, 2007, primarily due to the recognition of royalties from Endo in the fourth quarter of 2008.

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 share-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 share-based compensation.

In 2008, net cash provided by investing activities was $6.2 million primarily reflecting maturities of marketable securities, net of purchases, of $7.3 million. This was partially offset by the $1.0 million loan to Edison discussed below. Net cash provided by investing activities also reflected funds expended to secure patents on technology we have developed of $349,000 and proceeds from the sale of equipment of $318,000. In 2007, net cash provided by investing activities totaled $16.1 million, primarily reflecting maturities of marketable securities, net of purchases, 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 paid directly to Mr. Hamachek.

Financing activities in 2008 provided $20.8 million in cash, primarily from the private placement discussed above, partially offset by repayments of principal on our outstanding term loan described above. 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, financing activities provided $10.8 million in cash, substantially all due to net cash proceeds from stock option exercises.

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 on 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. During the first quarter of 2008, we recorded an impairment charge of $1.0 million to selling, general and administrative expense as a result of our collectability assessment of the loan to Edison. In addition, as a result of our continuing collectability assessment, we are not recognizing any accrued interest income on the loan to Edison. The amount of such accrued interest income not recognized by us was approximately $76,000 for 2008.

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. In 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. In 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.

Funding Requirements

We anticipate that, based upon our current operating plan, our existing capital resources, together with expected royalties from third parties, will be sufficient to fund our operations on an ongoing basis through at least the first half of 2010. If, however, we do not receive royalties from Endo for Opana ER in such amounts as we anticipate, we may not be able to fund our ongoing operations through at least the first half of 2010, without seeking additional funding from the capital markets.

We have taken measures to reduce our spending and to manage our costs more closely, including the staff reductions that we implemented in January 2009 as described above, and establishing a narrowed set of priorities for 2009, which recognize our limited financial resources and the challenging environment in which we operate. We are also seeking to enter into collaboration and licensing agreements for the development and marketing of Opana ER in territories outside the United States and for nalbuphine ER, and to enter into drug delivery technology collaborations. These collaborations may provide additional funding for our operations.

We expect our capital expenditures in 2009 to not exceed approximately $250,000.

Requirements for capital in our business are substantial. Our potential need to seek additional funding will depend on many factors, including:

- the commercial success of Opana ER, and the amount of royalties from Endo's sales of Opana ER, which may be adversely affected by any potential generic entry;
- the timing and amount of payments received under collaborative agreements, including our agreement with Mylan with respect to Pfizer's generic version of Procardia XL 30 mg;
- the timing and amount of our internal costs of development for drug candidates for which we acquire rights under the Edison agreement;
- the progress of our development projects, funding obligations with respect to the projects and the related costs to us of clinical studies for our product candidates;
- our ability to enter into collaborations for Opana ER outside the United States, nalbuphine ER and our drug delivery technologies, and the structure and terms of any such agreements;
- the prosecution, defense and enforcement of our patents and other intellectual property rights, such as our Orange Book listed patents for Opana ER;
- 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 accelerate the development of any of our own product candidates, we will need to seek additional funding through collaborative agreements, the selling of assets, or public financings of equity or debt securities.

We plan to meet our long-term cash requirements through our existing levels of cash and marketable securities, and revenues from collaborative agreements, as well as through equity or debt financings. On September 26, 2008, we filed a registration statement on Form S-3 with the SEC, which became effective on October 30, 2008. 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. No securities have been issued under this shelf registration statement. This shelf registration statement is a replacement of the registration statement filed in July 2005 that was to expire in December 2008.

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 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.

We cannot be certain that additional financing will be available in amounts or on terms acceptable to us, if at all. Under the current economic environment, market conditions have made it very difficult for companies like ours to obtain equity or debt financing. We believe that any such financing that we could conduct would be on significantly unfavorable terms. If we seek but 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 financial condition and operating results.

Contractual Obligations

Our outstanding contractual cash obligations include obligations under our operating leases primarily for our facilities in Danbury, CT and Patterson, NY, purchase obligations primarily relating to preclinical and 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, 2008 (in thousands):

	Total	Less than One Year	1-3 Years	4-5 Years	After 5 Years
Operating leases	$ 617	$ 617	$ —	$ —	$ —
Purchase obligations	3,432	3,432	—	—	—
Deferred compensation, including current portion	2,675	294	587	587	1,207
Payments due under credit facility	10,875	6,224	4,651	—	—
Edison agreement	125	125	—	—	—
Total	$17,724	$10,692	$5,238	$587	$1,207

We lease approximately 15,500 square feet of office, and research and development space in Patterson, New York. In June 2007, we signed an 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 us. In January 2009, we exercised the 10 month renewal option through December 31, 2009. The additional commitment under this lease, which is not included in the table above totals $207,000.

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, 2008, trust assets consisted of the cash surrender value of these life insurance policies totaling $1.9 million and $299,000 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 January of 2009, we announced staff reductions as part of our plan to aggressively manage our overhead cost structure. In connection with these staff reductions, total termination costs of approximately

$550,000 are expected to be paid out by the end of 2009. These additional obligations are not included in the contractual obligations table above.

Net Operating Loss Carryforwards

In 2008, we determined that an ownership change had occurred under Section 382 of the Internal Revenue Code. The utilization of our net operating loss, or NOL, carryforwards and other tax attributes through the date of ownership change will be limited to approximately $2.8 million per year over the next 20 years into 2028. We also determined that we were in a Net Unrealized Built-In Gain position (for purposes of Section 382) at the time of the ownership change, which increases its annual limitation over the next five years into 2013 by approximately $3.4 million per year. Accordingly, we have reduced our NOL carryforwards, and research and development tax credits to the amount that we estimate that we will be able to utilize in the future, if profitable, considering the above limitations. In accordance with FAS 109, "Accounting for Income Taxes," we have provided a valuation allowance for the full amount of our net deferred tax assets because it is not more likely than not that we will realize future benefits associated with deductible temporary differences and NOLs at December 31, 2008 and 2007.

At December 31, 2008, we had federal NOL carryforwards of approximately $91.3 million for income tax purposes, which expire at various dates beginning in 2018 through 2028. At December 31, 2008, we had state NOL carryforwards of approximately $90.4 million which expire at various dates beginning in 2023 through 2028. In addition, we had federal research and development tax credit carryforwards of approximately $485,000 which expire in 2028. The NOL's incurred subsequent to the 2008 ownership change of $18.8 million are not limited on an annual basis. Pursuant to Section 382, subsequent ownership changes could further limit this amount. The use of the NOL carryforwards, and research and development tax credit carryforwards are limited to our future taxable earnings.

For financial reporting purposes, at December 31, 2008 and 2007, respectively, valuation allowances of $40.6 million and $72.6 million have been recognized to offset net deferred tax assets, primarily attributable to our NOL carryforwards. As previously noted, in 2008, we reduced our tax attributes (NOL's and tax credits) as a result of our ownership change under Section 382 and the limitation placed on the utilization of our tax attributes, as a substantial portion of the NOL's and tax credits generated prior to the ownership change will likely expire unused. Accordingly, the NOL's were reduced by $123.3 million and the tax credits were reduced by $6.6 million upon the ownership change in 2008. The changes in the valuation allowance for the years ended December 31, 2008, 2007 and 2006 were a decrease of approximately $32.0 million due primarily to the limitations placed on the utilization of our tax attributes as noted above, and an increase of $9.9 million and $14.3 million, respectively.

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, 2008, we had no marketable securities. Due to the nature of our cash equivalents which are money market accounts at December 31, 2008, management believes there is no significant market risk. As of December 31, 2008, we had approximately $16.7 million in cash and cash equivalents, 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 $167,000.

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, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2008. 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, 2008, our chief executive 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, 2008 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 officer 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, 2008. 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, 2008, 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, 2008, 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, 2008, 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 December 31, 2008 and 2007, and the related statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2008 of Penwest Pharmaceuticals Co. and our report dated March 12, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Stamford, CT
March 12, 2009

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 2009 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 2009 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 2009 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 2009 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 2009 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, 2008 and 2007 and the related statements of operations, cash flows and shareholders' equity for each of the three years in the period ended December 31, 2008.

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, 2009

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 and principal financial officer)	Date: March 12, 2009
/s/ Frank P. Muscolo Frank P. Muscolo	Controller and Chief Accounting Officer (principal accounting officer)	Date: March 12, 2009
/s/ Paul E. Freiman Paul E. Freiman	Chairman of the Board	Date: March 12, 2009
/s/ Christophe Bianchi Christophe Bianchi, M.D.	Director	Date: March 12, 2009
/s/ Peter F. Drake Peter F. Drake, Ph.D.	Director	Date: March 12, 2009
/s/ Robert J. Hennessey Robert J. Hennessey	Director	Date: March 12, 2009
/s/ David P. Meeker David P. Meeker, M.D.	Director	Date: March 12, 2009
/s/ William J. O'Shea William J. O'Shea	Director	Date: March 12, 2009
/s/ John N. Staniforth John N. Staniforth, Ph.D.	Director	Date: March 12, 2009
/s/ Anne M. VanLent Anne M. VanLent	Director	Date: March 12, 2009

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, 2008 and 2007, and the related statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2008. Our audits also included the financial statement schedule listed in the index at Item 15(a). These financial statements and the 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, 2008 and 2007, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2008, 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 Note 16 to the financial statements, the Company adopted the provisions of the Financial Accounting Standards Board's 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), Penwest Pharmaceuticals Co.'s internal control over financial reporting as of December 31, 2008, 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, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Stamford, CT
March 12, 2009

PENWEST PHARMACEUTICALS CO.

BALANCE SHEETS

	December 31, 2008	December 31, 2007
	(In thousands, except share amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 16,692	$ 15,680
Marketable securities	—	7,293
Trade accounts receivable	4,894	781
Inventories	440	667
Prepaid expenses and other current assets	1,365	1,489
Total current assets	23,391	25,910
Fixed assets, net	2,177	3,582
Patents, net	1,819	2,539
Deferred charges	2,244	2,479
Other assets	2,223	2,472
Total assets	$ 31,854	$ 36,982
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 745	$ 2,239
Accrued expenses	1,695	1,602
Accrued development costs	385	1,483
Loan payable — current portion	5,483	2,405
Deferred compensation — current portion	291	290
Total current liabilities	8,599	8,019
Loan payable	4,112	9,595
Accrued financing fee	360	360
Deferred revenue	473	183
Deferred compensation	2,384	2,588
Total liabilities	15,928	20,745
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 31,697,250 shares at December 31, 2008 and 23,426,323 shares at December 31, 2007	32	23
Additional paid in capital	249,262	222,927
Accumulated deficit	(233,627)	(206,893)
Accumulated other comprehensive income	259	180
Total shareholders' equity	15,926	16,237
Total liabilities and shareholders' equity	$ 31,854	$ 36,982

See accompanying notes

PENWEST PHARMACEUTICALS CO.

STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2008	2007	2006
	(In thousands, except per share data)		
Revenues:			
Royalties	$ 6,805	$ 2,553	$ 3,104
Product sales	685	519	381
Collaborative licensing and development revenue	1,044	236	14
Total revenues	8,534	3,308	3,499
Operating expenses:			
Cost of revenues	1,438	605	231
Selling, general and administrative	12,052	14,260	14,075
Research and product development	21,041	23,561	22,857
Total operating expenses	34,531	38,426	37,163
Loss from operations	(25,997)	(35,118)	(33,664)
Investment income	541	1,770	2,352
Interest expense	(1,278)	(1,117)	—
Loss before income tax expense	(26,734)	(34,465)	(31,312)
Income tax expense	—	—	—
Net loss	$(26,734)	$(34,465)	$(31,312)
Basic and diluted net loss per common share	$ (0.89)	$ (1.48)	$ (1.38)
Weighted average shares of common stock outstanding — basic and diluted	29,923	23,216	22,751

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, 2005	21,890	$22	$201,659	$(141,116)	$(154)	$ 60,411
Net loss	—	—	—	(31,312)	—	(31,312)
Decrease 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)
Decrease in unrealized 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
Net loss	—	—	—	(26,734)	—	(26,734)
Decrease in unrealized gain on marketable securities	—	—	—	—	(7)	(7)
Adjustment for funded status of post retirement plan	—	—	—	—	86	86
Comprehensive loss	—	—	—	—		(26,655)
Proceeds from Employee Stock Purchase Plan exercises	41	—	70	—	—	70
Stock compensation charges in connection with stock incentive plans	89	—	3,125	—	—	3,125
Issuance of common stock pursuant to an equity financing, net	8,141	9	23,140	—	—	23,149
Balances, December 31, 2008	31,697	$32	$249,262	$(233,627)	$ 259	$ 15,926

See accompanying notes

PENWEST PHARMACEUTICALS CO.

STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2008	2007	2006
		(In thousands)	
Operating activities:			
Net loss	$(26,734)	$(34,465)	$(31,312)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	989	1,107	1,001
Amortization of patents	367	379	565
Inventory reserves	18	18	—
Patent impairment losses	702	584	254
Loss on disposal of fixed assets	209	—	—
Note receivable reserve	1,000	—	—
Deferred revenue	290	140	(14)
Deferred compensation	177	182	190
Deferred royalty termination costs amortization (paid)	101	(1,541)	—
Share-based compensation	3,125	3,792	4,978
Changes in operating assets and liabilities:			
Trade accounts receivable	(4,113)	(98)	259
Inventories	209	(483)	(61)
Accounts payable, accrued expenses and other	(2,298)	752	497
Net cash used in operating activities	(25,958)	(29,633)	(23,643)
Investing activities:			
Acquisitions of fixed assets, net	(112)	(918)	(1,818)
Proceeds from sale of fixed assets	318	—	—
Patent costs	(349)	(319)	(619)
Purchases of marketable securities	(7,859)	(24,605)	(27,739)
Proceeds from maturities of marketable securities	15,157	41,950	41,248
Proceeds from sales of marketable securities	—	—	1,600
Proceeds from cash surrender value of life insurance policy withdrawal	—	—	446
Loan disbursed to collaborator	(1,000)	—	—
Net cash provided by investing activities	6,155	16,108	13,118
Financing activities:			
Issuance of common stock, net	23,220	1,135	10,790
Proceeds from loan payable	—	12,000	—
Repayment of debt	(2,405)	—	—
Debt issuance costs	—	(112)	—
Net cash provided by financing activities	20,815	13,023	10,790
Net increase (decrease) in cash and cash equivalents	1,012	(502)	265
Cash and cash equivalents at beginning of year	15,680	16,182	15,917
Cash and cash equivalents at end of year	$ 16,692	$ 15,680	$ 16,182

See accompanying notes

1. BUSINESS

Penwest Pharmaceuticals Co. ("Penwest" or the "Company") is a drug development company focused on identifying and developing products that address unmet medical needs, primarily for rare disorders of the nervous system. The Company is currently developing A0001, a coenzyme Q analog drug candidate that it licensed from Edison Pharmaceuticals Inc. ("Edison") for inherited mitochondrial respiratory chain diseases. The Company is also applying its drug delivery technologies and drug formulation expertise to the formulation of product candidates under licensing collaborations ("drug delivery technology collaborations.")

Opana® ER is an extended release formulation of oxymorphone hydrochloride that the Company developed with Endo Pharmaceuticals Inc. ("Endo") using the Company's proprietary TIMERx® drug delivery technology. Opana ER was approved by the United States Food and Drug Administration ("FDA") in June 2006 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. In 2008, the Company recognized $5.0 million in royalties from Endo related to sales of Opana ER.

The Company is currently developing A0001, a product candidate that will be initially targeted for the treatment of inherited mitochondrial respiratory chain diseases, under a collaboration and license agreement with Edison that the Company entered into in July 2007 (the "Edison Agreement"). The Company is currently conducting a Phase Ib multiple ascending dose safety study in healthy volunteers. If A0001 demonstrates an acceptable safety profile and tolerability in this Phase Ib study, we plan to commence a Phase IIa trial in patients with inherited mitochondrial respiratory chain diseases in the second half of 2009. The goal of this trial will be to determine if A0001 has biological activity. Under the Edison Agreement, the Company has agreed to collaborate with Edison on the development of A0001 and up to one additional drug candidate of Edison's.

The Company is a party to a number of collaborations involving the use of its extended release drug delivery technologies as well as its formulation development expertise. Under these collaborations, the Company is responsible for completing the formulation work on a product specified by our collaborator. If the Company is successful in-vitro, the formulation is transferred to its collaborator, who is responsible for the completion of the clinical development, and ultimately, the commercialization of the product. Under the terms of these agreements, the Company generally receives up-front fees, reimbursement of research and development costs, and potential milestone and royalty payments. The Company is seeking to enter into additional drug delivery technology collaborations.

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. The changes in presentation described below were made to more closely align the presentation of the Company's operating results with its peers.

Effective with its year-end reporting for 2008, the Company reclassified its licensing revenue from what was previously presented in royalties and licensing fees, and its research and development reimbursements revenue to their current presentation as collaborative licensing and development revenue in its statements of operations. The reclassification of licensing fees totaled $210,000, $60,000 and $14,000 for 2008, 2007 and 2006, respectively. The reclassification of research and development reimbursements revenue totaled $834,000,

$176,000 and $0 for 2008, 2007 and 2006, respectively. Total revenue was not impacted by this change in presentation.

Effective with its year-end reporting for 2008, the Company presents its cost of revenues on a single line item within the operating expense section in its statements of operations. This change in presentation had no impact on the Company's loss from operations; however, total operating expenses as presented increased by $1,438,000, $605,000 and $231,000 for 2008, 2007 and 2006, respectively, as a result of the inclusion of cost of revenues in operating expenses.

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 historically have consisted 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, 2008 and 2007, no allowances for doubtful accounts were recorded by the Company on its trade accounts receivable. One customer of the Company, Mylan Pharmaceuticals Inc. ("Mylan") accounted for approximately 21%, 77% and 89% of the Company's total revenues in 2008, 2007 and 2006, respectively. Another customer of the Company, Endo, accounted for approximately 67% and 15% of the Company's total revenues for 2008 and 2007, respectively.

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

The carrying value of financial instruments at December 31, 2008, which includes cash, cash equivalents, receivables and accounts payable approximates fair value due to the short term nature of these instruments. The carrying value of the Company's loan payable approximates fair value and is estimated based on the market price of similar debt instruments.

Inventories

Inventories, which consist primarily of manufactured bulk TIMERx, 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 2008, 2007 or 2006.

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, 2008.

Accumulated Other Comprehensive Income (Loss)

Accumulated other comprehensive income (loss) at December 31, 2008, 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 the FASB Statements No. 87, 88, 106 and 132(R)" (see Note 16), and unrealized gains and 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 2008, 2007 and 2006, 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"), which clarifies the accounting for uncertain income tax positions. 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. The determination of which tax positions are more likely than not sustainable requires the Company to use judgments and estimates, which may or may not be borne out by actual results.

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, 2008, 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 — The Company recognizes revenue from royalties based on its collaborators' sales of products using its technologies, or their sales of other products as contractually provided for, as is the case with Mylan. Royalties are recognized as earned in accordance with contract terms when royalties from collaborators can be reasonably estimated and collectability is reasonably assured.

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 revenues.

Collaborative licensing and development revenue — The Company recognizes revenue from reimbursements received in connection with its drug delivery technology collaborations 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 collaborative licensing and development revenue in the Company's statements of operations. Amounts contractually owed to the Company under these 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, which are generally reimbursed to the Company, include its personnel conducting research and development, and its allocated overhead, as well as research and development performed by outside contractors or consultants.

The Company recognizes revenues from non-refundable up-front fees received under collaboration agreements ratably over the performance period as determined under the related collaboration agreement. If the estimated performance period is subsequently modified, the Company will modify the period over which the up-front fee is recognized accordingly on a prospective basis. Non-refundable milestones 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. All such recognized revenues are included in collaborative licensing and development revenue in the Company's statements of operations.

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.

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, preclinical 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, or may be performed by the Company's collaborators. In such cases, the Company may be required to make estimates of related service fees or of the Company's 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.

These estimates involve identifying services which have been performed on the Company's behalf, and estimating the level of service performed and associated cost incurred for such service as of each balance sheet date in the Company's financial statements. In connection with such service fees, the Company's estimates are most affected by its 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 the Company's judgment. The Company makes these judgments based upon the facts and circumstances known to it in accordance with generally accepted accounting principles.

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 2008, 2007 and 2006 as the effects would be antidilutive. Such securities, excluded due to their antidilutive effect, are as follows:

	December 31,		
	2008	2007	2006
	(In thousands of shares)		
Stock options outstanding	2,514	2,411	2,267
Restricted stock outstanding (unvested)	134	142	52
Warrants to purchase common stock	4,070	—	—
	6,718	2,553	2,319

Share-Based Compensation

The Company accounts for its share-based compensation using SFAS No. 123R, "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. The Company uses an 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 its 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 on January 1, 2006 were applied to stock options that the Company granted subsequent to its adoption of SFAS 123R; however, stock option expense recorded in 2008, 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.

As required under SFAS 123R, the Company 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 prior to vesting, (such as by employee separation) and ultimately records stock option expense for the fair values of awards that actually vest.

3. RECENT ACCOUNTING PRONOUNCEMENTS

In February 2007, the FASB issued Statement of Financial Accounting Standards ("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 adopted the provisions of SFAS 159 as of January 1, 2008. The Company chose not to elect the fair value option to measure its financial assets and liabilities existing at January 1, 2008 that had not been previously carried at fair value, or of financial assets and liabilities it transacted in the year ended December 31, 2008. Therefore, the adoption of SFAS No. 159 had no effect on the Company's financial statements. The Company continues to carry its marketable securities at fair value in

accordance with SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities," as amended.

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's adoption of the provisions of SFAS No. 157 as of January 1, 2008 did not 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 is 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 adopted the provisions of EITF No. 07-3 as of January 1, 2008. EITF No. 07-3 is applied prospectively for new contracts entered into on or after the effective date. The Company's adoption of this pronouncement did not have a material effect on its results of operations, financial position or cash flows.

In December 2007, the EITF 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. 07-1 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 plans to adopt the provisions of EITF No. 07-1 as of January 1, 2009 and does not expect the adoption to have a material effect on its results of operations, financial position or cash flows.

In April 2008, the FASB issued FSP No. SFAS 142-3, "Determination of the Useful Life of Intangible Assets" ("SFAS 142-3"). In determining the useful life of intangible assets, SFAS 142-3 removes the requirement to consider whether an intangible asset can be renewed without substantial cost or material modifications to the existing terms and conditions and, instead, requires an entity to consider its own historical experience in renewing similar arrangements. SFAS 142-3 also requires expanded disclosure related to the determination of intangible asset useful lives. SFAS 142-3 is effective for financial statements issued for fiscal

years beginning after December 15, 2008. The Company is currently evaluating the effect, if any, the adoption of SFAS 142-3 will have on its results of operations, financial position or cash flows.

In June 2008, the EITF reached a consensus Issue No. 07-5, "Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock ("EITF No. 07-5"). EITF No. 07-5 was issued to clarify how to determine whether certain instruments or features are indexed to an entity's own stock under EITF Issue No. 01-6, "The Meaning of Indexed to a Company's Own Stock" ("EITF No. 01-6"). The consensus in EITF No. 07-5 applies to any freestanding financial instrument or embedded feature that has the characteristics of a derivative as defined in FSP No. SFAS 133, "Accounting for Derivative Instruments and Hedging Activities" ("SFAS 133"). The consensus in EITF No. 07-5 supersedes EITF No. 01-6 and is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. The Company is currently evaluating the effect, if any, the adoption of EITF No. 07-5 will have on its results of operations, financial position or cash flows.

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

As of December 31, 2008, the Company had no marketable securities.

The amortized costs and estimated fair values of marketable securities for 2007 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

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.

5. FAIR VALUE MEASUREMENT

As stated in Note 3, "Recent Accounting Pronouncements," on January 1, 2008, the Company adopted the methods of fair value as described in SFAS No. 157 to value its financial assets and liabilities. As defined in SFAS No. 157, fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, SFAS No. 157 establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value.

Financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2008 are classified in the table below in one of the three categories described above:

	Level 1	Level 2	Level 3	Total
		(In thousands)		
Cash and cash equivalents	$16,692	$ —	$ —	$16,692

The Company chose not to elect the fair value option as prescribed by SFAS No. 159 for its financial assets and liabilities that had not been previously carried at fair value.

6. OTHER ASSETS

Other assets are comprised of the following:

	December 31, 2008	December 31, 2007
	(In thousands)	
Assets held in a trust for the Company's Supplemental Executive Retirement Plan and Deferred Compensation Plan (see Note 16):		
Cash surrender value of life insurance policies	$ 1,924	$2,468
Money market account	299	4
	2,223	2,472
Loan receivable from collaborator (see Note 17)	1,000	—
	3,223	2,472
Allowance for loan receivable from collaborator	(1,000)	—
Other assets, net	$ 2,223	$2,472

7. INVENTORIES

Inventories are summarized as follows:

	December 31,	
	2008	2007
	(In thousands)	
Raw materials	$ —	$ 37
Finished products	440	630
Total inventories	$440	$667

Inventories primarily consist of bulk TIMERx product. Inventories at December 31, 2008 and 2007 are net of allowances of $36,000 and $18,000, respectively.

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.

8. FIXED ASSETS

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

	December 31,	
	2008	2007
	(In thousands)	
Equipment and leasehold improvements	$5,707	$6,777
Software	2,425	2,442
Projects in progress	—	25
	8,132	9,244
Less: accumulated depreciation and amortization	5,955	5,662
	$2,177	$3,582

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 2008, 2007 or 2006. The Company includes software development costs within equipment and software, and generally amortizes the software development costs over a period of five years, once a working model is completed. Amortization expense related to software development costs totaled $168,000, $324,000 and $323,000 for 2008, 2007 and 2006, respectively. Unamortized software development costs totaled $15,000, $183,000 and $507,000 as of December 31, 2008, 2007 and 2006, respectively.

In 2008, the Company disposed of certain equipment, realized $318,000 in proceeds on the sale and recorded a loss on disposal totaling $209,000.

9. PATENTS

	December 31,	
	2008	2007
	(In thousands)	
Patents, net of accumulated amortization of $1,849 and $1,947, respectively:	$1,819	$2,539

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 generally from 17 to 20 years, unless a shorter amortization period is warranted. Amortization expense of approximately $367,000, $379,000 and $565,000 was recorded in the years ended December 31, 2008, 2007, and 2006, respectively.

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

Year	Amount (In thousands)
2009	$ 338
2010	327
2011	296
2012	249
2013	163
Thereafter	446
Total	$1,819

Patents are evaluated for potential impairment whenever events or circumstances indicate that the carry amount may not be recoverable. 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, 2008, 2007 and 2006, the Company recorded impairment losses of approximately $702,000, $584,000 and $254,000, respectively, relating to its patents. The impairment losses recorded in 2008, 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 Company's impairment losses in 2008 also included charges for existing and pending patents in certain geographic regions for which the Company determined further patent investment and maintenance is no longer warranted. Such impairment losses are reflected in research and product development expense in the statements of operations.

10. 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. which was acquired by GE Capital in February 2008 and is now known as GE 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 had the right to access until September 15, 2008, subject to conditions specified in the credit agreement. The Company did not access the second $12.0 million term loan prior to September 15, 2008, at which time it expired in accordance with the terms of the agreement.

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 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 16. In addition, the Company is precluded from paying cash dividends to its shareholders during the term of the Credit Facility. The outstanding term loan has a term of 42 months from the date of advance of March 13, 2007 with interest-only payments for the first nine months; 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 through its maturity date in September 2010.

The interest rate of the outstanding term loan is fixed at 10.32%. At the time of the final payment of the 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, 2008, principal payments due on the outstanding principal of $9.6 million under the Credit Facility are as follows:

	(In thousands)
Less than one year	$5,483
One to two years	4,112
	$9,595

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, 2008. 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 $1,144,000 and $905,000 of interest in 2008 and 2007, respectively.

11. SHAREHOLDERS' EQUITY

On September 26, 2008, the Company filed a registration statement on Form S-3 with the Securities and Exchange Commission (the "SEC"), which became effective on October 30, 2008. 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. The shelf registration statement is a replacement of the registration statement filed in July 2005 that was to expire in December 2008. As of March 10, 2009, no securities have been issued under the registration statement.

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 received net proceeds of approximately $23.1 million from this private placement, after deducting the placement agent's fees and other 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 under certain circumstances pursuant to cashless exercise provisions.

Pursuant to the securities purchase agreement entered into in connection with the private placement, the Company filed a registration statement with the SEC on April 10, 2008, registering for resale the shares sold in the private placement and the shares issuable under the warrants. The registration statement was declared effective by the SEC on April 28, 2008. The Company has agreed to use its reasonable best efforts to maintain the registration statement's effectiveness until the earlier of (i) the later of (a) March 11, 2009, 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.

Share-Based Compensation

The Company recognized share-based compensation in its statements of operations for 2008 and 2007 as follows:

	2008	2007
	(In thousands)	
Selling, general and administrative	$2,248	$3,194
Research and product development	877	598
Total	$3,125	$3,792

The decrease in total share-based compensation expense in 2008 as compared to 2007 is primarily attributable to lower average fair values associated with outstanding stock options and restricted stock in 2008 as compared to 2007, primarily as a result of decreases in the market price of the Company's common stock.

Penwest Stock Incentive Plans

As of December 31, 2008, 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. In 2008, amendments to the 2005 Plan were approved by the Company's Board of Directors on April 24, 2008 and by the Company's shareholders on June 11, 2008, which amendments among other things, increased the number of shares of common stock that may be issued pursuant to awards granted under the 2005 plan from 1,650,000 to 4,150,000. Stock option awards 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 generally 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 in November 2008, 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, 2011.

The following table presents a summary of the Company's stock option activity and related information for the year ended December 31, 2008:

	Shares	Weighted Average Exercise Price	Weighted-Average Remaining Contractual Terms in Years	Aggregate Intrinsic Value
Balance at December 31, 2007	2,410,960	$13.97		
Granted	496,990	$ 2.75		
Exercised	—	$ —		
Forfeited	(59,415)	$14.09		
Expired	(334,283)	$10.00		
Balance at December 31, 2008	2,514,252	$12.28	6.3	$ —
Options Exercisable	1,471,639	$14.27	4.8	$ —

The weighted average fair values of options granted during 2008, 2007 and 2006 were $1.79, $5.55 and $11.18 per share, respectively. There were no options exercised in 2008. The total intrinsic values of options exercised during 2007 and 2006 were approximately $247,000 and $14.8 million, respectively. The total fair value of options which vested during 2008, 2007 and 2006 were approximately $2.8 million, $2.8 million and $2.7 million, respectively. As of December 31, 2008, there was approximately $1.6 million of unrecognized compensation cost related to stock option awards that the Company expects to recognize as expense over a weighted average period of 0.9 years.

The fair values of each option grant in 2008, 2007 and 2006 were estimated using the Black-Scholes-Merton option pricing model with the following weighted average assumptions:

	2008	2007	2006
Expected dividend yield	None	None	None
Risk free interest rate	3.0%	4.7%	4.7%
Expected volatility	78%	56%	58%
Expected life of options	5.7 years	5.5 years	5.6 years

The following table presents a summary of restricted stock activity for 2008:

	Shares	Weighted-Average Grant-Date Fair Value	Aggregate Intrinsic Value
Restricted stock outstanding at December 31, 2007	142,000	$14.77	$827,860
Granted	48,000	$ 5.41	
Vested	(56,000)	$15.23	
Restricted stock outstanding at December 31, 2008	134,000	$11.22	$193,630

Total compensation cost recognized for restricted stock awards during 2008, 2007 and 2006 was approximately $791,000, $1.1 million and $771,000, respectively. The total fair value of restricted stock which vested during 2008, 2007 and 2006 was approximately $853,000, $655,000 and $452,000, respectively. As of December 31, 2008, there was approximately $422,000 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 2.2 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. As of December 31, 2008, there were 44,955 shares remaining and available for issuance under the Plan. There were 41,053 shares, 18,398 shares and 10,404 shares issued under the Plan during 2008, 2007 and 2006, respectively.

Rights Agreements

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. Under the terms of the Rights Agreement entered into by the Company, each Right entitled 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. On July 27, 2008, the Rights expired in accordance with the Rights Agreement.

On March 11, 2009, the Company's Board of Directors approved a new rights plan (see Note 19).

12. COST OF REVENUES

	2008	2007	2006
	(In thousands)		
Cost of royalties	$ 214	$ 43	$ 43
Cost of product sales	305	395	188
Cost of collaborative licensing and development revenue	919	167	—
Total cost of revenues	$1,438	$605	$231

Cost of royalties consists of the amortization of deferred royalty termination costs (see Note 15) and the amortization of certain patent costs associated with the Company's TIMERx technology. Cost of product sales consists of the costs related to sales of formulated TIMERx material to the Company's collaborators. Cost of collaborative licensing and development revenues consists of the Company's expenses under its research and development collaboration agreements involving the development of product candidates using the Company's TIMERx technology, and includes internal costs and outside contract services.

13. 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. In January 2009, the Company exercised the 10 month renewal option through 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 a total of $49,000 for 2009.

As of December 31, 2008, certain of the Company's property and equipment were leased under operating leases for up to one year. Rental expense under operating leases was $971,000, $931,000 and $873,000, for the years ended December 31, 2008, 2007 and 2006, respectively. Of such amounts, approximately $184,000, $195,000 and $171,000 in 2008, 2007 and 2006, 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, 2008 for noncancellable operating leases having initial lease terms of more than one year are as follows:

	Operating Leases
	(In thousands)
2009	$617
Thereafter	—
Total minimum lease payments	$617

As noted above, in January 2009, the Company extended the lease on its facility in Patterson, New York to December 31, 2009. The additional commitment under this lease, which is not included in the table above totals $207,000.

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. These arrangements may 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. The Company is also required to perform certain development activities under its drug delivery technology collaborations. As of December 31, 2008, the Company expects to incur approximately $3.4 million of future development costs related to its existing agreements, including both internal costs and outside contract services, relating to these development activities.

14. INCOME TAXES

There was no provision for income taxes for 2008, 2007 and 2006.

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

	2008	2007	2006
Statutory tax rate	(35)%	(34)%	(34)%
Valuation allowance	35	34	34
	—%	—%	—%

In 2008, the Company determined that an ownership change occurred under Section 382 of the Internal Revenue Code. The utilization of the Company's net operating loss ("NOL") carryforwards and other tax attributes through the date of ownership change will be limited to approximately $2.8 million per year over the next 20 years into 2028. The Company also determined that it was in a Net Unrealized Built-In Gain position (for purposes of Section 382) at the time of the ownership change, which increases its annual limitation over the next five years into 2013 by approximately $3.4 million per year. Accordingly, the Company has reduced

its NOL carryforwards, and research and development tax credits to the amount that the Company estimates that it will be able to utilize in the future, if profitable, considering the above limitations. In accordance with FAS 109, "Accounting for Income Taxes," the Company has provided a valuation allowance for the full amount of its net deferred tax assets because it is not more likely than not that the Company will realize future benefits associated with deductible temporary differences and NOLs at December 31, 2008 and 2007.

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

	2008	2007
	(In thousands)	
Deferred compensation and SERP liability	$ (1,145)	$ (1,190)
Deferred revenue	(184)	(71)
Share-based compensation	(3,442)	(2,782)
Tax credit carryforwards	(637)	(6,427)
Net operating loss carryforwards	(36,425)	(63,391)
Other	(129)	(359)
Total deferred tax assets	(41,962)	(74,220)
Depreciation and amortization	1,034	1,373
Other	305	257
Total deferred tax liabilities	1,339	1,630
Net deferred tax asset before valuation allowance	(40,623)	(72,590)
Valuation allowance	40,623	72,590
Net deferred tax liability	$ —	$ —

The Company made no income tax payments in 2008, 2007 and 2006.

At December 31, 2008, the Company had federal NOL carryforwards of approximately $91.3 million for income tax purposes, which expire at various dates beginning in 2018 through 2028. At December 31, 2008, the Company had state NOL carryforwards of approximately $90.4 million which expire at various dates beginning in 2023 through 2028. In addition, the Company had federal research and development tax credit carryforwards of approximately $485,000 which expire in 2028. The NOL's incurred subsequent to the 2008 ownership change of $18.8 million are not limited on an annual basis. Pursuant to Section 382, subsequent ownership changes could further limit this amount. 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 NOL carryforwards include approximately $5.2 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, 2008 and 2007, respectively, valuation allowances of $40.6 million and $72.6 million have been recognized to offset net deferred tax assets, primarily attributable to the Company's NOL carryforwards. As previously noted, in 2008, the Company reduced its tax attributes (NOL's and tax credits) as a result of the Company's ownership change under Section 382 and the limitation placed on the utilization of its tax attributes, as a substantial portion of the NOL's and tax credits generated prior to the ownership change will likely expire unused. Accordingly, the NOL's were reduced by

$123.3 million and the tax credits were reduced by $6.6 million upon the ownership change in 2008. The changes in the valuation allowance for the years ended December 31, 2008, 2007 and 2006 were a decrease of approximately $32.0 million due primarily to the limitations placed on the utilization of the Company's tax attributes as noted above, and an increase of $9.9 million and $14.3 million, respectively.

15. 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, in 2007, 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, in 2007, 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 in 2007 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, 2008 and 2007. Such amortization approximated $101,000 in 2008 and $17,000 in 2007, and is included in cost of revenues in the Company's statements of operations.

16. 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, at the discretion of the Company's Board of Directors, the Company may make quarterly employer matching contributions as defined in the Plan agreement, in an amount equal to 75% of each participant's pre-tax contributions to the Plan up to 6% of such participant's eligible compensation. 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, representing its employer matching contributions, was $250,000, $164,000 and $244,000 for 2008, 2007 and 2006, 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 2008, 2007, or 2006.

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. Tod R. Hamachek. For 2008, 2007 and 2006, the net expense for the SERP was $120,000, $120,000 and $122,000, 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 following disclosures summarize information relating to the Plan:

Change in benefit obligation:

	2008	2007
	(In thousands)	
Benefit obligation at beginning of period	$2,092	$2,187
Interest cost	119	118
Actuarial (gain) loss	(85)	(62)
Benefits paid	(151)	(151)
Benefit obligation at December 31,	$1,975	$2,092

Change in plan assets:

	2008	2007
	(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:

	2008	2007
	(In thousands)	
Current liabilities	$ (147)	$ (147)
Noncurrent liabilities	(1,828)	(1,945)
Net amount recognized at December 31, (included in deferred compensation)	$(1,975)	$(2,092)

Amounts recognized in accumulated other comprehensive income consist of:

	2008	2007
	(In thousands)	
Net gain	$(268)	$(184)
Prior service cost	9	11
Total	$(259)	$(173)

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

	2008	2007
	(In thousands)	
Projected benefit obligation	$1,975	$2,092
Accumulated benefit obligation	$1,975	$2,092
Plan assets at fair value	$ —	$ —

Components of net periodic benefit cost:

	2008	2007
	(In thousands)	
Interest cost	$119	$118
Amortization of prior service cost	1	2
Amortization of gains	—	—
Net periodic benefit cost	$120	$120

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 2009 is approximately $2,000.

Other changes in benefit obligations recognized in other comprehensive income:

	2008	2007
	(In thousands)	
Net gain	$(85)	$(62)
Amortization of prior service cost	(1)	(1)
Total recognized in other comprehensive income	$(86)	$(63)

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

	2008	2007
Discount rate	6.35%	5.90%
Rate of compensation increase	N/A	N/A

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

	2008	2007
Discount rate	5.90%	5.60%
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 2009. Effective February 14, 2005, Mr. Hamachek resigned from his positions as Chairman and Chief Executive Officer. 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):

2009	$151
2010	151
2011	151
2012	151
2013	151
Years 2014-2018	751

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 2008, 2007 and 2006. Under the DCP, the Company recognized interest expense of $59,000, $62,000 and $68,000 for 2008, 2007 and 2006, respectively. The liability for the DCP was approximately $700,000 and $786,000 as of December 31, 2008 and 2007, respectively, and is included in deferred compensation on the Company's balance sheets, including the current portion of approximately $144,000 at December 31, 2008. 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 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 six remaining annual installments (in thousands):

2009	$143
2010	143
2011	143
2012	143
2013	143
2014	143

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 $1,924,000 and $2,472,000 as of December 31, 2008 and 2007, respectively. Trust assets, including $299,000 and $4,000 held in a money market account at December 31, 2008 and 2007, 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 $631,000, $710,000 and $685,000 in 2008, 2007 and 2006, respectively.

17. COLLABORATIVE 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 or to perform research and development for collaborators utilizing the Company's drug delivery technology and formulation expertise.

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 and in July 2008, as described below.

Under the agreement, the Company agreed to supply bulk TIMERx material to Endo, the selling price of which is contractually determined and may be adjusted annually, 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. The Company is currently seeking licensing opportunities for Opana ER in territories outside the United States.

Under the terms of the agreement:

- Endo has agreed to 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 were 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"). In the third quarter of 2008, this Royalty Holiday ended. The Company recognized royalties from Endo related to sales of Opana ER in the amount of $5.0 million for 2008.
- The Company's share of the development costs for Opana ER that it opted out of funding in April 2003 totaled $28 million and will be recouped by Endo through a temporary 50% reduction in royalties. Commencing in the third quarter of 2008, the Company began to receive reduced royalty payments from Endo, with such temporary reductions to continue until the $28 million is fully recouped. As of December 31, 2008, $5.0 million of the $28 million has been recouped by Endo.
- 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 and Endo entered into a Second Amendment to the Amended and Restated Strategic Alliance Agreement with respect to Opana ER, effective July 14, 2008. Under the terms of this amendment, Endo agreed to directly reimburse the Company for costs and expenses incurred by the Company in connection with patent enforcement litigation related to Opana ER. If any of such costs and expenses are not reimbursed to the Company by Endo, the Company may bill Endo for these costs and expenses through adjustments to the pricing of TIMERx material that the Company supplies to Endo for use in Opana ER. In connection with the amendment, in July 2008, Endo reimbursed the Company for such costs and expenses incurred prior to June 30, 2008, totaling approximately $470,000. The Company credited such reimbursement to selling, general and administrative expense. Such costs incurred by the Company subsequent to June 30, 2008 were not significant and have been reimbursed to the Company by Endo.

Edison Pharmaceuticals, Inc.

On July 16, 2007, the Company entered into the Edison Agreement under which the Company and Edison agreed to collaborate on the development of Edison's lead drug candidate, A0001, and up to one additional candidate of Edison's. Under the terms of the Edison Agreement, the Company has exclusive worldwide rights to develop and commercialize A0001 and the additional compound of Edison's, which the Company may exercise its option to select, for all indications, subject to the terms and conditions in the Edison Agreement. The Company initially intends to develop A0001 for the treatment of inherited mitochondrial respiratory chain diseases. A0001 has been granted orphan drug designation by the FDA for treatment of inherited mitochondrial respiratory chain diseases.

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, and any other compound as to which the Company has exercised its option. In connection with the Company commencing dosing in July 2008 in a Phase Ia clinical trial of A0001, the Company made a milestone payment to Edison.

On February 5, 2008, the Company loaned Edison $1.0 million pursuant to the loan agreement provisions of the Edison Agreement. The loan bears interest at an annual rate 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 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. During the first quarter of 2008, the Company recorded an impairment charge of $1.0 million to selling, general and administrative expense as a result of its collectability assessment of the loan to Edison. In addition, as a result of the Company's continuing collectability assessment, the Company is not recognizing any accrued interest income on the loan to Edison. The amount of such accrued interest income not recognized by the Company approximated $76,000 for the full year ended December 31, 2008.

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. The funding is in the form of payments made in advance each quarter. As of December 31, 2008, the Company had paid approximately $5.4 million of the $5.5 million to Edison. The Company had 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. The Company did not exercise this option upon the expiration of the initial 18 month research period. During the initial 18 months 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. Edison has not yet presented the Company with the additional compound and has the option to continue their work at their own expense. Until Edison presents the Company with the additional compound, they are not able to present compounds to any parties, or develop or commercialize any compounds by itself or on behalf of a third party. If they are unable

to present the additional compound, then the agreement calls for credits which will be applied against payments on A0001.

Following the end of the Research Period, the license for 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. 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 2008 of Pfizer's generic version of Procardia XL 30 mg totaled approximately $14.9 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 2008, 2007 and 2006, royalties from Mylan were approximately $1.8 million, $2.6 million and $3.1 million, respectively, or 21%, 77% and 89%, respectively, of the Company's total revenue.

Drug Delivery Technology Collaborations

The Company enters into development and licensing agreements with third parties under which the Company develops formulations of generic or third parties' compounds, utilizing the Company's TIMERx drug delivery technologies and formulation expertise. In connection with these agreements, the Company generally receives nonrefundable up-front payments which are recorded as deferred revenue upon receipt and are recognized as revenue over the respective contractual performance periods. Under these agreements, the Company may also be reimbursed for development costs incurred up to amounts specified in each agreement. Additionally, under these agreements, the Company may receive milestone payments upon the achievement of specified events. Finally, these agreements may provide for the Company to receive payments from the sale of bulk TIMERx material and royalties on product sales upon commercialization of the product. As of December 31, 2008, the Company is a party to three such drug delivery technology collaborations.

18. 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.

Impax ANDA Litigation

On October 3, 2007, the Company received a letter from IMPAX notifying the Company of the filing by IMPAX 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 U.S. District Court of Delaware, or U.S. Dist. Delaware. The lawsuit against IMPAX not only alleged infringement of U.S. Patent Nos. 5,662,933 and 5,958,456 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 noted above and that 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 U.S. Patent Nos. 5,662,933 and 5,958,456 in response to IMPAX's December notice. Given the FDA's acceptance of IMPAX's ANDA as of November 23, 2007, they believe that we are entitled to a 30-month stay under the Hatch-Waxman Act beginning on December 14, 2007.

On or around June 14, 2008, the Company and Endo each received a notice from IMPAX advising the Company and Endo that IMPAX had amended its ANDA for Opana ER to include three additional strengths, 7.5 mg, 15 mg and 30 mg. This ANDA amendment contained a Paragraph IV certification against the Company's Orange Book listed patents, U.S. Patent Nos. 5,662,933, 5,958,456 and 7,276,250. On July 25, 2008, the Company and Endo filed a lawsuit against IMPAX in U.S. Dist. Delaware, alleging infringement of U.S. Patent Nos. 5,662,933 and 5,958,456 in response to the notice. The Company and Endo believe that we are entitled to a 30-month stay under the Hatch-Waxman Act beginning on June 14, 2008 with respect to IMPAX's amended ANDA for 7.5 mg, 15 mg and 30mg.

In January 2009, the cases against IMPAX were reassigned to the U.S. District Court of New Jersey ("U.S. Dist. NJ").

Actavis ANDA Litigation.

On or around February 14, 2008, the Company 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 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. On March 28, 2008, Endo and the Company filed a lawsuit against Actavis in the U.S. District Court of New Jersey, or U.S. Dist. NJ, alleging infringement of U.S. Patent No. 5,958,456. On June 2, 2008, the Company

and Endo each received a notice from Actavis advising the Company and Endo that Actavis had amended its ANDA for Opana ER to include two additional strengths, 7.5 mg and 15 mg. On July 2, 2008, the Company and Endo each received a third notice from Actavis advising that Actavis had further amended its ANDA to include the 30mg strength. Each ANDA amendment contained a Paragraph IV certification against the Company's Orange Book listed patents, U.S. Patent Nos. 5,128,143, 5,662,933, 5,958,456 and 7,276,250. On July 11, 2008, the Company and Endo filed a lawsuit against Actavis in the U.S. Dist. NJ alleging infringement of U.S. Patent No. 5,958,456 based on these two additional Paragraph IV certification notices from Actavis. The Company and Endo believe they are entitled to a 30-month stay with respect to Actavis' ANDA covering Opana ER 5 mg, 10 mg, 20 mg and 40 mg beginning February 14, 2008, with respect to Actavis' amended ANDA covering Opana ER 7.5 mg and 15 mg beginning June 2, 2008 and against its amended ANDA covering Opana ER 30 mg beginning July 2, 2008.

On February 20, 2009, the Company and Endo settled all of the Actavis litigation. Both sides agreed to dismiss their respective claims and counterclaims with prejudice. Under the terms of the settlement, Actavis agreed not to challenge the validity or enforceability of the Company's four Orange Book-listed patents. The Company and Endo agreed to grant Actavis a license under US Patent No. 5,958,456 and a covenant not to sue for its generic formulation of Opana ER under the Company's four Orange Book-listed patents. The license and covenant not to sue will take effect on July 15, 2011, and earlier under certain circumstances.

The settlement is subject to the review of the of U.S. Federal Trade Commission and Department of Justice.

Sandoz ANDA Litigation.

On or around July 10, 2008, the Company and Endo each received a notice from Sandoz advising the Company and Endo that Sandoz had filed with the FDA an ANDA for Opana ER in four strengths, 5 mg, 10 mg, 20 mg and 40 mg. This ANDA contained a Paragraph IV certification against our Orange Book listed patents, U.S. Patent Nos. 5,662,933, 5,958,456 and 7,276,250. On August 22, 2008, the Company and Endo filed a lawsuit against Sandoz in the U.S. Dist. Delaware, alleging infringement of U.S. Patent No. 5,958,456 in response to this notice.

On or around November 17, 2008, the Company received a notice from Sandoz that it had filed an amendment to its ANDA containing Paragraph IV certifications for the 7.5 mg, 15 mg and 30 mg dosage strengths of oxymorphone hydrochloride extended release tablets. The notice covers Penwest's U.S. Patent Nos. 5,128,143, 7,276,250, 5,958,456 and 5,662,933. On December 30, 2008, the Company and Endo, filed suit against Sandoz in the United States District Court for the District of New Jersey. The lawsuit alleges infringement of an Orange Book-listed U.S. patent that covers the Opana® ER formulation. In response, Sandoz filed an answer and counterclaims, asserting claims for declaratory judgment that the patents listed in the Orange Book are invalid, not infringed and/or unenforceable. The Company cannot predict the outcome of this litigation. The Company and Endo intend to pursue all available legal and regulatory avenues in defense of Opana® ER, including enforcement of the Company's intellectual property rights and approved labeling.

In January 2009, the case against Sandoz was reassigned to the U.S. Dist. NJ.

Barr ANDA Litigation.

On or around September 12, 2008, the Company and Endo each received a notice from Barr advising the Company and Endo that Barr had filed with the FDA an ANDA for Opana ER in 40 mg strength. On or around September 13, 2008, the Company and Endo received an additional notice that Barr's ANDA was amended to include the strengths of 5 mg, 10 mg and 20 mg. Barr's ANDA as amended contained a Paragraph IV certification against the Company's Orange Book listed patents, U.S. Patent Nos. 5,662,933,

5,958,456 and 7,276,250. On October 20, 2008, the Company and Endo filed a lawsuit against Barr in the U.S. Dist. Delaware, alleging infringement of U.S. Patent Nos. 5,662,933 and 5,958,456.

In January 2009, the case against Barr was reassigned to the U.S. Dist. NJ.

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.

19. SUBSEQUENT EVENTS

Staff Reductions

In January 2009, the Company announced staff reductions of approximately 18% of its workforce as part of its efforts to aggressively manage its overhead cost structure. The terms of the severance arrangements include severance pay and continuation of certain benefits including medical insurance over the respective severance periods. In connection with these staff reductions, the Company expects to record a severance charge in its statement of operations in the first quarter of 2009 in the amount of approximately $550,000. In addition, as a result of these terminations, in the first quarter of 2009, the Company expects to record a non-cash credit of approximately $885,000 under SFAS No. 123R associated with the forfeiture of stock options held by these former employees.

Rights Plan

On March 11, 2009, the Company adopted a rights plan pursuant to which it will issue a dividend of one preferred share purchase right for each share of common stock held by Company stockholders of record on March 23, 2009. Each right will entitle Company stockholders to purchase one one-thousandth of a share of the Company's Series A Junior Participating Preferred Stock at a price of $12.50, subject to adjustment under certain circumstances.

The rights issued under the rights plan will automatically trade with the underlying Company common stock, and they will initially not be exercisable. If a person acquires or commences a tender offer for 15% or more of the Company's common stock (or (A) in the case of Perceptive Life Sciences Master Fund Ltd. and its affiliates and associated persons ("Perceptive"), the greater of (x) 21% or (y) that percentage which Perceptive beneficially owned of the common stock outstanding as of the close of business on March 11, 2009 (the "Perceptive Percentage"), or (B) in the case of Tang Capital Management, LLC and its affiliates and associated persons ("Tang"), the greater of (x) 22% or (y) that percentage which Tang beneficially owned of the common stock outstanding as of the close of business on March 11, 2009 (the "Tang Percentage")) in a transaction that was not approved by the Company's Board of Directors, each right, other than those owned by the acquiring person, would entitle the holder to purchase $25.00 worth of common stock for a $12.50 exercise price. If the Company is involved in a merger or other transaction with another company that is not approved by its Board of Directors, in which the Company is not the surviving corporation or which transfers more than 50% of its assets to another company, then each right, other than those owned by the acquiring person, would instead entitle the holder to purchase $25.00 worth of the acquiring company's common stock for a $12.50 exercise price. If at any time Perceptive or Tang cease to beneficially own at least 15% of the Company's common stock outstanding, the Perceptive Percentage or the Tang Percentage, as the case may be, will no longer be applicable and such shareholder will be subject to the same 15% thresholds as other shareholders.

The Company's Board of Directors may redeem the rights for $0.001 per right at any time until ten business days after a person acquires 15% (or in the case of Perceptive or Tang, the Perceptive Percentage or the Tang Percentage, as applicable) of the Company's common stock, or on the date on which any executive officer of the Company has actual knowledge of such acquisition, whichever is later. The rights will expire

upon the close of business on the earlier of (1) March 11, 2019 or (2) July 1, 2010, if the Company's stockholders do not approve the rights plan by that date.

20. QUARTERLY FINANCIAL DATA (UNAUDITED)

Summarized quarterly financial data for the years ended December 31, 2008 and 2007 is as follows:

	Quarter Ended			
	Mar. 31, 2008(a)	June 30, 2008	Sept. 30, 2008(b)	Dec. 31, 2008
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
	(In thousands, except per share data)			
Total revenues	$ 739	$ 1,316	$ 1,361	$ 5,118
Net loss	$(10,297)	$(6,928)	$(7,277)	(2,232)
Net loss per share	$ (0.41)	$ (0.22)	$ (0.23)	$ (0.07)

	Quarter Ended			
	Mar. 31, 2007	June 30, 2007	Sept. 30, 2007	Dec. 31, 2007(c)
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
	(In thousands, except per share data)			
Total revenues	$ 842	$ 712	$ 882	$ 872
Net loss	$(6,954)	$(8,958)	$(9,251)	$(9,302)
Net loss per share	$ (0.30)	$ (0.39)	$ (0.40)	$ (0.40)

(a) In the first quarter of 2008, the Company recognized an impairment loss of $1.0 million to establish a reserve against the collectability of the loan that the Company made to Edison in February 2008 under the Company's agreement with Edison. The $1.0 million was charged against selling, general and administrative expenses.

(b) In the third quarter of 2008, the Company recorded a credit to selling, general and administrative expense in the amount of $470,000 for the reimbursement of legal fees by Endo in connection with patent enforcement litigation related to Opana ER (see Note 17). In addition, in the third quarter of 2008, the Company recorded an impairment charge to research and product development expense in the amount of $490,000 in connection with patent costs related to development programs that the Company no longer plans to pursue and patents that the Company determined it would no longer maintain.

(c) 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, 2008

	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, 2008					
Inventory Allowances	$ 18	$ 18	$ —	$ —	$ 36
Year ended December 31, 2007					
Inventory Allowances	$ —	$ 18	$ —	$ —	$ 18
Year ended December 31, 2006					
Inventory Allowances	$208	$ —	$ —	$208(a)	$ —

(a) Disposals of unrecoverable inventory costs.

Corporate Directory and Shareholder Information

Officers

Jennifer Good
President and
Chief Executive Officer

Anand Baichwal, Ph.D.
Senior Vice President,
Licensing

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

Paul Hayes
Vice President,
Strategic Marketing

Frank Muscolo
Controller and
Chief Accounting Officer

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

Board Committees

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

Compensation Committee
W. James O'Shea, Chair
Christophe Bianchi, M.D.
Peter Drake, Ph.D.
Paul Freiman

Nominating and Governance Committee
Paul Freiman, Chair
David Meeker, M.D.
Anne VanLent

Scientific Review Committee
David Meeker, M.D., Chair
Christophe Bianchi, M.D.

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

Technical Operations
2981 Route 22
Patterson, NY 12563-2335
(845) 878-8400
Fax: (845) 878-3420

Website
www.penwest.com

Annual Meeting
10:00 a.m., June 10, 2009
Danbury, Connecticut

Form 10-K
We filed our annual report on Form 10-K for the fiscal year ended December 31, 2008 with the SEC on March 16, 2009, 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 Form 10-K in its entirety on our website www.penwest.com. The Form 10-K is included in this annual report.

Legal Counsel
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109

Independent Registered Public Accounting Firm
Ernst & Young LLP
1111 Summer Street
Stamford, CT 06905

Proxy Solicitor
MacKenzie Partners, Inc.
105 Madison Avenue
New York, NY 10016

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

Transfer Agent & Registrar
BNY Mellon Shareowner Services
480 Washington Boulevard
Jersey City, NJ 07310

Website: www.bnymellon.com/shareowner/isd

TOLL FREE number:
1-877-264-3692
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 1A.- Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008 included in this annual report.

39 Old Ridgebury Road
Suite 11
Danbury , CT 06810-5120
(203) 796-3700
(877) PENWEST
www.penwest.com