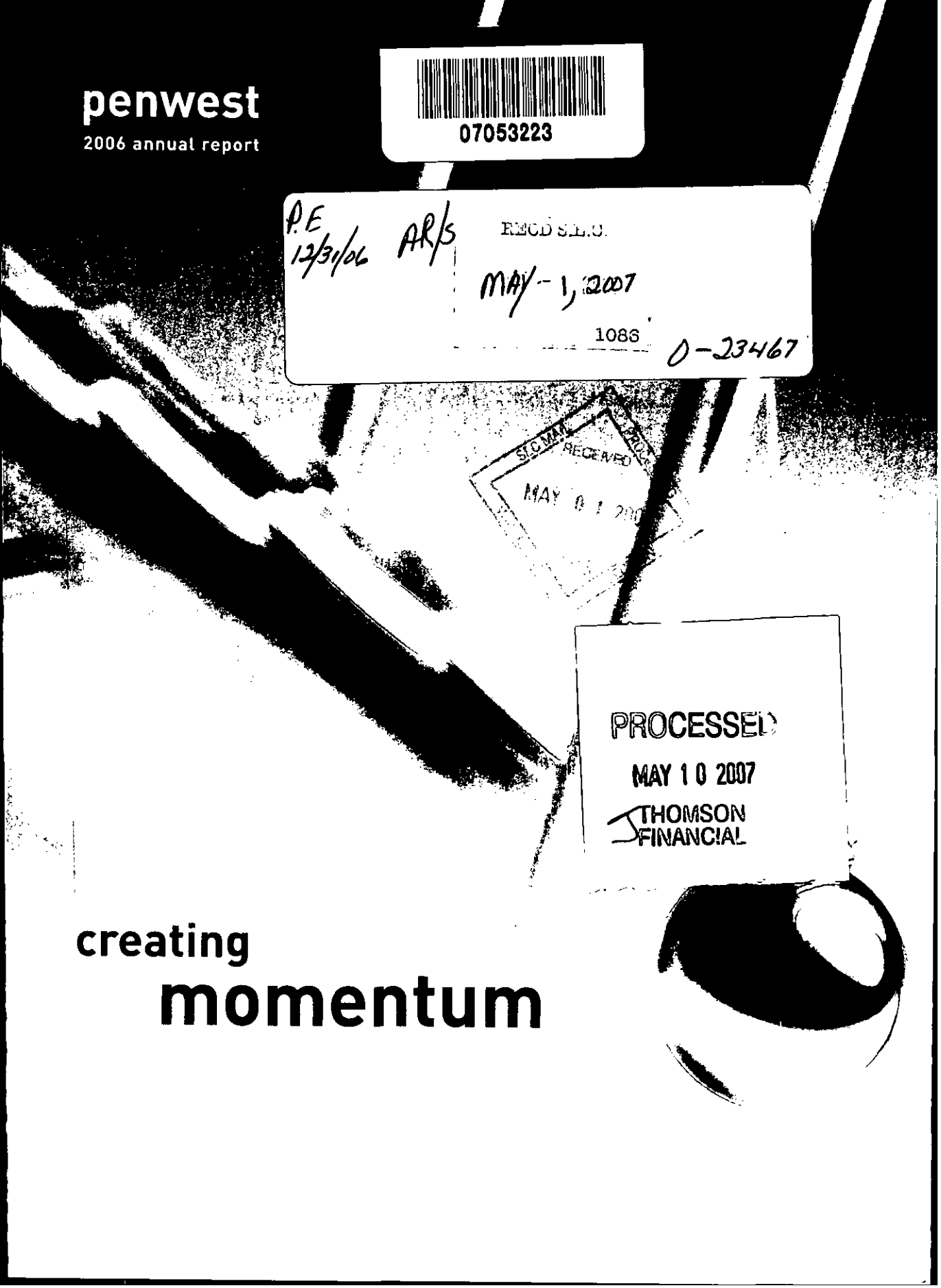
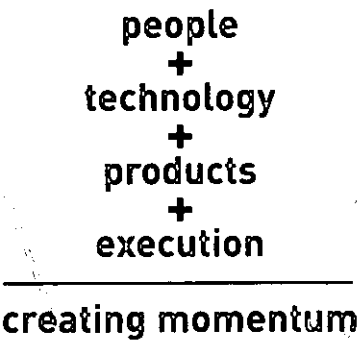
# penwest

2006 annual report





## creating momentum




**penwest** is a specialty pharmaceutical company dedicated to developing innovative products that help improve the lives of patients. We are focusing our development efforts principally on products that address disorders of the nervous system.

# penwest highlights for 2006

**February** Penwest reported positive results for a Phase IIa trial of nalbuphine ER

**June** Penwest announced that Endo received Final FDA Approval for oxymorphone ER — Opana® ER

**June** Penwest appointed Benjamin L. Palleiko as Senior Vice President, Corporate Development and CFO

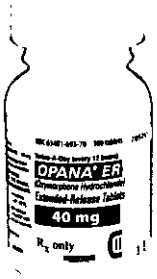
**June** Penwest appointed Jennifer L. Good as Chief Executive Officer and a Member of the Board of Directors

**October** Penwest was named one of Connecticut's Fastest Growing Technology Companies in Deloitte's Technology Fast 50 Program

**October** Penwest appointed Dr. Amy O'Donnell as Senior Director, Clinical Development

# financial highlights

| (amounts in thousands, except per share data) | **2006** | 2005 | 2004 |
|---|---|---|---|
| Revenues | **$ 3,499** | $ 6,213 | $ 5,108 |
| Research & product development | **$ 22,857** | $ 17,797 | $ 20,205 |
| Net loss | **$(31,312)** | $(22,898) | $(23,785) |
| Loss per share (basic & diluted) | **$ (1.38)** | $ (1.05) | $ (1.28) |
| Weighted average shares outstanding | **22,751** | 21,711 | 18,627 |
| Cash, cash equivalents and marketable securities | **$ 40,590** | $ 55,294 | $ 74,370 |
| Shareholders' equity | **$ 45,121** | $ 60,411 | $ 78,801 |




We are developing products with compelling medical and market value to **generate shareholder value**. We remain focused on advancing our portfolio aimed at disorders of the nervous system.

# dear fellow shareholders

Penwest has a clear, well defined growth strategy: to leverage our strength in drug delivery and drug formulation to develop a portfolio of products targeting disorders of the nervous system. Our current development pipeline includes products for the treatment of pain, epilepsy, Parkinson's disease, spasticity and edema. We are continually evaluating new growth opportunities, both internally and externally.

During 2006, we made important progress in pursuit of that strategy. Our key accomplishments included the approval and launch of Opana ER® by Endo Pharmaceuticals, development of our internal pipeline and enhancement of our organizational capabilities and processes.

**Launch of Opana ER** Penwest reached an important milestone in June with the FDA's approval of Opana ER and the launch by Endo of this valuable new product for the treatment of moderate to severe chronic pain. Since this product was launched in the second half of 2006, prescriptions have been steadily increasing. Initial feedback on Opana ER has been favorable, and Endo has invested significant resources in the sales and marketing of the product.

We expect that our involvement with Endo and Opana ER will continue in the future as we seek to fully leverage the value of this product as a global franchise through commercialization with an

Jennifer L. Good
President and
Chief Executive Officer

international partner. We have a successful relationship with Endo, and we will continue to pursue opportunities to create value together.

**Progress on Our Pipeline** As we build our internal portfolio, we are both advancing the product candidates currently in our pipeline and generating new product concepts. We plan to continue to focus primarily on products that can be developed using a 505(b)(2) regulatory strategy because we believe it enables us to move more quickly by focusing on improved formulations of products that have previously been approved by the FDA.

We placed strong emphasis on building our pipeline in 2006 and setting the stage for a busy clinical year in 2007. We plan to advance nalbuphine ER, a compound we are developing for moderate chronic pain into a Phase II study, and continue formulation studies on torsemide ER, a once daily treatment for edema resulting from congestive heart failure, in 2007. Our upcoming trials on nalbuphine ER are designed to explore whether it is an effective treatment for chronic pain, while the studies of torsemide will focus on optimizing the formulation.

In 2006, we also completed extensive formulation work and Phase I studies on several earlier-stage compounds in our portfolio. We are hopeful that we can advance one or two of these compounds into Phase II trials by the end of 2007.

In addition to developing our internal pipeline, we continually evaluate opportunities to in-license new technologies and product candidates to augment our portfolio. In 2006, we initiated work on compounds utilizing novel drug delivery technologies accessed through collaborations. We believe this is a good way to expand our product opportunities, diversify our technology risk and, importantly, develop products that fulfill unmet medical needs. In addition, we are exploring possible collaborations with companies that own new chemical entities in early stage development that relate to the treatment of specific neurological diseases, and need our expertise in drug formulation and clinical development to advance the product candidates.

Left to right

Mehrdad Abedin
VP IT and Project Management Office, Chief Information Officer

Benjamin Palleiko
Senior VP Corporate Development and Chief Financial Officer

Anand Baichwal, Ph.D.
Senior VP Licensing and Chief Scientific Officer

Jennifer Good
President and Chief Executive Officer

Thomas Sciascia, M.D.
Senior VP and Chief Medical Officer

Paul Hayes
VP Strategic Marketing

Phil Goliber
VP Pharmaceutical Development

**Enhanced Organizational Capabilities** In 2006, we continued to strengthen our organization to establish the end-to-end capabilities necessary for effectively executing our growth strategy. This initiative involved, among other things, bringing on board a number of talented people with pharmaceutical development and clinical expertise, developing a disciplined process for evaluating new product concepts and utilizing project management tools to efficiently execute the development of our pipeline.

In addition, we expanded our Board of Directors to enhance its ability to support the growth and transition of Penwest. We were pleased to begin 2007 by welcoming to the Board Dr. David Meeker, President of the Lysosomal Storage Diseases Therapeutics unit of Genzyme Corporation. We believe Dr. Meeker's knowledge and experience in clinical development and regulatory strategy will be invaluable as we move forward.

**Priorities for 2007** Penwest spent 2006 creating momentum, a theme you will see reflected in this annual report. We expect that these efforts will accelerate the pace of our growth. Our primary focus in 2007 is on the disciplined execution of our clinical development programs. Given the risks inherent in drug development, we recognize that we will not be successful with every product candidate. However, we are confident that we have the organizational strengths and processes in place to grow our company with the creativity and discipline it takes to be successful.

I look forward to keeping all of you apprised of our progress going forward. Thank you for your continued support.

Jennifer L. Good
President and Chief Executive Officer

people +

# technology+

# products

execution

creating
momentum

# creating

## people

One of the major components of any successful business is its people, and identifying talented people that work well together is pivotal to our company's success. Over the past several years, we have transitioned from a drug delivery company primarily engaged in formulation work for other companies, to a company focused on effectively completing the full development of a product. This evolution of our strategy required us to expand our organizational capabilities in regulatory, clinical, and pharmaceutical development.

In 2006, we added seventeen new employees across the company in critical areas such as pharmaceutical development, regulatory, clinical, and quality. We believe that, with its leadership and expertise, this team will make valuable contributions to the continued growth of the company. Dr. Amy O'Donnell, for example, who fills the company's newly created position of senior director of clinical development, plays a key role in driving our clinical programs. A board certified

**We currently hold 34 U.S. patents and over 200 patents worldwide. We intend to build on our valuable technology assets by developing, in-licensing and/or acquiring new technologies and products.**

# momentum

neurologist, Dr. O'Donnell joined Penwest in October of 2006 and provides the medical and scientific leadership necessary for the successful development of Penwest products, including overseeing the planning, execution, and interpretation of clinical trials. Prior to joining Penwest, Dr. O'Donnell was a director in neuroscience global clinical research at Bristol-Myers Squibb.

In order to enhance our product development capabilities, we added Dr. Phil Goliber to the Penwest team in February of 2006 as Vice President of Pharmaceutical Development. Dr. Goliber, who came to Penwest from Purdue Pharma L.P. where he served as Senior Director of Analytical Sciences, is responsible for the pharmaceutical development of new products for Penwest.

The addition of Doctors O'Donnell and Goliber exemplify the valuable additions made to our team over the last year, to help advance our products and build upon the momentum in our pipeline.

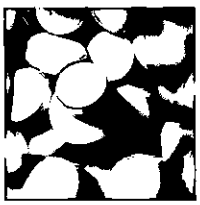
# technology

Penwest is expanding in new directions with its strategy of developing drug products primarily for disorders of the nervous system. We intend to develop products based on the application of our oral technologies as well as non-oral technologies accessed through third parties.

Our drug delivery technology platform is based on TIMERx®, an extended release delivery system that is adaptable to soluble and insoluble drugs and that is flexible for a variety of controlled release profiles. We have also developed three additional oral drug delivery systems: Geminex®, SyncroDose™, and a gastroretentive system. We hold 34 U.S. patents and over 200 foreign patents covering these technologies.

## Creativity, experience and expertise in drug delivery and formulation spark the ideas that result in **improved medicines** and outcomes for patients.

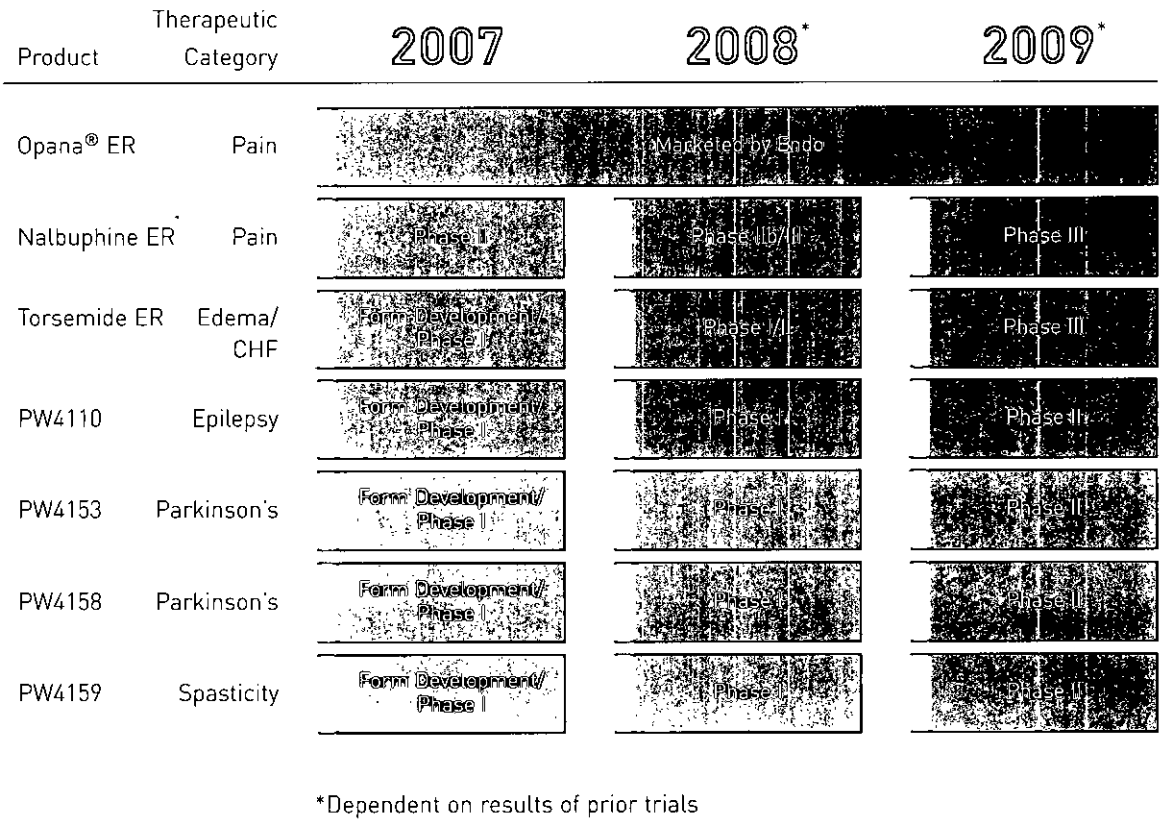
Historically, all of our products have been developed utilizing our TIMERx based oral extended release technologies; however, in 2006, we made a strategic decision to broaden our technology reach to include non-oral drug delivery technologies. In October of 2006, we signed an agreement to conduct a feasibility trial in animals to demonstrate the applicability of an emerging non-oral technology to a product concept developed by Penwest. Our goal is to complete the animal studies on this product candidate by the third quarter of 2007, after which we will determine if the resulting data supports further development of this prospective product.



# products

The nervous system is a complex, sophisticated structure that regulates and coordinates the body's basic functions and is vulnerable to numerous disorders. Many of these disorders are chronic and require innovative drug delivery methods to optimize the therapeutic benefit of medicines. Because of the combination of the high level of unmet medical needs, the importance of drug delivery in the effective treatment of these disorders, and the specialization of the physicians that treat the disorders,

## product pipeline




*Dependent on results of prior trials

Penwest has focused on the opportunity to build value by developing a pipeline of products to treat disorders of the nervous system. While most of these products will be based on the reformulation of existing drugs, we will also undertake the selective development of new chemical entities that target neurological indications.

We expect 2007 to be a busy clinical year for Penwest as we complete multiple studies on product candidates in our pipeline. Our current product candidates include treatments for epilepsy, Parkinson's disease, spasticity, and pain. These product candidates are all reformulations of existing marketed products; most include our proprietary TIMERx technology, but some use non-oral technologies we have accessed through collaborative arrangements. We are also developing a compound for edema associated with congestive heart failure. While the edema product does not fall within our therapeutic focus, we believe if we are successful in formulating this drug, it could be a valuable therapy for congestive heart failure. We plan to out-license the product once it has achieved certain development milestones.

Penwest believes that by building a portfolio of products that address unmet medical needs, capitalize upon our drug delivery expertise and provide a sizable commercial opportunity, we can create long-term shareholder value and establish a strong position in the marketplace.

# execution

Effective execution of scientifically-based drug development for product candidates in our portfolio is the key to achieving our near-term business goals. To accomplish this, we have worked to create a talented organization with strong leadership, clear objectives and well-coordinated activities aimed at improving our ability to successfully develop products as efficiently as

possible. We are striving to develop a culture in which we can quickly advance projects that meet our criteria — and quickly drop those that do not. Our scientific development efforts are supported by market assessments, risk plans and a project management system that highlights key milestones and defines the critical items and timing required to reach both the next milestone and the ultimate goal.

Our projects begin with the creation of a development plan that is communicated across the organization. This ensures that the company is focused and working to achieve mutually understood goals. It is a disciplined yet dynamic process aimed at the efficient execution of the development of product candidates. We have applied the same principles to our business development activities to create efficiencies in our search for new technologies and compounds. We believe that operating decisively and executing effectively will position us well for future success.

# creating value

Through the combination of our people, technologies, products and execution efforts, we strive to create value for the patients who use our drugs, our shareholders and our employees. In 2006, Penwest focused on building these four components and forming a disciplined, scientifically-based, nimble organization. In short, we created momentum. Our objective for 2007 is to use that momentum to propel our portfolio and accelerate our evolution into a specialty pharmaceutical company and to continue to increase value for all of our stakeholders.

# Board of Directors

## Paul E. Freiman

Paul Freiman is Chairman of the Board of Penwest and President and Chief Executive Officer of Neurobiological Technologies, Inc. (NTI). Mr. Freiman served as Chairman and Chief Executive Officer of Syntex Corporation (Syntex) from 1990 to 1995.

Mr. Freiman serves on the boards of Calypte Biomedical Corporation, NeoPharm, Inc., NovaCal Pharmaceuticals, Otsuka America Pharmaceuticals, Inc. and ALS Foundation – UCSF, a non-profit organization. He has been Chairman of the Pharmaceutical Manufacturers Association of America (PhRMA) and has also chaired a number of key PhRMA committees. Mr. Freiman holds a B.S. degree from Fordham University and an honorary doctorate from the Arnold & Marie Schwartz College of Pharmacy.

## Peter F. Drake, Ph.D.

Peter Drake is Managing General Partner of Mayflower Partners, a healthcare sector-focused investment fund. He served from 1999 to 2002 as Managing Director at Prudential Securities and was the co-founder of Vector Securities International, an investment banking firm, for which he served as Executive Vice President from 1988 to 1998. Dr. Drake joined Kidder, Peabody and Co. as a Biotechnology Analyst in 1983, becoming a partner in 1986.

Dr. Drake serves on the boards of Trustmark Insurance, a healthcare insurance provider; the Alliance for Aging Research, a non-profit organization dedicated to improving the health and quality of life for the elderly; TLContact, a private medical information services company; MetaMorphix, a private animal healthcare company; and Cortex Pharmaceuticals, a publicly traded neuroscience company. He holds a B.A. in Biology and Russian from Bowdoin College and a Ph.D. in Biochemistry and Neurobiology from Bryn Mawr College.

## Jennifer L. Good

Jennifer Good was appointed President and Chief Executive Officer of Penwest in June 2006. Ms. Good had been President, Chief Operating Officer and Chief Financial Officer of Penwest since November of 2005. Prior to that, she had served as Penwest's Chief Financial Officer since February 1997. Before joining the Company, Ms. Good served as Corporate Controller and Corporate Director of Finance of Penford Corporation, Penwest's former parent company, from 1993 to 1997. From 1987 to 1993, She was employed by Ernst & Young LLP in a number of positions, the most recent being audit manager where she focused primarily on high-tech and biotech clients.

Ms. Good holds a Bachelor of Business Administration degree from Pacific Lutheran University and is a Certified Public Accountant in the state of Washington.

## Rolf H. Henel

Rolf Henel serves as an advisor to the health care industry as a partner in Naimark & Associates, a health care consulting firm. He is the retired President of Cyanamid International's Lederle Division.

Mr. Henel is a director of both SciClone Pharmaceuticals and Draxis Health Inc., a Canadian company. He earned a B.A. from Yale University and an M.B.A. from New York University.

## Robert J. Hennessey

Robert Hennessey served as President and Chief Executive Officer of Penwest from February 2005 to December 2005. He was Chairman, President and Chief Executive Officer of Genome Therapeutics Corporation (now known as Oscient Pharmaceuticals) from March 1993 until his retirement in November 2000, and served as its Chairman of the Board until March 2003. Previously, Mr. Hennessey was an independent consultant of Hennessey & Associates, Ltd. Prior to that, he was Senior Vice President of Corporate Development for Sterling Drug, Inc. and served in various executive positions at Merck & Co., Inc., SmithKline Beecham PLC, and Abbott Laboratories.

Mr. Hennessey is a director of Oscient Pharmaceuticals and Repligen Corporation. He holds an A.B. and an M.A. from the University of Connecticut.

## David P. Meeker, M.D.

David Meeker is President of the LSD (Lysosomal Storage Diseases) Therapeutics business unit of Genzyme Corporation. During his leadership of the LSD business unit, Dr. Meeker has held development responsibility for its therapeutics portfolio and global responsibility for three marketed enzyme replacement products.

Since joining Genzyme in 1994, Dr. Meeker has served in various roles including Senior Vice President, Therapeutics Europe and Senior Vice President, Medical Affairs. Prior to that, he served at the Cleveland Clinic Foundation, initially joining in 1988 as Staff Physician for the Department of Pulmonary and Critical Care Medicine and later serving as the Program Director for the Department's fellowship program.

Dr. Meeker is a Fellow of the American College of Physicians (FACP) and the American College of Chest Physicians (ACCP), and has published more than 50 articles in academic journals and research publications. He graduated from Dartmouth College and holds an M.D. from The University of Vermont. His post-doctoral training included a Fellowship in Pulmonary Medicine at Boston University, a Clinical Fellowship in Medicine at Harvard Medical School and Residency in Internal Medicine at Beth Israel Hospital Boston.

## John N. Staniforth, Ph.D.

John Staniforth is Chief Scientific Officer of PharmaKodex Ltd, a specialty pharmaceuticals company in the United Kingdom. Prior to joining PharmaKodex, he was Chief Scientific Officer of Vectura Group plc from August 1999 to November 2006. Dr. Staniforth serves as a scientific advisor to a number of international pharmaceutical companies and has extensive teaching and research experience. He is a Professor of the University of Bath in England and has past associations with a number of American universities, as well as Monash University in Australia. His research in the field of powder technology has been widely published and is the recipient of numerous research awards.

Dr. Staniforth is a Churchill Fellow and has been elected Fellow of a number of scientific societies around the world, including the American Association of Pharmaceutical Scientists. Dr. Staniforth has been a consultant to Penwest since the company's inception and is the co-inventor of TIMERx, its flagship technology platform. Dr. Staniforth is a director of PharmaKodex Ltd. and Halation Ltd. Dr. Staniforth holds a BSc in pharmacy from Aston University, Birmingham. He is a UK Registered Pharmacist and Chartered Chemist in the UK, and also holds a PhD in pharmaceutics from Aston University.

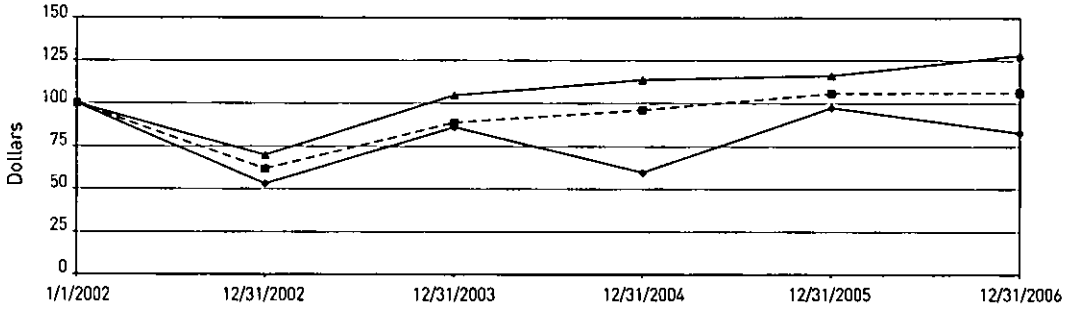
## Anne M. VanLent

Anne VanLent is Executive Vice President and Chief Financial Officer of Barrier Therapeutics, Inc. an emerging specialty pharmaceutical company in the field of dermatology, a position she has held since May 2002. Prior to joining Barrier, Ms. VanLent was a founder of The Technology Compass Group, LLC, a healthcare/technology consulting firm. From mid-1997 through October 2001, Ms. VanLent served in various executive roles at Sarnoff Corporation, a privately held research and development company that creates and commercializes electronic, biomedical, and information technologies, ultimately as Executive Vice President, Portfolio Management. In that position, she oversaw the creation of spin-off companies and patent and licensing activities. From March 1994 through August 1997, Ms. VanLent served as President of AMV Associates, an emerging growth healthcare consulting firm.

Ms. VanLent serves as a director of Integra LifeSciences Holdings and American Red Cross of Central New Jersey. She received a B.A. in Physics from Mount Holyoke College.

# form 10-K

**Compare 5-Year Cumulative Total Return**
**Among Penwest Pharmaceuticals Co.,**
**NASDAQ Market Index and NASDAQ Pharmaceutical Index**




Assumes $100 Invested on Jan. 1, 2002
Assumes Dividend Reinvested
Fiscal Year Ending Dec. 31, 2006

# 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, 2006**

**OR**

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

**For the transition period from to**

**Commission File Number 000-23467**

# PENWEST PHARMACEUTICALS CO.

*(Exact name of registrant as specified in its charter)*

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

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

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

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

**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 Securities Exchange Act of 1934. 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 Exchange Act 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, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer ☐ Accelerated Filer ☑ Non-Accelerated Filer ☐

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

The aggregate market value of the Registrant's Common Stock held by non-affiliates as of June 30, 2006 was approximately $496,840,000 based on the last sale price of the Registrant's Common Stock on the Nasdaq National Market on June 30, 2006. The number of shares of the Registrant's Common Stock outstanding as of March 9, 2007 was 23,226,570.

## DOCUMENTS INCORPORATED BY REFERENCE

Portions of our definitive Proxy Statement relating to the 2007 Annual Meeting of Shareholders to be held on June 13, 2007 are incorporated by reference into Part III of this Form 10-K.

PENWEST PHARMACEUTICALS CO.

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**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 develop pharmaceutical products based on innovative proprietary drug delivery technologies with a focus on products that address disorders of the nervous system. In June 2006, the United States Food and Drug Administration, or FDA, approved for marketing Opana® ER, an extended release formulation of oxymorphone hydrochloride that we developed with Endo Pharmaceuticals Inc, or Endo, using our proprietary TIMERx® drug delivery technology. We are currently developing product candidates designed for the treatment of pain, epilepsy, Parkinson's disease and spasticity, as well as a product candidate for the treatment of edema resulting from congestive heart failure.

*Opana ER.* Opana ER is an oral extended release opioid analgesic, which we developed with Endo using our proprietary TIMERx technology. Opana ER has been approved in the United States 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 is responsible for marketing Opana ER in the United States. The product was launched by Endo in the United States in July 2006 in 5mg, 10mg, 20mg and 40mg tablets.

In January 2007, we signed an amendment to our strategic alliance agreement with Endo. Under 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 Opana ER rather than on operating profit and agreed to other related changes to the agreement. The amendment also resolved the parties' dispute with regard to the sharing of marketing expenses during the period prior to when Opana ER reaches profitability.

*Additional Product Candidates.* Of the products we are developing, we have two product candidates in clinical development.

- *Nalbuphine ER.* We are developing nalbuphine ER, a controlled release formulation of nalbuphine hydrochloride, for the treatment of pain. Nalbuphine ER, which we are developing using our TIMERx drug delivery technology, is designed to be taken as a tablet twice daily. We expect that nalbuphine ER, if approved, would compete in the moderate pain market with products such as Nubain®, Tramadol® ER, codeine and Demerol®. We have completed a Phase I pharmacokinetic study of nalbuphine ER in which the formulation achieved the targeted blood levels, as well as a Phase IIa trial in which a single dose of nalbuphine ER positively reduced mean pain intensity in a dose-dependent manner over the 12-hour study period when compared to placebo. In January 2007, we commenced a Phase I dose escalation to steady state trial. The intent of this trial is to collect additional safety and pharmacokinetic data to assist us in designing a Phase IIa trial of the product candidate for chronic pain that we plan to commence in the third quarter of 2007.

- *Torsemide ER.* We are developing torsemide ER, a controlled release formulation of torsemide, a loop diuretic for the treatment of chronic edema, a condition involving excess fluid accumulation resulting from congestive heart failure, or CHF. Torsemide ER, which we are developing using our TIMERx drug delivery technology, is designed to be taken as a tablet once daily. We expect that torsemide ER, if approved, would compete with furosemide and other loop diuretics. We have completed several Phase I pharmacokinetic studies of torsemide ER and completed a Phase IIa study in which torsemide ER caused prolonged urinary sodium excretion in CHF patients. We intend to further refine our formulation and complete an additional Phase I pharmacokinetic study for torsemide ER in the first half of 2007. If the data from this Phase I study confirms the formulation and achieves the targeted blood level profiles, we intend to conduct a Phase II study comparing torsemide ER to Lasix, which we plan to commence in the second half of 2007.

We are also developing four other product candidates for the treatment of disorders of the nervous system. We are currently developing formulations and conducting pilot scale biostudies of these product candidates in either animals or humans to obtain pharmacokinetic data.

**Our Strategies**

Our business strategy is to build a specialty pharmaceutical company that develops and commercializes products that address disorders of the nervous system. The elements of our strategy include:

- *Focus on products that address disorders of the nervous system.* We are focusing on products that address disorders of the nervous system because we believe many of the currently approved products for the treatment of nervous system disorders can be enhanced by drug delivery technologies. In addition, we believe the market for treating nervous system disorders is an attractive market because many of these disorders are chronic in nature and are largely treated by specialist physicians that can be addressed with a relatively small sales force. If, however, we believe that we could develop a product that would address an unmet medical need and have a substantial market value, we may also selectively develop product candidates for diseases outside of the nervous system.

- *Reformulate existing drugs using drug delivery technologies.* We develop products by reformulating existing drugs utilizing proprietary drug delivery technologies. These drug delivery technologies include our own internally developed oral extended release technologies, as well as drug delivery technologies we may access through collaborations. When appropriate, we intend to utilize a "505(b)(2) regulatory strategy" to seek approval for our reformulations of existing drugs. Under this strategy, we will file a section 505(b)(2) New Drug Application, or a section 505(b)(2) NDA, which will rely on the FDA's previous findings for the safety and effectiveness of the existing drug in addition to the data we generate regarding our reformulated drug. Because a section 505(b)(2) NDA may rely on the FDA's previous findings, the trials that need to be conducted are generally more limited. Therefore, the development of a drug using the 505(b)(2) regulatory strategy is generally less costly and time consuming than the full NDA process.

- *Develop product candidates that have the potential for at least five years of exclusivity in the marketplace.* We intend to expand our portfolio to include product candidates for which we or our collaborators could obtain at least five years of exclusivity in the marketplace following marketing approval. This exclusivity could arise from meeting certain regulatory criteria for market exclusivity with the FDA, for example, in connection with the approval of new chemical entities or orphan drugs, or from intellectual property protection.

- *Continue to leverage and expand our proprietary drug delivery technologies.* We believe that we have significant expertise in drug formulation and in oral drug delivery technologies. Our proprietary drug delivery technologies, TIMERx controlled release, Geminex® dual delivery, SyncroDose® site-specific delivery and the gastroretentive system, are applicable to a wide range of drugs with different physical and chemical properties including water soluble and insoluble drugs, as well as high dose and low dose drugs. Using these technologies, we believe that we can formulate drugs with precise release profiles and improve the characteristics of existing drugs. In selecting product candidates for development, we intend to continue to focus on opportunities in which either our drug delivery technologies or other drug delivery technologies that we can access, can provide benefits to patients and result in branded, proprietary products. We intend to expand our proprietary drug delivery technologies by continuing to develop our core technologies, in-licensing or acquiring new technologies.

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

## Drug Delivery Technologies

We currently have four proprietary drug delivery technologies: TIMERx, a controlled-release technology; Geminex, a technology enabling drug release at two different rates; SyncroDose, a technology enabling controlled release at the appropriate site in the body; and our gastroretentive system, a technology enabling drug delivery to the upper gastrointestinal tract. Specifically, our 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. The physical interaction between these components works to form a strong, binding gel in the presence of water. We believe our drug delivery technologies have broad applicability across multiple therapeutic areas. To date, our technologies have been used in four products that have received regulatory approval, one in the United States and the others in countries in Europe or South America.

### *TIMERx*

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

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.

### *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 sutbstance 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.

### *Gastroretentive*

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.

## Products

### *Approved Products*

*Opana ER.* Opana ER is an oral extended release opioid analgesic that we developed with Endo using our proprietary TIMERx technology. In June 2006, Opana ER was approved in the United States 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 is responsible for marketing Opana ER in the United States. The product was launched by Endo in the United States in July 2006 in 5mg, 10mg, 20mg and 40mg tablets.

Opana ER competes in the market for long acting, strong opioid analgesics with products such as Purdue Pharma's OxyContin® and MS Contin, Johnson and Johnson's Duragesic® patch, King Pharmaceuticals' Avinza® and Alpharma's Kadian®, as well as generic versions of some of these products. Products in the long acting, strong opioids market had aggregate sales in the United States in 2006 of approximately $3.0 billion.

To date, several other drug formulations utilizing our TIMERx technology have received regulatory approval in the United States, United Kingdom, Italy and Finland:

- Nifedipine XL, a generic version of Pfizer, Inc.'s Procardia® XL for the treatment of hypertension and angina that we developed with Mylan Pharmaceuticals Inc., is approved for sale in the United States. Mylan, which has the marketing rights for Nifedipine XL, is not marketing Nifedipine XL as a result of its acquisition from Pfizer of the right to market Pfizer's generic versions of three strengths of Procardia XL under Pfizer's NDA.
- Cystrin CR, an extended release version of oxybutynin for the treatment of urge urinary incontinence, is approved for sale in Finland and has been licensed to Schering Oy.
- Slofedipine XL, an extended release version of nifedipine for the treatment of angina, is approved for sale in the United Kingdom and Italy, and has been licensed to Sanofi-Aventis S.A. This product is no longer being marketed.
- Cronodipin, an extended release version of nifedipine for the treatment of angina, is approved for sale in Brazil and has been licensed to Merck S.A. Industries Quimicas. We do not believe this product is being marketed any longer.

### *Products in Our Pipeline*

We have a number of products in our development pipeline. The table below summarizes each of the products in this pipeline, including their respective intended therapeutic use. To date, we have retained all rights to these products.

| Product | Therapeutic Category |
|---|---|
| **Clinical Development** | |
| Nalbuphine ER (PW4142) | Moderate Chronic Pain |
| Torsemide ER (PW2132) | Edema/Congestive Heart Failure |
| **Formulation and Phase 1 Biostudies** | |
| PW4110 | Epilepsy |
| PW4153 | Parkinson's Disease |
| PW4158 | Parkinson's Disease |
| PW4159 | Spasticity |

*Nalbuphine ER (PW4142)*

We are developing nalbuphine ER, a controlled release formulation of nalbuphine hydrochloride, for the treatment of chronic pain. Nalbuphine ER, which we are developing 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 blocks certain opioid receptors and potentially attenuates the development of tolerance and dependence. Nalbuphine hydrochloride is currently only available as a sterile solution suitable for subcutaneous, intramuscular or intravenous injection in a brand under the name Nubain and in a generic version. The annual sales of Nubain and its generic version were approximately $7.9 million in 2006, but we believe the market for this drug is limited by currently available formulations of the drug. We expect that nalbuphine ER, if approved, would compete in the moderate pain market against Nubain and oral drugs such as Tramadol ER, codeine and Demerol.

In December 2005, we completed a Phase IIa trial of nalbuphine ER designed to determine the degree and duration of pain relief of two different dose levels of nalbuphine ER in acute pain. The 165-patient Phase IIa trial was a pharmacokinetic-pharmacodynamic investigation of patients undergoing third molar extractions designed to correlate the level of analgesia in patients with the plasma level of the drug. Two different doses of nalbuphine ER were evaluated as single doses against placebo. Results from this Phase IIa study demonstrated that in the study nalbuphine ER reduced mean pain intensity in a dose-dependent manner over the twelve-hour period of the study. At both the higher and the lower dose level, we also observed in patients longer time to ingestion of rescue medication and lower proportion of patients requiring rescue analgesic therapy during the twelve-hour study period when compared to placebo. Finally, the percentage of patients experiencing at least a 50% reduction in pain intensity during the twelve-hour study period was higher for the both nalbuphine ER dose levels compared to placebo. No unusual side effects were reported during the twelve-hour dosing interval.

In 2006, we decided to develop this product for a chronic pain indication and conducted reformulation work and several Phase I studies to optimize the formulation for this purpose. In January 2007, we commenced a Phase I dose escalation to steady state trial. The intent of this trial is to collect additional safety and pharmacokinetic information which we can use to bridge the safety data from the acute pain trial we conducted in 2005 to a trial we intend to conduct in the second half of 2007. We expect data from this Phase I safety study in the second quarter of 2007. If the data from this trial supports a chronic pain trial, we intend to commence in the second half of 2007 a Phase IIa proof of concept trial in a chronic pain study comparing nalbuphine ER to placebo. We expect data from this Phase IIa trial by the end of 2007.

*Torsemide ER (PW2132)*

We are developing torsemide ER, a controlled release formulation of torsemide, a loop diuretic, for the treatment of edema related to CHF, which we are developing using our TIMERx drug delivery technology. CHF is a major cardiovascular disease affecting approximately 5 million patients in the United States according to the American Heart Association's 2004 statistics on heart disease. The class of products to which torsemide belongs, loop diuretics, remains a key part of the clinical management of CHF. CHF patients are administered loop diuretics to facilitate the requirement that such patients excrete between 150mEq and 200mEq of sodium per day to prevent water retention related weight gain that can eventually lead to cardiac failure.

The current formulations of loop diuretics, which are all immediate release products, including Demadex, have short periods of action during which most of the sodium excretion caused by the drug occurs. These short periods of action can leave the patient unprotected for long periods of time during the day, when sodium retention can occur related to food intake. The short periods of action of existing loop diuretics can also create large urinary volume after drug ingestion, resulting in unpleasant side effects that can affect patient compliance.

We are developing torsemide ER to be taken as a tablet once-a-day, with the active drug ingredient designed to be released into the blood stream over a period of approximately 16 hours. We believe that this controlled release profile can provide more effective treatment of edema for patients with CHF by providing more measured diuresis over the course of the day. In particular, torsemide ER would provide release of torsemide during the waking hours when patients with CHF need protection from absorbing salt in connection with eating multiple meals over the course of the day.

In 2004, we conducted a pharmacokinetic biostudy of torsemide ER outside the United States in approximately 20 healthy volunteers. In the study, torsemide ER achieved the plasma profiles we had targeted as endpoints of the study. Based on the results of the pilot biostudy, we filed an investigational new drug application, or IND, for torsemide ER in the United States. In the fourth quarter of 2005, we completed a Phase IIa study of torsemide ER in 37 patients. The study was an open-label, single-center study using a dose escalation trial design and studying the safety, pharmacokinetics and pharmacodynamics of single dose torsemide ER in patients with Class II or Class III CHF. Patients were placed on a sodium-restricted diet for three days prior to dosing. The study also included a comparator arm of Demadex 200 mg. The goal of the study was to investigate the total urinary sodium excretion in a 24-hour period, as well as the rate of sodium excretion over the 24-hour period. Administration of torsemide ER 100 mg resulted in a total urinary sodium excretion in a 24-hour period comparable to Demadex 200 mg. The study also showed that the total sodium excretion of torsemide ER was accomplished at a more sustained and slower rate over the course of the day using half the amount of drug that was in the Demadex formulation.

During 2006, we reformulated the product to address certain findings from our pervious studies and conducted two additional Phase I studies to optimize the formulation and the delivery of the drug. During the first half of 2007, we plan to conduct additional reformulation work on torsemide ER and conduct an additional Phase I study. If we are able to achieve the targeted blood levels in the Phase I study and are satisfied that the formulation has been optimized, then we intend to initiate a Phase II trial late in 2007. The Phase II study would be designed to compare the efficacy of torsemide ER to furosemide, a commonly prescribed generic loop diuretic. Following completion of these Phase II studies, we would seek to discuss further with the FDA the regulatory pathway for the approval of torsemide ER, including whether one Phase III pivotal safety and efficacy trial would be sufficient for approval if we seek approval under Section 505(b)(2) relying on the clinical data for Demadex, and the design of any required trials. We currently intend to seek a collaborator to market this product if approved. Our timing in seeking a collaborator will depend on a number of factors, including the results of our planned trials and our interactions with the FDA.

*Additional Product Opportunities*

We are developing formulations and conducting pilot scale Phase I biostudies on several product candidates primarily for the treatment of disorders of the nervous system. One of these product candidates is designed to treat epilepsy, two to treat Parkinson's disease, and one to treat spasticity. Through our pilot scale Phase I biostudies, we are seeking to obtain pharmacokinetic data in either humans or animals. If the Phase I biostudies of any of these product candidates show the desired blood level profiles, we expect to advance the product candidate into further clinical trials, after considering a number of factors, such as our available resources, the size of the potential market, competitors in the potential market, the availability of intellectual property protection, the regulatory pathway and the development status of our other products. We will also determine how to advance the product, whether to develop the product, on our own and, if not, when to seek a collaborator.

**Collaborative Agreements**

We enter into collaborative agreements with pharmaceutical companies to develop, market or manufacture some of our products. We currently are parties to two types of collaborative agreements: joint development collaborative agreements and technology licensing collaborative agreements. In joint development collaborative agreements, such as our agreement with Endo, we jointly fund research and development with our collaborator. In these arrangements, we may receive up-front licensing fees or milestone payments. We may also receive royalties on the sales of the products by our collaborators. Technology licensing collaborative agreements involve the licensing of our TIMERx technology to a collaborator who is responsible for the development and marketing of a product using our technology. We may receive up-front licensing fees and milestone payments, and be entitled to receive royalties on our collaborators' sales of the products covered by such collaborative arrangements and payments for the purchase of formulated TIMERx material by our collaborators.

In the future, we may enter into collaborative agreements involving the licensing of a product candidate after we complete some or all of the development work on the product candidate. Under this type of

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

***Joint Development Collaborative Agreements***

*Endo Pharmaceuticals Inc.*

In September 1997, we entered into a strategic alliance agreement with Endo with respect to the development of Opana ER, an extended release formulation of oxymorphone hydrochloride based on our TIMERx technology. This agreement was amended and restated in April 2002, and amended again in January 2007. Endo is a specialty pharmaceutical company with a market leadership position in pain management. Endo has a broad product line, including established brands such as Lidoderm®, Percodan®, Percocet® and Frova® as well as three newly launched products in 2006 including Opana ER, Opana® and Synera™.

During the development of Opana ER, we formulated the product using our TIMERx technology and Endo conducted all clinical studies, and prepared and filed all regulatory applications. We have agreed to supply TIMERx material to Endo, and Endo has agreed to manufacture and market Opana ER in the United States. We also have 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. Endo is currently seeking collaborators for sales and marketing of Opana ER in Europe.

Prior to April 17, 2003, we shared with Endo the costs involved in the development of Opana ER. On April 17, 2003, we exercised our option under the terms of the Agreement and discontinued our participation in the funding of the development of Opana ER. We took this action because we believed that our strategic focus should be on funding other products in our development pipeline. As a result of this termination of funding, Endo completed the development of Opana ER and has the right to recoup the portion of development costs incurred by Endo that otherwise would have been funded by us.

We entered into an amendment in January 2007 as part of the resolution of a dispute between the parties with regard to the sharing of marketing expenses during the period prior to when Opana ER reaches profitability. Under the terms of the 2007 Amendment, 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 will pay us royalties on U.S. sales of Opana ER calculated based on a tiered royalty rate starting at 22% of annual net sales of the product up to $150 million of annual net sales, with the royalty rate increasing, based on agreed-upon levels of annual net sales achieved, from 25% up to a maximum of 30%.
- No royalty payments will be due to 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.
- Endo will pay us a percentage of any sublicense income it receives.
- Endo will also pay us milestone payments up to $90 million based upon the achievement of agreed-upon annual sales thresholds.
- Our share of the development costs for Opana ER that we opted out of funding in April 2003 is fixed at $28 million and will be recouped by Endo through a temporary 50% reduction in royalties. This temporary reduction in royalties will not apply until the threshold for the $41 million royalty holiday referred to above has been met.

*Technology Licensing Collaborative Agreements*

*Mylan Pharmaceuticals Inc.*

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

In March 2000, Mylan announced that it had signed a supply and distribution agreement with Pfizer to market an authorized generic version of all three strengths, 30 mg, 60 mg and 90 mg, of Procardia XL under Pfizer's NDA. In connection with that agreement, Mylan decided not to market Nifedipine XL. As a result, Mylan entered a letter agreement with us under which Mylan agreed to pay us a royalty on all future net sales of Pfizer's generic Procardia XL 30 mg. The royalty rate is comparable to that in our original agreement with Mylan for Nifedipine XL. Mylan has retained the marketing rights for Nifedipine XL 30mg. Mylan's sales in the United States in 2006 of Pfizer's generic Procardia XL 30 mg totaled approximately $25.9 million. The term of this letter agreement continues until such time as Mylan permanently ceases to market Pfizer's generic Procardia XL. In 2006, 2005 and 2004, royalties from Mylan were approximately $3.1 million, $3.9 million and $4.8 million, respectively, or 89%, 63% and 94%, respectively, of our total revenue.

**Research and Development**

We conduct research and development activities on the development of product candidates utilizing our existing drug delivery technologies, as well as external drug delivery technologies we access through collaborators. Our research and development expenses in 2006, 2005 and 2004 were $22.9 million, $17.8 million and $20.2 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 the 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 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 have taken steps toward qualifying a second contract manufacturer as a second source of supply, including the completion of initial validation work. However, there is additional work required before the site is validated and we have decided that we will not complete this effort at the present time. 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

purchase these gums from a primary supplier. We have also qualified alternate suppliers with respect to these gums. To date we have not experienced difficulty acquiring these materials.

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

**Marketing and Distribution**

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

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

**Patents and Proprietary Rights**

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

***Patents and Protection of Proprietary Information***

As of February 28, 2007, we owned a total of 34 U.S. and 207 foreign patents. The U.S. patents principally cover our TIMERx technology, and its modifications and improvements, including the combination of the xanthan and locust bean gums, the oral solid dosage form of TIMERx and the method of preparation. Our patents also cover the application of TIMERx technology to various active drug substances. These patents will expire between 2008 and 2020.

We own one issued U.S. patent listed in the Orange Book for Opana ER. This patent expires in September 2008, although the product was granted New Dosage Form exclusivity which expires in June 2009. Endo and we are each prosecuting several additional patent applications to cover Opana ER. These U.S. patent applications and corresponding foreign patent applications relate to sustained release formulations of Opana ER, and methods of making and using the same formulation. Should any of these U.S. patent applications issue as patents, which is not guaranteed, they are likely to have patent expiration dates beyond 2022.

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.

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 conflicting patent rights. Under the Waxman-Hatch Act, when an applicant files a section 505(b)(2) NDA or an Abbreviated New Drug Application, or 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 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 notice to the patent owner or the sponsor of the NDA for the brand name product. If 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 final judgment 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 certification. Patent litigation can be complex and costly, and could take up to several years to complete. The outcomes of patent litigation are difficult to predict. We evaluate the risk of patent infringement litigation with respect to each product we determine to develop.

***Trademarks***

TIMERx, Geminex and SyncroDose are our registered trademarks. Other tradenames and trademarks appearing in this annual report on Form 10-K are the property 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 U.S. requirements, both before and after approval, may subject us to administrative and judicial sanctions, such as rejection of pending applications or delay in approving, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, and/or criminal prosecutions.

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, and 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 "bioequivalent" to a drug which the FDA has previously approved.

*NDAs:* The steps required for the approval of an NDA include pre-clinical laboratory and animal tests and formulation studies; submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin; adequate and well-controlled clinical trials to establish the safety and effectiveness of the product candidate for each indication for which approval is sought; submission to the FDA of the application; satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with 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 results of the pre-clinical tests, together with manufacturing information and analytical data, 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. 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 are conducted 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 must be reviewed and approved by an independent Institutional Review Board before it can begin. Phase I usually involves the initial introduction of the investigational drug candidate into people to evaluate its

safety, dosage tolerance, pharmacodynamics and, if possible, to gain an early indication of its effectiveness. Phase II 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 III 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, or the FDA may suspend clinical trials at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk.

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

*505(b)(2) NDAs:* Section 505(b)(2) NDAs may be submitted for drug products that represent a modification of an already approved drug (such as a new indication or new dosage form) and for which investigations, in addition to bioavailability or bioequivalence studies, are essential to the drug's approval. A section 505(b)(2) NDA may rely on the FDA's previous findings of safety and effectiveness of the approved drug as well as information obtained by the Section 505(b)(2) applicant needed to support the modification of the listed drug. Preparing a 505(b)(2) NDA is generally less costly and time-consuming than preparing a full NDA.

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

*ANDA's:* The FDA may approve an ANDA if the product is the same in important respects as an already approved drug, or if the FDA has declared the drug suitable for an ANDA submission. For example, the FDA approved the ANDA submitted by our collaborator, Mylan, for the 30 mg dosage strength of a generic version of Procardia XL that we developed with Mylan. An ANDA must contain the same manufacturing and composition information as the NDA for the listed drug, but applicants need not submit preclinical and clinical safety and effectiveness data. Instead, they must submit studies showing that the product is bioequivalent to the already approved drug. Drugs are bioequivalent if the rate and extent of absorption of the drug does not show a significant difference from the rate and extent of absorption of the already-approved drug. Conducting bioequivalence studies is generally less time-consuming and costly than conducting pre-clinical and clinical studies necessary to support an NDA.

Like 505(b)(2) NDAs, final approvals of ANDAs are subject to certain conditions in various circumstances such as marketing exclusivity and patent certification. The regulations governing marketing exclusivity and patent certification relating to ANDAs are complex and often uncertain.

***Other FDA Requirements:***

After the marketing approval of a 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 certain requirements concerning advertising and promotion for 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 problems such as safety problems may result in changes in labeling, or restrictions on a product manufacturer or NDA holder, including 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, 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.

Our products in development will face competition from products with the same indication as the products we are developing. For instance, Opana ER competes with OxyContin and MS Contin, Duragesic patch, Avinza, Kadian and the generic version of some of these drugs. Each of these products is a potential treatment option for a physician managing a patient with moderate to severe, chronic pain.

**Employees**

As of March 1, 2007, we employed approximately 75 people, of whom 54 were primarily involved in research and development activities, and 21 were primarily involved in selling, general and administrative activities. As of March 1, 2007, none of our employees were covered by collective bargaining agreements. We consider our employee relations to be good.

**Information Available on the Internet**

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

## ITEM 1A. — *RISK FACTORS*

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

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

We have incurred net losses since 1994, including net losses of $31.3 million, $22.9 million and $23.8 million during 2006, 2005 and 2004, respectively. As of December 31, 2006, our accumulated deficit was approximately $172 million.

Our strategy includes a significant commitment to spending on research and development targeted at identifying and developing products for the treatment of disorders of the nervous system. As a result, we expect to continue to incur net losses in 2007 as we continue to conduct development of and seek regulatory approvals for our product candidates. These net losses have had and will continue to have an adverse effect on our shareholders' equity, total assets and working capital.

Our future profitability will depend on several factors, including:

- the commercial success of Opana ER, and the timing and amount of royalties from Endo's sales of Opana ER;
- the level of our investment in research and development activities;
- the successful development and commercialization of product candidates in our portfolio;
- the level of investment for acquisitions or in-licensing of technologies or compounds intended to support our growth; and
- royalties from Mylan's sales of Pfizer's generic Procardia XL 30 mg.

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

As of December 31, 2006, we had cash, cash equivalents and short-term investments of $40.6 million. On March 13, 2007, we entered into a $24.0 million senior secured credit facility with Merrill Lynch Capital, a divison of Merrill Lynch Business Financial Services Inc. The credit facility consists of: (i) a $12.0 million term loan issued upon the closing of the credit facility and (ii) a $12.0 million term loan that we may access until September 15, 2008, subject to conditions specified in the agreement. We anticipate that, based on our current operating plan, our existing capital resources, the credit facility noted above and anticipated internally generated funds from royalties from Mylan will be sufficient to fund our operations on an ongoing basis without requiring us to seek additional external financing until at least late 2008.

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

- the commercial success of Opana ER;
- the timing and amount of payments received under collaborative agreements, including in particular our agreement with Endo with respect to Opana ER and our agreement with Mylan with respect to Pfizer's generic Procardia XL 30 mg;
- the progress of our collaborative and internal development projects, funding obligations with respect to the projects, and the related costs to us of clinical studies for our product candidates;
- the level of investment for the acquisition or in-licensing of technologies or compounds intended to support our growth;
- the structure and terms of any future collaborative agreements;

- the prosecution, defense and enforcement of our patents and other intellectual property rights; and
- the level of our investments in capital expenditures for facilities and equipment.

Subject to these factors, we may need to sell additional equity or debt securities or seek additional financing through other arrangements to fund operations beyond late 2008. In addition, if we decide to increase development work in our own internal portfolio or to acquire additional products or technologies, we may need to seek additional funding for such actions through collaborative agreements, research and development arrangements, or public or private financing of equity or debt.

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

***We depend heavily on the success of Opana ER, which may not be widely accepted by physicians, patients, third-party payors, or the medical community in general***

We have invested a significant portion of our financial resources in the development of Opana ER. In the near term, our ability to generate significant revenues will depend primarily on the growth of Opana ER sales by Endo. Opana ER, which was approved by the FDA in June 2006 and launched by Endo in July 2006, may not be accepted by customers in the pharmaceutical market. In 2006, sales of Opana ER were less than was generally expected. 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 that are not yet marketed. 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 safety and effectiveness 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; and
- the level of stocking of Opana ER by wholesalers and retail pharmacies.

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 and our drug delivery technologies.

***We are dependent on our collaborator Endo to manufacture, market and sell Opana ER, and in the future expect to be dependent on other collaborators to manufacture, market, and sell our other products***

Opana ER and some of our other products have been developed and commercialized in collaboration with other pharmaceutical companies. Under these collaborations, we have typically been dependent on our collaborators to fund some portion of development, conduct clinical trials, obtain regulatory approvals for, and/or manufacture, market and sell products utilizing our drug delivery technologies. In particular, we are dependent on Endo to manufacture, market and sell Opana ER in the United States and on Mylan to market and sell Pfizer's generic Procardia XL 30 mg.

We have limited experience in manufacturing, marketing and selling pharmaceutical products. Accordingly, if we cannot maintain our existing collaborations or establish new collaborations with respect to our other products in development, 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 product. There can be no assurance that we will be successful in developing these capabilities.

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

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

- Our collaborators may be pursuing alternative technologies or developing alternative products, either on their own or in collaboration with others, that may be competitive to the product on which we are collaborating, which could affect our collaborator's commitment to our collaboration.
- Our collaborators may reduce marketing or sales efforts, or discontinue marketing or sales of our products. This could reduce the revenues we receive on the products.
- Our collaborators may terminate their collaborations with us under certain circumstances. As a result, we may have to terminate the development of some drug candidates. This could also adversely affect perception of us in the business and financial communities and make it difficult for us to attract new collaborators.
- Our collaborators may pursue higher priority programs or change the focus of their development programs, which could affect the collaborator's commitment to us. Pharmaceutical and biotechnology companies re-evaluate their priorities from time to time, including following mergers and consolidations, which have been common in recent years in these industries.
- Disputes may arise between us and our collaborators from time to time regarding contractual or other matters. In 2006, we were engaged in a dispute with Endo with regard to the sharing of marketing expenses during the period prior to when Opana ER reaches profitability. In January 2007, we resolved our dispute as part of an amendment to the agreement. 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.

***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 substances in Opana ER, oxymorphone, is listed by the DEA as a Schedule II substance. Consequently, the manufacture, shipment, storage, sale and use of Opana ER

are subject to a higher degree of regulation. For example, all Schedule II drug prescriptions must be 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 substances used in Opana ER. As a result, Endo's procurement quota of the active drug substances 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 position and results of operations.

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

The pharmaceutical industry is highly competitive and is affected by new technologies, governmental regulations, health care legislations, 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; and
- collaborative arrangements in our target markets with leading companies and research institutions.

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

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

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

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

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

In order to obtain regulatory approvals for the commercial sale of our products, we or our collaborators will be required to complete clinical trials in humans to demonstrate the safety and efficacy of the products. However, we may not be able to commence or complete these clinical trials in any specified time period,

either because the FDA or other regulatory agencies object or for other reasons. With respect to our approved products, including Opana ER, we have relied on our collaborators to conduct clinical trials and obtain regulatory approvals. We intend to develop a significant portion of our current product candidates 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 independently sought or obtained approval for the marketing of a drug product.

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, in the approvable letter for Opana ER, the FDA required Endo to conduct an additional clinical trial which significantly delayed the approval of Opana ER. In another example, we terminated the development of PW2101, a beta blocker that we were developing for the treatment of hypertension and angina, because additional trials would have been required in order to address the concerns expressed in the non-approvable letter we received from the FDA in 2005. In addition, regulators may require post marketing testing and surveillance to monitor the safety and efficacy of a product.

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

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

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.

***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 on the drug of alcohol use, showed that when Palladone is taken with alcohol, the extended-release mechanism is harmed 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 alcohol has on the time release mechanism of the product. In the human testing in the presence of alcohol, Endo does not believe that there was evidence of dose-dumping or signs of degradation of the controlled-release mechanism. Endo did note in this human testing a transient effect on blood levels that Endo believes reflects a short-lived increase in the absorption rate of oxymorphone already released from the tablet.

***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. In certain cases when we seek to develop a controlled release formulation of a 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.

In addition, both before and after regulatory approval, we, our collaborators, our products, and our product candidates are subject to numerous FDA regulations covering testing, manufacturing, quality control, cGMP, adverse event reporting, labeling, advertising, promotion, distribution and export. We and our collaborators are subject to surveillance and periodic inspections 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.

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

Opana ER contains a narcotic ingredient. Misuse or abuse of drugs containing narcotic ingredients can lead to physical or other harm. In the past few years, for example, reporteded 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 regulations of Opana ER and subject us and Endo to litigation.

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

Our success depends in significant part on our ability to obtain patent protection for our products, both in the United States and in other countries, and our ability to enforce these patents. Patent positions can be uncertain and may involve complex legal and factual questions. Patents may not be issued from any patent applications that we own or license. If patents are issued, the claims allowed may not be as broad as we have anticipated and may not sufficiently cover our drug products or our technologies. In addition, issued patents that we own or license may be challenged, invalidated or circumvented. There is currently only one patent listed in the Orange Book for Opana ER, which expires in September 2008. We are currently prosecuting several additional patent applications that may cover Opana ER. However, there can be no assurance any of or all of these patent applications may be isssued.

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 profit 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 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 may file patent applications that claim technology also claimed by us, we or our collaborators may participate in interference or opposition proceedings to determine the priority of invention.
- If third parties initiate litigation claiming that our processes or products infringe their patent or other intellectual property rights, we and our collaborators will need to defend our rights in such proceedings.

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

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

compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

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

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

We believe that there are a limited number of manufacturers that comply with cGMP regulations who are capable of manufacturing our TIMERx materials. Although we have qualified alternate suppliers with respect to the xanthan gum and locust bean gums used to manufacture our TIMERx materials, we currently do not have a second supplier of TIMERx. 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 effected. 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 gums, in the presence of dextrose. These gums are also used in our Geminex, gastroretentive and SyncroDose drug delivery systems. We purchase these gums from a primary supplier. We have qualified alternate suppliers with respect to such materials, but we can provide no assurance that interruptions in supplies will not occur in the future. 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 health care system. Further proposals are likely. The finally 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 health care, 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 sales of pharmaceutical products. Product liability claims might be made by consumers, health care providers, other pharmaceutical companies, or third parties that sell our products. These claims may be made even with respect to those products that are manufactured in regulated facilities or that otherwise possess regulatory approval for commercial sale.

We are currently covered by a primary product liability insurance in amounts of $15 million per occurrence and $15 million annually in the aggregate on a claims-made basis, and by excess product liability insurance in the amount of $25 million. This coverage may not be adequate to cover all product liability claims. Product liability coverage is expensive. In the future, we may not be able to maintain or obtain such product liability insurance at a reasonable cost or in sufficient amounts to protect us against potential liability claims. Claims that are not covered by product liability insurance could have a material adverse effect on our business, financial condition and results of operations.

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

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

***The market price of our common stock may be volatile***

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

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

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

## ITEM 1B. *UNRESOLVED STAFF COMMENTS*

Not Applicable.

## ITEM 2. *PROPERTIES*

Our corporate offices comprise approximately 21,500 square feet and are located in Danbury, Connecticut. We lease these offices under a lease that currently expires on December 30, 2007, although we may extend this lease through December 30, 2008 by giving written notice by March 31, 2007.

We also lease research facilities, comprising approximately 15,500 square feet, in Patterson, New York, which we owned prior to the sale of our excipient business to Josef Rettenmaier Holding GmbH & Co. KG. in 2003. In November 2006, we exercised the third of three one year renewal options, extending the lease term to February 26, 2008.

The space we currently lease in Danbury, Connecticut and Patterson, New York is adequate for our present needs. We are exploring alternatives for new or additional space to meet our anticipated future requirements.

## ITEM 3. *LEGAL PROCEEDINGS*

Not Applicable.

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

Not Applicable.

## EXECUTIVE OFFICERS OF THE REGISTRANT

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

| Name | Age | Title | Dates |
|---|---|---|---|
| Jennifer L. Good | 42 | 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. | 52 | Senior Vice President, Licensing and Chief Scientific Officer | 2006 — current |
| | | Senior Vice President, Research & New Technology Development and Chief Scientific Officer | 1997 — 2006 |
| Benjamin L. Palleiko | 41 | Senior Vice President, Corporate Development and Chief Financial Officer | 2006 — current |
| | | Director, Investment Banking, SunTrust Robinson Humphrey | 2003 — 2006 |
| | | Vice President, Investment Banking, Robertson Stephens, Inc. | 2000 — 2002 |
| Thomas Sciascia, M.D. | 53 | 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 2006 and 2005 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 |
|---|---|---|
| **PERIOD 2006** | | |
| Quarter Ended March 31 | $23.70 | $19.00 |
| Quarter Ended June 30 | $23.10 | $15.73 |
| Quarter Ended September 30 | $22.74 | $16.20 |
| Quarter Ended December 31 | $19.35 | $15.67 |
| **PERIOD 2005** | | |
| Quarter Ended March 31 | $12.91 | $ 9.75 |
| Quarter Ended June 30 | $13.80 | $10.29 |
| Quarter Ended September 30 | $17.59 | $10.20 |
| Quarter Ended December 31 | $20.00 | $15.02 |

On March 9, 2007, we had 655 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 the senior secured credit facility. See "Sources of Liquidity" under the caption "Liquidity and Capital Resources" in "Item 7 — Management's Discussion and Analysis of Financial Condition and Results of Operations."

## ITEM 6. *SELECTED FINANCIAL DATA*

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

| | Year Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2006 | 2005 | 2004 | 2003 | 2002 |
| | (In thousands, except for per share data) | | | | |
| **STATEMENT OF OPERATIONS DATA:** | | | | | |
| Revenues | $ 3,499 | $ 6,213 | $ 5,108 | $ 4,678 | $ 5,537 |
| Cost of revenues | 231 | 39 | 104 | 169 | 170 |
| Gross profit | 3,268 | 6,174 | 5,004 | 4,509 | 5,367 |
| Selling, general and administrative | 14,075 | 13,247 | 9,485 | 10,361 | 7,568 |
| Research and product development | 22,857 | 17,797 | 20,205 | 20,590 | 16,955 |
| Loss from continuing operations before cumulative effect of change in accounting principle | (31,312) | (22,898) | (23,785) | (26,006) | (19,028) |
| Earnings from discontinued operations, net of income tax expense | — | — | — | 177 | 1,929 |
| Gain on sale of discontinued operations | — | — | — | 9,894 | — |
| Total discontinued operations | — | — | — | 10,071 | 1,929 |
| Net loss | $(31,312) | $(22,898) | $(23,785) | $(15,935) | $(17,099) |
| Basic and diluted loss per share: | | | | | |
| Continuing operations | $ (1.38) | $ (1.05) | $ (1.28) | $ (1.56) | $ (1.23) |
| Discontinued operations | — | — | — | 0.60 | 0.12 |
| Net loss per share | $ (1.38) | $ (1.05) | $ (1.28) | $ (0.96) | $ (1.11) |
| Weighted average shares of common stock outstanding | 22,751 | 21,711 | 18,627 | 16,678 | 15,462 |

| | December 31, | | | | |
|---|---|---|---|---|---|
| | 2006 | 2005 | 2004 | 2003 | 2002 |
| | (In thousands) | | | | |
| **BALANCE SHEET DATA:** | | | | | |
| Cash and cash equivalents | $ 16,182 | $ 15,917 | $ 14,249 | $ 8,241 | $ 1,629 |
| Marketable securities | 24,408 | 39,377 | 60,121 | 55,652 | 2,057 |
| Working capital | 38,254 | 53,912 | 71,946 | 60,697 | 26,355 |
| Total assets | 52,742 | 67,021 | 87,522 | 78,503 | 50,220 |
| Long term obligations-deferred compensation | 2,763 | 2,977 | 3,314 | 3,104 | 2,889 |
| Accumulated deficit | (172,428) | (141,116) | (118,218) | (94,433) | (78,025) |
| Shareholders' equity | 45,121 | 60,411 | 78,801 | 67,696 | 31,423 |

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

### Overview

We develop pharmaceutical products based on innovative proprietary drug delivery technologies with a focus on products that address disorders of the nervous system. In June 2006, the FDA approved for marketing Opana® ER, an extended release formulation of oxymorphone hydrochloride that we developed with Endo using our proprietary TIMERx drug delivery technology. We are currently developing product candidates designed for the treatment of pain, epilepsy, Parkinson's disease and spasticity, as well as a product candidate for the treatment of edema resulting from congestive heart failure.

Opana ER is an oral extended release opioid analgesic, which we developed with Endo using our proprietary TIMERx technology. Opana ER has been approved in the United States 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 is responsible for marketing Opana ER in the United States. The product was launched by Endo in the United States in July 2006 in 5mg, 10mg, 20mg and 40mg tablets.

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

We have incurred net losses since 1994. As of December 31, 2006, our accumulated deficit was approximately $172 million. We expect operating losses and negative cash flows to continue until substantial sales of Opana ER or other products developed using our drug delivery technologies occur. We currently generate revenues primarily from royalties received from Mylan. Our future profitability will depend on several factors, including:

- the commercial success of Opana ER, and the timing and amount of royalties from Endo's sales of Opana ER;
- the level of our investment in research and development activities;
- the successful development and commercialization of product candidates, other than Opana ER, in our portfolio;
- the level of investment for acquisitions or in-licensing of technologies or compounds intended to support our growth; and
- royalties from Mylan's sales of Pfizer's generic version of Procardia XL 30 mg.

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

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

Effective January 1, 2006, all share-based payments to employees and directors, including grants of stock options and grants under compensatory employee stock purchase plans, are being recognized as an expense in

the statement of operations based on their fair values as they are earned by the employees and directors under the vesting terms, in accordance with Statement of Financial Accounting Standards, or SFAS, No. 123R, "Share-Based Payment". The effect of our adoption of SFAS 123R was an additional $4.0 million of compensation expense, or approximately $.18 per share, basic and diluted, in the year ended December 31, 2006, substantially all related to employee and director stock options. Of such amount, $2.1 million and $1.9 million were recorded as selling, general and administrative, or SG&A, expense, and research and product development, or R&D, expense, respectively.

Total share-based compensation expense recognized in the years ended December 31, 2006 and 2005 was $5.0 million and $2.9 million, respectively.

## Critical Accounting Policies and Estimates

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

### *Revenue Recognition*

*Royalties and Licensing Fees*

We recognize revenues from non-refundable upfront licensing fees received under collaboration agreements ratably over the development period of the related collaboration agreement when this period involves development risk associated with the incomplete stage of a product's development, or over the estimated or contractual licensing and supply term when there exists an obligation to supply inventory for manufacture. Non-refundable milestone fees received for the development funding of a product are partially recognized upon receipt based on our proportionate development efforts achieved to date relative to the total expected development efforts and the remainder is generally recognized ratably over the remaining expected development period. The proportionate development efforts achieved are measured by estimating the percentage of work completed that is required of us in the development effort for the product. This estimate is primarily derived from the underlying project plans and timelines, developed by qualified personnel who work closely on such projects. In particular, we review output measures such as job specifications and tasks completed, compared to all such job specifications and tasks outlined for a particular project. Job specifications vary with each project and primarily include development activities regarding initial formulation work, manufacturing scale-up, proof-of-principle biostudies, clinical development and regulatory matters.

Non-refundable contractual fees received in connection with a collaborator's launch of a product are also recognized ratably over the estimated or contractual licensing and supply term. Upon termination of a collaboration agreement, any remaining non-refundable licensing fees we received which had been deferred, are generally recognized in full.

Product royalty fees are recognized when earned as reported by our collaborators, and are generally subject to our review or audit.

*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.

***Research and Development Expenses***

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

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

***Deferred Taxes — Valuation Allowance***

Valuation allowances are established against the recorded deferred income tax assets to the extent that we believe it is more likely than not that a portion of the deferred income tax assets are not realizable. While we may consider any potential future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for the valuation allowance, in the event we were to determine that we would be able to realize our deferred tax assets in the future in excess of our net recorded amount, an adjustment to the deferred tax asset would increase income in the period such determination was made. At December 31, 2006, we had recorded full valuation allowances totaling approximately $69.2 million against our net deferred tax assets, as we believe it more likely than not that our deferred income tax assets will not be realized due to our historical losses.

***Impairment of Long-Lived Assets***

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

***Share-Based Compensation***

Effective January 1, 2006, we adopted SFAS 123R, "Share-Based Payment" requiring the expense recognition of the estimated fair value of all share-based payments granted to employees and directors, including grants of stock options and grants under compensatory employee stock purchase plans. Prior to this, we did not record the estimated fair value associated with such awards as an expense, but rather, we disclosed

the estimated fair value in the notes to our financial statements as was permitted prior to our adoption of SFAS 123R. For the year ended December 31, 2006, we recorded approximately $5.0 million of expense associated with share-based payments, with the majority of this expense, approximately $4.0 million, attributable to employee and director stock options, and $771,000 attributable to restricted stock awards. As of December 31, 2006, there was approximately $4.4 million and $79,000 of unrecognized compensation cost related to stock option awards and outstanding restricted stock awards, respectively, that we expect to recognize as expense over a weighted average period of 1.1 years and 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, we used a Black-Scholes-Merton pricing model, which requires the consideration of the following variables for purposes of estimating fair value:

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

Of the variables above, we believe that the selection of an expected term and expected stock price volatility are the most subjective. We use historical employee exercise and option expiration data to estimate the expected term assumption for the Black-Scholes-Merton grant date valuation. We believe that this historical data is currently the best estimate of the expected term of a new option, and that generally, all groups of our employees exhibit similar exercise behavior. In general, the longer the expected term used in the Black-Scholes-Merton pricing model, the higher the grant-date fair value of the option. For options granted prior to 2006, we used historical volatility to estimate the grant-date fair value of stock options. Historical volatility is calculated based on a period equal to the expected term of stock option awards, and actual stock prices during this period. Following a review of alternative methods of estimating expected volatility, we changed our method of estimating expected volatility for all stock options granted after 2005 from exclusively relying on historical volatility to using an average of implied volatility and historical volatility. In accordance with SFAS 123R, we selected the average of implied volatility and historical volatility as we believe neither of these measures is better than the other in estimating the expected volatility of our common stock. We believe that our estimates, both expected term and stock price volatility, are reasonable in light of the historical data we analyzed.

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

Upon the adoption of SFAS 123R, we were also required to estimate the level of award forfeitures expected to occur, and record compensation cost only for those awards that are ultimately expected to vest. This requirement applies to all awards that are not yet vested, including awards granted prior to January 1, 2006. Accordingly, we performed a historical analysis of option awards that were forfeited (such as by

employee separation) prior to vesting, and ultimately recorded stock option expense that reflected this estimated forfeiture rate.

## Results of Operations for Years Ended December 31, 2006, 2005 and 2004

### *Revenues*

| | 2006 | Percentage Increase (Decrease) from 2005 | 2005 | Percentage Increase (Decrease) from 2004 | 2004 |
|---|---|---|---|---|---|
| | (In thousands, except percentages) | | | | |
| Royalty and Licensing Fees | $3,118 | (50)% | $6,213 | 27% | $4,882 |
| Product Sales | 381 | n/a | — | (100)% | 226 |
| Total Revenues | $3,499 | (44)% | $6,213 | 22% | $5,108 |

Substantially all of the royalty and licensing fees for 2006 and 2004 were generated from royalties received from Mylan. In 2005, royalties and licensing fees included $2.25 million in revenue recognized under our license agreement with Prism, which was terminated in the third quarter of 2005, and $3.9 million of royalties from Mylan on its sales of Pfizer's 30 mg generic version of Procardia XL. Royalties from Mylan decreased in 2006 as compared to 2005, and in 2005 as compared to 2004, as a result of a decrease in Mylan's net sales of Pfizer's 30 mg generic version of Procardia XL. We believe that the decrease from 2005 to 2006 was due to two of Mylan's customers purchasing significantly less product in 2006 than in 2005, as well as lower pricing overall. We believe that the decrease from 2004 to 2005 was due primarily to a reduction in sales volume attributable to reduced purchases by a single customer.

Product sales in 2006 and 2004 consisted of sales of formulated TIMERx to collaborators, with no comparable product sales occurring in 2005. Product sales in 2006 exclude shipments of TIMERx to Endo for use in Opana ER that occurred prior to FDA approval. We recognize the sales price and related costs of these pre-commercial shipments as offsets to research and development expense in accordance with our policy for cost-sharing arrangements, such as with Endo in connection with Opana ER. Following the FDA approval of Opana ER in June 2006, we recognized TIMERx shipments to Endo for use in Opana ER as product sales. As a result, we expect product sales to increase modestly in future periods.

### *Selling, General and Administrative Expense*

Selling , general and administrative, or SG&A, expenses increased by 6% in 2006 to $14.1 million as compared to $13.2 million in 2005. This increase was primarily due to increased compensation expense, primarily relating to the $2.1 million recorded for employee stock options resulting from our adoption of SFAS 123R effective January 1, 2006, as well as increased market research expenses associated with the review of several product candidates in our pipeline. In 2005, SG&A included a one-time charge of approximately $3.0 million that we recorded in connection with the agreement we entered into with Tod Hamachek, our former Chairman and Chief Executive Officer, upon his resignation in February 2005. This $3.0 million charge included a non-cash charge of approximately $2.4 million related to the accelerated vesting and extension of exercise periods of stock options held by Mr. Hamachek.

SG&A expenses increased by 40% in 2005 to $13.2 million as compared to $9.5 million in 2004. This increase was primarily due to the one-time charge of approximately $3.0 million in the first quarter of 2005 that we recorded in connection with the agreement with Mr. Hamachek noted above. The increase in SG&A expenses in 2005 was also due to increased professional fees of approximately $600,000, primarily related to market research activities, and increased directors' fees of approximately $345,000, of which approximately $280,000 was non-cash and related to stock-based compensation.

### *Research and Product Development Expenses*

Research and product development, or R&D, expenses increased by $5.1 million or 28% in 2006 as compared to 2005, primarily due to increased spending in 2006 on the development of nalbuphine ER and

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

Total R&D expense decreased by $2.4 million or 12% in 2005 as compared to 2004, primarily due to a decrease in spending on PW2101 in 2005. The decrease was partially offset by increased spending on our products in clinical development and on the development of other Phase I compounds intended for the treatment of disorders of the nervous system, increased compensation costs of research and product development personnel and a write-off of inventory primarily related to a change in specifications for our TIMERx material.

| | 2006 | Percentage Increase (Decrease) from 2005 | 2005 | Percentage Increase (Decrease) from 2004 | 2004 |
|---|---|---|---|---|---|
| | (In thousands, except percentages) | | | | |
| Nalbuphine ER | $ 4,211 | 256% | $ 1,184 | 451% | $ 215 |
| Torsemide ER | 2,196 | 111% | 1,043 | 181% | 371 |
| Venlafaxine ER | 639 | (31)% | 921 | 232% | 277 |
| PW2101 | — | (100)% | 1,817 | (80)% | 9,228 |
| Phase I Products, Internal Costs and Other | 13,596 | 22% | 11,154 | 53% | 7,296 |
| Research and New Technology Development | 2,215 | 32% | 1,678 | (40)% | 2,818 |
| Total Research and Product Development Expense | $22,857 | 28% | $17,797 | (12)% | $20,205 |

In the preceding table, R&D expenses are set forth in the following six categories:

- *Nalbuphine ER* — These expenses reflect our direct external expenses relating to the development of nalbuphine ER. These expenses approximated 18% of our R&D expenses in 2006, and consisted primarily of payments to third parties in connection with clinical trials of nalbuphine ER, including payments for drug active. The expenses for this compound increased in 2006 as compared to 2005 as we advanced the drug from Phase I through Phase IIa clinical trials and completed additional preparation for further clinical trials in 2007. We expect our R&D expenses on nalbuphine ER to increase in 2007 as we commence additional clinical trials, including a Phase I safety trial and Phase II chronic efficacy trial.

- *Torsemide ER* — These expenses reflect our direct external expenses relating to the development of torsemide ER. These expenses consisted primarily of payments to third parties in connection with clinical trials of torsemide ER, including payments for drug active, and approximated 10% of our R&D expenses in 2006. The expenses for this compound increased in 2006 as compared to 2005 as we conducted reformulation work and two additional Phase I studies to optimize the formulation and the delivery of the drug. We expect our expenses on torsemide ER to increase in 2007 if the Phase I study we conduct in the first half of 2007 confirms the targeted blood level profile and we commence a planned Phase II comparative trial.

- *Venlafaxine ER* — These expenses reflect our direct external expenses related to the development of venlafaxine ER. These expenses consisted primarily of payments to third parties in connection with the manufacture of venlafaxine ER, including payments for the drug active, and approximated 3% of our R&D expenses in 2006. During the second quarter of 2006, we ceased development work on this compound based on an assessment of the market opportunity and our estimated financial returns. We do not expect to incur additional R&D expenses with respect to venlafaxine ER in future periods.

- *PW2101* — These expenses reflect our direct external expenses relating to the development of PW2101. These expenses consisted primarily of payments to third parties in connection with clinical trials of PW2101, the manufacturing of PW2101, including our development work related to the qualification of an alternative manufacturing site, and the preparation of an NDA for PW2101. We received a nonapprovable letter on this drug in 2005, and we discontinued development work on PW2101 in the second quarter of 2005. We do not expect to incur additional R&D expenses with respect to PW2101 in future periods.

- *Phase I Products, Internal Costs and Other* — These expenses primarily reflect expenses such as salaries and benefits for our product development personnel, including our formulation, clinical and regulatory groups, and other costs primarily related to our laboratory facilities that are not allocated to specific programs. These expenses also reflect both our direct external expenses and our allocated internal expenses relating to the development of Phase I product candidates, and expenses incurred to support the approval of Opana ER of approximately $866,000 in 2006, which included expenses related to manufacturing process characterization of TIMERx for FDA compliance and in connection with our obligations under our agreement with Endo. Our direct external expenses primarily reflect payments to third parties for the drug active and proof-of-principle biostudies conducted on our Phase I products. These costs increased in 2006 as compared to 2005, primarily as a result of the recording of compensation expense related to employee stock options resulting from our adoption of SFAS 123R effective January 1, 2006. The increase was partially offset by a write-off of TIMERx inventory in the second quarter of 2005, primarily related to a change in specifications for TIMERx. We continually evaluate the Phase I product candidates we are developing, and may terminate or accelerate development of product candidates based on study results, product development risk, commercial opportunity, perceived time to market and other factors.

- *Research and New Technology Development* — These expenses reflect both our direct external expenses and our allocated internal expenses relating to research on new or existing technologies within the Company that support the product pipeline. These direct external expenses consist primarily of payments to third parties in connection with consulting and outside laboratory fees. Our internal expenses primarily include salaries and benefits of our research and new technology development group, and other costs such as depreciation on purchased equipment, and the amortization or any write-downs of patent costs, other than product patent write-offs charged directly to a product development project or amortization of patent costs relating to commercialized products which are included in cost of revenues. These expenses increased in 2006 as compared to 2005, primarily due to increased professional fees and amortization of patents associated with development programs.

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

***Tax Rates***

The effective tax rates for 2006, 2005 and 2004 were essentially zero. The effective tax rates are higher than the federal statutory rate of a 34% benefit due primarily to valuation allowances recorded to offset net deferred tax assets relating to our net operating losses, and foreign income taxes.

## Liquidity and Capital Resources

### *Sources of Liquidity*

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, the sale of our excipient business, sales of excipients, sales of formulated bulk TIMERx, royalties and milestone payments from Mylan and other collaborators, and advances under credit facilities. As of December 31, 2006, we had cash, cash equivalents and short-term investments of $40.6 million.

On March 13, 2007, we entered into a $24.0 million senior secured credit facility with Merrill Lynch Capital, a divison of Merrill Lynch Business Financial Services Inc. The credit facility consists of: (i) a $12.0 million term loan advanced upon the closing of the credit facility and (ii) a $12.0 million term loan that we may access until September 15, 2008, subject to conditions specified in the agreement. Under the agreement, we may not access this second amount unless our market capitalization at the time of the advance request is greater than $250 million. In connection with this credit facility, we granted the lender a perfected first priority security interest in all existing and after-acquired assets, excluding our intellectual property which is subject to a negative pledge; royalty payments from Mylan on their sales of Pfizer's generic version of Procardia XL 30mg, if we pledge such royalty payments to another lender; and up to $3,000,000 of equipment which we may, at our election, pledge to another lender in connection with an equipment financing facility separate from this credit facility. In addition, we are precluded from paying cash dividends to our shareholders during the term of the agreement. Each loan has a term of 42 months from the date of advance with interest-only payments for the first nine months, but in any event, not beyond September 30, 2008; interest plus monthly principal payments equal to 1.67% of the loan amount for the period from the end of the interest-only period through December 2008; and interest plus straight line amortization payments with respect to the remaining principal balance for the remainder of the term.

Amounts outstanding under the credit facility bear interest at an annual rate of one month LIBOR at the time of the advance plus 5%, which rate will be fixed for the term of the applicable loan. At the time of final payment of each loan under the credit facility, we will pay an exit fee of 3.0% of the original principal loan amount. We are also required to pay prepayment penalties of 3.0% of any prepaid amount in the first year, 2.0% of any prepaid amount in the second year and 1% of any prepaid amount thereafter. As of March 13, 2007, the interest rate on the credit facility was 10.32% and $12.0 million was outstanding.

### *Cash Flows*

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

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

In 2006 and 2005, financing activities provided $10.8 million and $1.5 million, respectively, in cash, substantially all due to net cash proceeds from stock option exercises.

On February 1, 2007, we entered into a termination agreement with Anand 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. We agreed to pay Dr. Baichwal $770,000 in cash and to issue 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 termination agreement with John 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. We agreed to pay Dr. Staniforth $770,000 in cash and to issue 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 Penwest.

Our Board of Directors approved the termination agreements entered into with Drs. Baichwal and Staniforth.

***Funding Requirements***

We anticipate that, based on our current operating plan and excluding any potential revenues from Opana ER, our existing capital resources, the credit facility noted above and anticipated internally generated funds from royalties from Mylan will be sufficient to fund our operations on an ongoing basis without requiring us to seek external financing until at least late 2008. We expect to invest approximately $750,000 for capital expenditures in 2007, primarily for laboratory equipment for our drug development activities.

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

- the commercial success of Opana ER and royalties received from Endo on sales of Opana ER;
- the timing and amount of payments received under collaborative agreements, including in particular our agreement with Endo with respect to Opana ER and our agreement with Mylan with respect to Pfizer's generic Procardia XL 30 mg;
- the progress of our collaborative and independent development projects, funding obligations with respect to the projects, and the related costs to us of clinical studies for our products;
- the level of investment for the acquisition or in-licensing of technologies or compounds intended to support our growth;
- the structure and terms of any future collaborative agreements;
- the prosecution, defense and enforcement of our patents and other intellectual property rights; and
- the level of our investment in capital expenditures for facilities or equipment.

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

We plan to meet our long-term cash requirements through our existing cash balance, the credit facility noted above, revenues from collaborative agreements, as well as through equity or debt financings. In July 2005, we filed a registration statement on Form S-3 with the SEC, which became effective on August 17, 2005. This shelf registration statement covers the issuance and sale by us, of any combination of common stock, preferred stock, debt securities and warrants having an aggregate purchase price of up to $75 million.

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 with third parties, it may be necessary to relinquish valuable rights to our technologies, research programs or potential product, or grant licenses on terms that may not be favorable to us. We cannot be certain that additional financing will be available in amounts or on terms acceptable to us, if at all. If we are unable to obtain this additional financing, we may be required to delay, reduce the scope of, or eliminate one or more of our planned research, development and commercialization activities, which could harm our financial condition and operating results.

***Contractual Obligations***

Our outstanding contractual cash obligations include obligations under our operating leases primarily for facilities, purchase obligations primarily relating to clinical development and obligations under deferred compensation plans as discussed below. Following is a table summarizing our contractual obligations as of December 31, 2006 (in thousands).

| | Total | Less than One Year | 1-3 Years | 4-5 Years | After 5 Years |
|---|---|---|---|---|---|
| Operating Leases | $ 797 | $ 765 | $ 32 | $ — | $ — |
| Purchase Obligations | 3,645 | 3,645 | — | — | — |
| Deferred Compensation, including current portion | 3,053 | 294 | 588 | 588 | 1,583 |
| Total | $7,495 | $4,704 | $620 | $588 | $1,583 |

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, 2006, trust assets comprised of the cash surrender value of these life insurance polices totaling $2.7 million and $2,000 held in a money market account.

**Net Operating Loss Carryforwards**

As of December 31, 2006, we had federal net operating loss, or NOL, carryforwards of approximately $161.3 million for income tax purposes, of which approximately $6.2 million, $8.4 million, $9.1 million, $17.7 million, $19.4 million, $13.5 million, $22.8 million, $21.8 million and $42.4 million expire in 2018, 2019, 2020, 2021, 2022, 2023, 2024, 2025 and 2026, respectively. In addition, we had research and development tax credit carryforwards of approximately $5.3 million of which $67,000, $359,000, $341,000, $777,000, $828,000, $858,000, $760,000, $669,000 and $650,000 expire in 2018, 2019, 2020, 2021, 2022, 2023, 2024, 2025 and 2026, respectively. The use of the NOLs and research and development tax credit carryforwards are limited to our future taxable earnings. For financial reporting purposes, as of December 31, 2006, a valuation allowance of $62.7 million has been recognized to offset net deferred tax assets, primarily attributable to the NOL carryforward. The change in the valuation allowance in 2006 was an increase of $14.3 million. Utilization of the operating losses is subject to a limitation due to the ownership change provisions of the Internal Revenue Code.

**Market Risk and Risk Management Policies**

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

The primary objectives for our investment portfolio are liquidity and safety of principal. Investments are made to achieve the highest rate of return, 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, 2006, our marketable securities consisted primarily of corporate debt and U.S. - Government-agency backed discounted notes, and approximated $24.4 million. These marketable securities had maturity dates of up to six months. Due to the relatively short-term maturities of these securities, management believes there is no significant market risk. As of December 31, 2006, market values approximated carrying values. As of December 31, 2006, we had approximately $40.6 million in cash, cash equivalents and short-term investments, and accordingly, a sustained decrease in the rate of interest earned of 1% would have caused a decrease in the annual amount of interest earned of up to approximately $406,000.

As of December 31, 2005, our marketable securities consisted primarily of corporate debt and U.S. Government-agency backed discounted notes and approximated $39.4 million.

**Recent Accounting Pronouncements**

In February 2007, the FASB issued SFAS No. 159 "The Fair Value Option for Financial Assets and Financial Liabilities — Including an Amendment of FASB Statement No. 115." SFAS No. 159 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. The Company is in the process of evaluating the impact this pronouncement may have on its results of operations and financial position.

In September 2006, the FASB issued 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. SFAS No. 158 is effective as of the end of fiscal years ending after December 15, 2006; therefore, the Company adopted the recognition and disclosure provisions of SFAS No. 158 on December 31, 2006. The effect of adopting SFAS No. 158 on the Company's financial position was to decrease the liability under its SERP and to increase accumulated other comprehensive income by $110,000. SFAS No. 158 had no effect on the Company's financial position as of December 31, 2005 (see Note 12).

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements." SFAS No. 157 provides a common definition of fair value to be applied to existing GAAP requiring the use of fair value measures, establishes a framework for measuring fair value and enhances disclosure about fair value measures under other accounting pronouncements. However, SFAS No. 157 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 fiscal years beginning after November 15, 2007, and, as such, the Company plans to adopt the provisions of SFAS No. 157 on January 1, 2008. The Company is in the process of evaluating the effect the adoption of this pronouncement will have on its results of operations, financial position and cash flows.

In June 2006, the FASB issued Interpretation No. 48, "Accounting for Uncertainty in Income Taxes", an interpretation of FASB Statement No. 109, "Accounting for Income Taxes" ("FIN 48"), to create a single model to address accounting for uncertainty in tax positions. FIN 48 clarifies the accounting for income taxes by prescribing a minimum recognition threshold that a tax position is required to meet before being recognized in the financial statements. FIN 48 also provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company will adopt FIN 48 as of January 1, 2007, as required. The Company is in the process of evaluating the effect the adoption of this interpretation will have on its results of operations, financial position and cash flows.

In June 2005, the FASB issued SFAS No. 154, "Accounting Changes and Error Corrections-a replacement of APB Opinion No. 20 and FASB Statement No. 3". SFAS No. 154 replaces APB Opinion No. 20, "Accounting Changes", and FASB Statement No. 3, "Reporting Accounting Changes in Interim Financial Statements", and changes the requirements for the accounting and reporting of a change in accounting principle. SFAS No. 154 applies to all voluntary changes in accounting principle and to changes required by an accounting pronouncement in the unusual instance that the pronouncement does not include specific transition provisions. SFAS No. 154 also requires that a change in depreciation, amortization, or depletion method for long-lived, nonfinancial assets be accounted for as a change in accounting estimate effected by a change in accounting principle. SFAS No. 154 requires that the change in accounting principle be applied to the balances of assets and liabilities as of the beginning of the earliest period for which retrospective application is practicable and that a corresponding adjustment be made to the opening balance of retained earnings for that period, rather than being reported in an income statement. Such a change would require a company to restate its previously issued financial statements to reflect the change in accounting principle to prior periods presented. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. Our adoption of SFAS No. 154 on January 1, 2006 had no effect on the Company's results of operations, financial position and cash flows.

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs — an amendment of ARB No. 43, Chapter 4". This Statement amends the guidance in ARB No. 43, Chapter 4, "Inventory Pricing," to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). Paragraph 5 of ARB 43, Chapter 4, previously stated that ". . .under some circumstances, items such as idle facility expense, excessive spoilage, double freight, and rehandling costs may be so abnormal as to require treatment as current period charges. . ." This Statement requires that those items be recognized as current-period charges regardless of whether they meet the criterion of "so abnormal." In addition, this Statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The provisions of this Statement shall be effective for inventory costs incurred during fiscal years beginning after June 15, 2005. Our adoption of SFAS No. 151 on January 1, 2006 had no effect on the Company's results of operations, financial position and 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.

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

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

## ITEM 8. *FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA*

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

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

None.

## ITEM 9A. *CONTROLS AND PROCEDURES*

(a) *Evaluation of Disclosure Controls and Procedures.* Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2006. 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, 2006, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

(b) *Changes in Internal Control Over Financial Reporting.* No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act) occurred during the fiscal quarter ended December 31, 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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

**Management's Annual Report on Internal Control Over Financial Reporting**

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

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

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

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2006. 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, 2006, our internal control over financial reporting is effective based on those criteria.

Management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2006 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which appears below.

## Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders
Penwest Pharmaceuticals Co.

We have audited management's assessment, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting that Penwest Pharmaceuticals Co. maintained effective internal control over financial reporting as of December 31, 2006, 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. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of 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, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, 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, management's assessment that Penwest Pharmaceuticals Co. maintained effective internal control over financial reporting as of December 31, 2006, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Penwest Pharmaceuticals Co. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of Penwest Pharmaceuticals Co. as of December 31, 2006 and 2005, and the related statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2006 and our report dated March 13, 2007 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Stamford, Connecticut
March 13, 2007

## ITEM 9B. *OTHER INFORMATION*

On March 13, 2007, we entered into a credit and security agreement with Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services Inc., as Lender and Administrative Agent. A description of the terms of the agreement is included under "Sources of Liquidity" under the caption "Liquidity and Capital Resources" in "Item 7 — Management's Discussion and Analysis of Financial Condition and Results of Operations."

# 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 2007 annual meeting of shareholders under the captions "Discussion of Proposals," "Information About Corporate Governance," "Information About Our Executive Officers" 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 its 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 2007 proxy statement under the captions "Corporate Governance," "Information About Our Executive Officers" and "Other Information" 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 2007 proxy statement under the captions "Information About Our Executive Officers" 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 2007 proxy statement under the caption "Information About Our Executive Officers" 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 2007 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, 2006 and 2005 and the related statements of operations, cash flows and shareholders' equity for each of the three years in the period ended December 31, 2006.

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 13, 2007

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<br>Jennifer L. Good | President and Chief Executive Officer, Director (principle executive officer) | Date: March 13, 2007 |
| /s/ Benjamin L. Palleiko<br>Benjamin L. Palleiko | Senior Vice President, Corporate Development and Chief Financial Officer (principal financial and accounting officer) | Date: March 13, 2007 |
| /s/ Paul E. Freiman<br>Paul E. Freiman | Chairman of the Board | Date: March 13, 2007 |
| /s/ Peter F. Drake<br>Peter F. Drake, Ph.D. | Director | Date: March 13, 2007 |
| /s/ Rolf H. Henel<br>Rolf H. Henel | Director | Date: March 13, 2007 |
| /s/ Robert J. Hennessey<br>Robert J. Hennessey | Director | Date: March 13, 2007 |
| /s/ David P. Meeker<br>David P. Meeker, M.D. | Director | Date: March 13, 2007 |
| /s/ John N. Staniforth<br>John N. Staniforth, Ph.D. | Director | Date: March 13, 2007 |
| /s/ Anne M. VanLent<br>Anne M. VanLent | Director | Date: March 13, 2007 |

## APPENDIX A

## PENWEST PHARMACEUTICALS CO.

## INDEX TO FINANCIAL STATEMENTS AND FINANCIAL STATEMENT SCHEDULE


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## 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, 2006 and 2005, and the related statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2006. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Penwest Pharmaceuticals Co. at December 31, 2006 and 2005, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2006, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

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

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Penwest Pharmaceuticals Co.'s internal control over financial reporting as of December 31, 2006, 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 13, 2007 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Stamford, Connecticut
March 13, 2007

## PENWEST PHARMACEUTICALS CO.

## BALANCE SHEETS

| | December 31, 2006 | December 31, 2005 |
|---|---|---|
| | (In thousands, except share amounts) | |
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 16,182 | $ 15,917 |
| Marketable securities | 24,408 | 39,377 |
| Trade accounts receivable | 683 | 942 |
| Inventories | 201 | 140 |
| Prepaid expenses and other current assets | 1,595 | 1,112 |
| Total current assets | 43,069 | 57,488 |
| Fixed assets, net | 3,787 | 2,990 |
| Patents, net | 3,184 | 3,383 |
| Other assets | 2,702 | 3,160 |
| Total assets | $ 52,742 | $ 67,021 |
| **LIABILITIES AND SHAREHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,324 | $ 1,064 |
| Accrued expenses | 2,096 | 1,722 |
| Accrued development costs | 1,105 | 499 |
| Deferred compensation — current portion | 290 | 291 |
| Total current liabilities | 4,815 | 3,576 |
| Deferred revenue | 43 | 57 |
| Deferred compensation | 2,763 | 2,977 |
| Total liabilities | 7,621 | 6,610 |
| Shareholders' equity: | | |
| Preferred stock, par value $.001, authorized 1,000,000 shares, none outstanding | — | — |
| Common stock, par value $.001, authorized 60,000,000 shares, issued and outstanding 23,132,815 shares at December 31, 2006 and 21,889,940 shares at December 31, 2005 | 23 | 22 |
| Additional paid in capital | 217,427 | 201,659 |
| Accumulated deficit | (172,428) | (141,116) |
| Accumulated other comprehensive income (loss) | 99 | (154) |
| Total shareholders' equity | 45,121 | 60,411 |
| Total liabilities and shareholders' equity | $ 52,742 | $ 67,021 |

See accompanying notes

## PENWEST PHARMACEUTICALS CO.

## STATEMENTS OF OPERATIONS

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2006 | 2005 | 2004 |
| | (In thousands, except per share data) | | |
| Revenues: | | | |
| Royalties and licensing fees | $ 3,118 | $ 6,213 | $ 4,882 |
| Product sales | 381 | — | 226 |
| Total revenues | 3,499 | 6,213 | 5,108 |
| Cost of revenues | 231 | 39 | 104 |
| Gross profit | 3,268 | 6,174 | 5,004 |
| Operating expenses: | | | |
| Selling, general and administrative | 14,075 | 13,247 | 9,485 |
| Research and product development | 22,857 | 17,797 | 20,205 |
| Total operating expenses | 36,932 | 31,044 | 29,690 |
| Loss from operations | (33,664) | (24,870) | (24,686) |
| Investment income | 2,352 | 1,974 | 906 |
| Loss before income tax expense | (31,312) | (22,896) | (23,780) |
| Income tax expense | — | 2 | 5 |
| Net loss | $(31,312) | $(22,898) | $(23,785) |
| Basic and diluted net loss per common share | $ (1.38) | $ (1.05) | $ (1.28) |
| Weighted average shares of common stock outstanding | 22,751 | 21,711 | 18,627 |

See accompanying notes

## PENWEST PHARMACEUTICALS CO.

## STATEMENTS OF SHAREHOLDERS' EQUITY

| | Common Stock Shares | Common Stock Amount | Additional Paid-In Capital | Accumulated Deficit | Accumulated Other Comprehensive (Loss) Income | Total |
|---|---|---|---|---|---|---|
| | | | | (In thousands) | | |
| Balances, December 31, 2003 | 18,423 | $18 | $162,068 | $ (94,433) | $ 43 | $ 67,696 |
| Net loss | — | — | — | (23,785) | — | (23,785) |
| Changes in unrealized gain/loss on marketable securities | — | — | — | — | (143) | (143) |
| Comprehensive loss | — | — | — | — | — | (23,928) |
| Issuance of common stock pursuant to an equity financing, net | 3,125 | 4 | 32,795 | — | — | 32,799 |
| Issuance of common stock pursuant to stock compensation plans | 130 | — | 2,081 | — | — | 2,081 |
| Issuance of common stock pursuant to Stock Purchase Plan | 15 | — | 153 | — | — | 153 |
| Balances, December 31, 2004 | 21,693 | 22 | 197,097 | (118,218) | (100) | 78,801 |
| Net loss | — | — | — | (22,898) | — | (22,898) |
| Changes in unrealized loss on marketable securities | — | — | — | — | (54) | (54) |
| Comprehensive loss | — | — | — | — | — | (22,952) |
| Issuance of common stock pursuant to stock compensation plans | 183 | — | 2,027 | — | — | 2,027 |
| Stock compensation charge in connection with modification of stock options | — | — | 2,398 | — | — | 2,398 |
| Issuance of common stock pursuant to Stock Purchase Plan | 14 | — | 137 | — | — | 137 |
| Balances, December 31, 2005 | 21,890 | 22 | 201,659 | (141,116) | (154) | 60,411 |
| Net loss | — | — | — | (31,312) | — | (31,312) |
| Changes in unrealized loss on marketable securities | — | — | — | — | 143 | 143 |
| Comprehensive loss | — | — | — | — | — | (31,169) |
| Transition adjustment for funded status of post retirement plan | — | — | — | — | 110 | 110 |
| Issuance of common stock pursuant to stock compensation plans | 1,233 | 1 | 11,511 | — | — | 11,512 |
| Stock compensation charges in connection with stock options and Stock Purchase Plan | — | — | 4,098 | — | — | 4,098 |
| Issuance of common stock pursuant to Stock Purchase Plan | 10 | — | 159 | — | — | 159 |
| Balances, December 31, 2006 | 23,133 | $23 | $217,427 | $(172,428) | $ 99 | $ 45,121 |

See accompanying notes

## PENWEST PHARMACEUTICALS CO.

## STATEMENTS OF CASH FLOWS

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2006 | 2005 | 2004 |
| | | (In thousands) | |
| Operating activities: | | | |
| Net loss | $(31,312) | $(22,898) | $(23,785) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation | 1,001 | 987 | 1,042 |
| Amortization of patents | 565 | 464 | 410 |
| Inventory reserves | — | 497 | 75 |
| Patent impairment losses | 254 | 137 | 417 |
| Deferred revenue | (14) | (14) | (14) |
| Deferred compensation | 190 | 194 | 211 |
| Stock compensation | 4,978 | 3,083 | 297 |
| Changes in operating assets and liabilities: | | | |
| Trade accounts receivable | 259 | 184 | 27 |
| Inventories | (61) | 5 | (62) |
| Accounts payable, accrued expenses and other | 497 | (2,700) | (1,505) |
| Net cash used in operating activities | (23,643) | (20,061) | (22,887) |
| Investing activities: | | | |
| Proceeds from sale of discontinued operations | — | — | 1,250 |
| Acquisitions of fixed assets, net | (1,818) | (276) | (1,226) |
| Patent costs | (619) | (479) | (643) |
| Purchases of marketable securities | (27,739) | (51,499) | (57,681) |
| Proceeds from maturities of marketable securities | 41,248 | 47,054 | 17,795 |
| Proceeds from sales of marketable securities | 1,600 | 25,450 | 35,150 |
| Proceeds from cash surrender value of life insurance policy withdrawal | 446 | — | — |
| Net cash provided by (used in) investing activities | 13,118 | 20,250 | (5,355) |
| Financing activities: | | | |
| Issuance of common stock, net | 10,790 | 1,479 | 34,250 |
| Net cash provided by financing activities | 10,790 | 1,479 | 34,250 |
| Net increase in cash and cash equivalents | 265 | 1,668 | 6,008 |
| Cash and cash equivalents at beginning of year | 15,917 | 14,249 | 8,241 |
| Cash and cash equivalents at end of year | $ 16,182 | $ 15,917 | $ 14,249 |

See accompanying notes

## 1. BUSINESS

Penwest Pharmaceuticals Co. (the "Company" or "Penwest") develops pharmaceutical products based on innovative proprietary drug delivery technologies with a focus on products that address disorders of the nervous system. On June 22, 2006, the United States Food and Drug Administration (the "FDA"), approved Opana® ER, which the Company previously referred to as oxymorphone ER. Opana ER is an extended release formulation of oxymorphone that the Company developed with Endo Pharmaceuticals Inc. ("Endo") using the Company's proprietary TIMERx drug delivery technology. Opana ER is approved for twice-a-day dosing in patients with moderate to severe pain requiring continuous, around-the-clock opioid therapy for an extended period of time. The Company is also developing additional product candidates designed for the treatment of pain, epilepsy, Parkinson's disease and spasticity, as well as a product candidate designed for the treatment of edema resulting from congestive heart failure. The Company conducts its business primarily in North America.

The Company has incurred net losses since 1994. As of December 31, 2006, the Company's accumulated deficit was approximately $172 million. The Company expects operating losses and negative cash flows to continue until substantial sales of Opana ER or other products commercialized utilizing TIMERx technology or other technologies occur. The Company's revenues for 2004, 2005 and 2006 were generated primarily from royalties received from Mylan Pharmaceuticals Inc ("Mylan"). The Company's future profitability will depend on several factors, including: the commercial success of Opana ER, and the timing and amount of royalties from Endo's sales of Opana ER; the level of our investment in research and development activities; the successful development and commercialization of product candidates other than Opana ER in our portfolio; the level of investment for acquisitions or in-licensing of technologies or compounds intended to support our growth; and royalties from Mylan's sales of Pfizer, Inc's. ("Pfizer") 30 mg. generic version of Procardia XL.

The Company is subject to the risks and uncertainties associated with drug development. These risks and uncertainties include, but are not limited to, a history of net losses, technological changes, dependence on collaborators and key personnel, the successful completion of development efforts and obtaining regulatory approval, the successful commercialization of products compliant with government regulations, patent infringement litigation, competition from current and potential competitors, dependence on third party manufacturers and a requirement for additional funding.

## 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.

### *Cash and Cash Equivalents*

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

### *Marketable Securities*

The Company accounts for marketable securities in accordance with Statement of Financial Accounting Standards ("SFAS") No. 115, "Accounting for Certain Investments in Debt and Equity Securities." The Company classifies its marketable securities as available-for-sale securities. Such securities are stated at fair value and primarily consist of corporate bonds, commercial paper and discounted notes backed by U.S. government agencies. Unrealized holding gains or losses are included in shareholders' equity as a separate component

of accumulated other comprehensive income (loss). The specific identification method is used to compute the realized gains and losses, if any, on marketable securities.

***Credit Risk and Fair Value of Financial Instruments***

The Company performs ongoing credit evaluations of its customers and generally does not require collateral. Revenues from product sales and licensing fees are primarily derived from major pharmaceutical companies that generally have significant cash resources. Allowances for doubtful accounts receivable are maintained based on historical payment patterns, aging of accounts receivable and actual write-off history. As of December 31, 2006 and December 31, 2005, no allowances for doubtful accounts were recorded by the Company. One customer of the Company accounted for approximately 89%, 63% and 94% of total revenues in 2006, 2005 and 2004, respectively. Another customer of the Company accounted for approximately 36% of total revenues for 2005.

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

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

***Inventories***

Inventories, which consist of raw materials and manufactured bulk TIMERx finished products, are stated at the lower of cost (first-in, first-out) or market. The costs of any such raw materials and finished products 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-commercial 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 sales were not material in 2006, 2005 or 2004.

***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 each year in the three year period ended December 31, 2006.

***Accumulated Other Comprehensive Income (Loss)***

Accumulated other comprehensive income (loss) at December 31, 2006 consisted of the transition adjustment for the funded status of the Company's Supplemental Executive Retirement Plan ("SERP") recorded in connection with the adoption of SFAS 158 (see Note 3) and unrealized losses on marketable securities. Accumulated other comprehensive income (loss) at December 31, 2005 and 2004 consisted of unrealized losses on marketable securities.

***Income Taxes***

The liability method, prescribed by SFAS No. 109, "Accounting for Income Taxes," is used in accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities. The Company recorded no income tax benefits relating to the net operating losses generated during 2006, 2005 and 2004, 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.

***Revenue Recognition***

*Royalties and licensing fees* — The Company recognizes revenues from non-refundable upfront licensing fees received under collaboration agreements ratably over the development period of the related collaboration agreement when this period involves development risk associated with the incomplete stage of a product's development, or over the estimated or contractual licensing and supply term when there exists an obligation to supply inventory for manufacture. Non-refundable milestone fees received for the development funding of a product are partially recognized upon receipt based on the Company's proportionate development efforts achieved to date relative to the total expected development efforts and the remainder is generally recognized ratably over the remaining expected development period. The proportionate development efforts achieved are measured by estimating the percentage of work completed that is required of the Company in the development effort for the product. This estimate is primarily derived from the underlying project plans and timelines, developed by qualified personnel who work closely on such projects. In particular, the Company reviews output measures such as job specifications and tasks completed, compared to all such job specifications and tasks outlined for a particular project. Job specifications vary with each project and primarily include development activities regarding initial formulation work, manufacturing scale-up, proof-of-principle biostudies, clinical development and regulatory matters. Non-refundable contractual fees received in connection with a collaborator's launch of a product are also recognized ratably over the estimated or contractual licensing and supply term. Upon termination of a collaboration agreement, any remaining non-refundable licensing fees received by the Company, which had been deferred, are generally recognized in full. Product royalty fees are recognized when earned, as reported by our collaborators, and are generally subject to review or audit by the Company.

*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 cost of revenues.

*Research and Development Expenses*

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

*Per Share Data*

Loss per common share is computed based on the weighted average number of shares of common stock outstanding during the period. For all years reported, diluted loss per share was the equivalent of basic loss per share due to the respective net losses. No dilution for common stock equivalents is included in 2006, 2005 and 2004 as the effects would be antidilutive. Such securities, excluded due to their antidilutive effect, are as follows:

| | December 31, | | |
|---|---|---|---|
| | 2006 | 2005 | 2004 |
| | (In thousands of shares) | | |
| Stock options outstanding | 2,267 | 3,016 | 2,647 |
| Restricted stock outstanding (unvested) | 52 | 68 | 50 |
| | 2,319 | 3,084 | 2,697 |

*Share-Based Compensation*

Effective January 1, 2006, the Company adopted SFAS No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123R") using the modified prospective transition method. SFAS 123R requires all share-based payments to employees, including grants of employee stock options as well as grants under 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. Pro forma disclosure of stock-based compensation expense, as was the Company's practice under SFAS 123, "Accounting for Stock-Based Compensation", is no longer permitted (see Note 8).

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, an option pricing model is utilized to derive an estimated fair value. In calculating the estimated fair value of stock options granted, a Black-Scholes-Merton pricing model is used which requires the consideration of the following variables for purposes of estimating fair value:

- the stock option exercise price;
- the expected term of the option;
- the grant date price of the Company's common stock, which is issuable upon exercise of the option;
- the expected volatility of the Company's common stock;

- expected dividends on the Company's common stock (the Company does not anticipate paying dividends for the foreseeable future); and
- the risk free interest rate for the expected option term.

Of the variables above, the Company believes that the selection of an expected term and expected stock price volatility are the most subjective. The Company uses historical employee exercise and option expiration data to estimate the expected term assumption for the Black-Scholes-Merton grant date valuation. The Company believes that this historical data is currently the best estimate of the expected term of a new option, and that generally, all groups of its employees exhibit similar exercise behavior. In general, the longer the expected term used in the Black-Scholes-Merton pricing model, the higher the grant-date fair value of the option. For options granted prior to 2006, the Company used historical volatility to estimate the grant-date fair value of stock options. Historical volatility is calculated based on a period equal to the expected term of stock option awards, and actual stock prices during this period. Following a review of alternative methods of estimating expected volatility, the Company changed its method of estimating expected volatility for all stock options granted after 2005 from exclusively relying on historical volatility to using an average of implied volatility and historical volatility. In accordance with SFAS 123R, the Company selected the average of implied volatility and historical volatility as it believes neither of these measures is better than the other in estimating the expected volatility of the Company's common stock. The Company believes that its estimates, both expected term and stock price volatility, are reasonable in light of the historical data analyzed.

The valuation assumptions selected upon the adoption of SFAS 123R were applied to stock options that the Company granted subsequent to its adoption of SFAS 123R; however, stock option expense recorded in the year ended December 31, 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 Company uses the accelerated attribution method to recognize expense for all options granted.

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

## 3. RECENT ACCOUNTING PRONOUNCEMENTS

In February 2007, the FASB issued SFAS 159 "The Fair Value Option for Financial Assets and Financial Liabilities — Including an amendment of FASB Statement No. 115". 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. The Company is in the process of evaluating the impact this pronouncement may have on its results of operations and financial position.

In September 2006, the FASB issued 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. SFAS No. 158 is effective as of the end of fiscal years ending after December 15, 2006; therefore, the Company adopted the recognition and disclosure provisions of SFAS No. 158 at December 31, 2006. The effect of adopting SFAS No. 158 on the Company's financial position was to decrease the liability under its SERP and to increase accumulated other comprehensive income by $110,000. SFAS No. 158 had no effect on the Company's financial position as of December 31, 2005 (see Note 12).

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements". SFAS No. 157 provides a common definition of fair value to be applied to existing GAAP requiring the use of fair value measures, establishes a framework for measuring fair value and enhances disclosure about fair value measures under other accounting pronouncements, but does not change existing guidance as to whether or not an asset or liability is carried at fair value. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007, and, as such, the Company plans to adopt the provisions of SFAS No. 157 on January 1, 2008. The Company is in the process of evaluating the effect the adoption of this pronouncement will have on its results of operations, financial position and cash flows.

In June 2006, the FASB issued Interpretation No. 48, "Accounting for Uncertainty in Income Taxes", an interpretation of FASB Statement No. 109, "Accounting for Income Taxes" ("FIN 48"), to create a single model to address accounting for uncertainty in tax positions. FIN 48 clarifies the accounting for income taxes, by prescribing a minimum recognition threshold that a tax position is required to meet before being recognized in the financial statements. FIN 48 also provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company will adopt FIN 48 as of January 1, 2007, as required. The Company is in the process of evaluating the effect the adoption of this interpretation will have on its results of operations, financial position and cash flows.

In June 2005, the FASB issued SFAS No. 154, "Accounting Changes and Error Corrections-a replacement of APB Opinion No. 20 and FASB Statement No. 3". This standard replaces APB Opinion No. 20, "Accounting Changes", and FASB Statement No. 3, "Reporting Accounting Changes in Interim Financial Statements", and changes the requirements for the accounting and reporting of a change in accounting principle. SFAS No. 154 applies to all voluntary changes in accounting principle and to changes required by an accounting pronouncement in the unusual instance that the pronouncement does not include specific transition provisions. SFAS No. 154 also requires that a change in depreciation, amortization, or depletion method for long-lived, nonfinancial assets be accounted for as a change in accounting estimate effected by a change in accounting principle. SFAS No. 154 requires that the change in accounting principle be applied to the balances of assets and liabilities as of the beginning of the earliest period for which retrospective application is practicable and that a corresponding adjustment be made to the opening balance of retained earnings for that period, rather than being reported in an income statement. Such a change would require a company to restate its previously issued financial statements to reflect the change in accounting principle to prior periods presented. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The adoption of SFAS No. 154 had no effect on the Company's results of operations, financial position and cash flows.

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs — an amendment of ARB No. 43, Chapter 4". This Statement amends the guidance in ARB No. 43, Chapter 4, "Inventory Pricing," to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). Paragraph 5 of ARB 43, Chapter 4, previously stated that ". . .under some circumstances, items such as idle facility expense, excessive spoilage, double freight, and rehandling costs may be so abnormal as to require treatment as current period charges. . ." This Statement requires that those items be recognized as current-period charges regardless of whether they meet the criterion of "so abnormal." In addition, this Statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The provisions of this Statement shall be effective for inventory

costs incurred during fiscal years beginning after June 15, 2005. The adoption of SFAS No. 151 had no effect on the Company's results of operations, financial position and 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

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

| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Estimated Fair Value |
|---|---|---|---|---|
| | | (In thousands) | | |
| December 31, 2006: | | | | |
| Corporate debt securities | $21,381 | $ 3 | $ 10 | $21,374 |
| U.S. government agency-backed discounted notes | 3,038 | — | 4 | 3,034 |
| Total marketable securities | $24,419 | $ 3 | $ 14 | $24,408 |
| December 31, 2005: | | | | |
| Corporate debt securities | $32,472 | $— | $113 | $32,359 |
| U.S. government agency-backed discounted notes | 7,059 | — | 41 | 7,018 |
| Total marketable securities | $39,531 | $— | $154 | $39,377 |

Maturities of marketable securities at fair value as of December 31, 2006, are as follows (in thousands):

| | |
|---|---|
| Contractual maturity — maturing in one year or less | $24,408 |

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

A decline in the market value of any security below cost that is deemed to be other than temporary results in a reduction in carrying amount to fair value. Such impairments are charged to the results of operations and a new cost basis for the security is established. Unrealized losses on marketable securities held at December 31, 2006 and 2005 were not deemed other than temporary, as all such securities are investment grade, and management believes the impairments are attributable to increased market rates.

## 5. INVENTORIES

Inventories are summarized as follows:

| | December 31, | |
|---|---|---|
| | 2006 | 2005 |
| | (In thousands) | |
| Raw materials | $ 64 | $ 44 |
| Finished products | 137 | 96 |
| Total inventories | $201 | $140 |

As of December 31, 2006, there were no inventory allowances. Inventories at December 31, 2005 are net of allowances of $208,000. During 2005, the Company recorded write-offs of inventory totaling approximately

$497,000 relating primarily to a change in specifications for TIMERx. Such write-offs are reflected in research and product development expense in the statements of operations.

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 purchases these gums from a primary supplier. Although the Company has qualified alternate suppliers with respect to these gums and to date has not experienced difficulty acquiring these materials, there can be no assurance that interruptions in supplies will not occur in the future or that the Company will not have to obtain substitute suppliers.

## 6. FIXED ASSETS

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

| | December 31, | |
|---|---|---|
| | 2006 | 2005 |
| | (In thousands) | |
| Equipment and leasehold improvements | $6,382 | $5,092 |
| Software | 1,998 | 1,834 |
| Projects in progress | 308 | 76 |
| | 8,688 | 7,002 |
| Less: accumulated depreciation and amortization | 4,901 | 4,012 |
| | $3,787 | $2,990 |

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 2006, 2005 or 2004. The Company includes software development costs within equipment and software, and generally amortizes the software development costs over a period of five years, once the systems are placed in service. Amortization expense related to software development costs totaled $323,000, $323,000 and $313,000 for 2006, 2005 and 2004, respectively. Unamortized software development costs totaled $507,000 and $830,000 as of December 31, 2006 and 2005, respectively.

## 7. PATENTS

| | December 31, | |
|---|---|---|
| | 2006 | 2005 |
| | (In thousands) | |
| Patents, net of accumulated amortization of $2,101 and $1,625: | $3,184 | $3,383 |

Patents include costs to secure patents on technology and products developed by the Company. Patents are amortized on a straight-line basis over their estimated useful lives of 17 to 20 years. Amortization expense of approximately $565,000, $464,000 and $410,000 was recorded in the years ended December 31, 2006, 2005, and 2004, respectively.

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

| Year | Amount |
|---|---|
| 2007 | $ 379 |
| 2008 | 376 |
| 2009 | 363 |
| 2010 | 330 |
| 2011 | 284 |
| Thereafter | 1,452 |
| Total | $3,184 |

Patents are evaluated for potential impairment whenever events or circumstances indicate that future undiscounted cash flows may not be sufficient to recover their carrying amounts. An impairment loss is recorded to the extent the asset's carrying value is in excess of the fair value of the asset. When fair values are not readily available, the Company estimates fair values using expected discounted future cash flows. During the years ended December 31, 2006, 2005 and 2004, the Company recorded impairment losses of approximately $254,000, $137,000 and $417,000, respectively, relating to its patents. The impairment losses recorded in 2006 related to the write-off of patent costs primarily in connection with early stage development programs discontinued by the Company, and that the Company determined no longer had value. The impairment losses recorded in 2005 primarily related to the write-off of patents in connection with the termination of the PW2101 development program, which patents the Company determined no longer had value. The impairment losses recorded in 2004 primarily related to the write-off of patents covering inhalation technology which patents the Company determined no longer had value. Such impairment losses are reflected in research and product development expense in the statements of operations.

## 8. SHAREHOLDERS' EQUITY

On July 27, 2005, the Company filed a registration statement on Form S-3 with the Securities and Exchange Commission (the "SEC"), which became effective on August 17, 2005. This shelf registration statement covers the issuance and sale by the Company of any combination of common stock, preferred stock, debt securities and warrants having an aggregate purchase price of up to $75 million.

On December 14, 2004, the Company completed the sale of a total of 3,125,000 shares of common stock through a private placement to selected institutional investors, resulting in net proceeds to the Company, after fees and expenses, of approximately $32.8 million, to fund the research, development, marketing and commercialization of the Company's products and technologies, and for general corporate purposes.

### *Share-Based Compensation*

In December 2004, the FASB issued SFAS 123R, which is a revision of SFAS 123. SFAS 123R supersedes Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees", and amends SFAS No. 95, "Statement of Cash Flows". The approach to quantifying stock-based compensation expense in SFAS 123R is similar to SFAS 123. However, the revised statement requires all share-based payments to employees, including grants of employee stock options as well as grants under 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. Pro forma disclosure of stock-based compensation expense, as was the Company's practice under SFAS 123, is no longer permitted. The Company adopted SFAS 123R effective beginning January 1, 2006 using the modified prospective transition method. The effect of the adoption was an additional $4.0 million in compensation expense, or approximately $0.18 per share, basic and diluted, substantially all related to employee stock options, for the year ended December 31, 2006. Of such amounts, $2.1 million was recorded to selling, general and administrative expense, and $1.9 million was recorded to research and product development expense, for the year ended December 31, 2006. Total share-based compensation expense recognized in 2006 and 2005 was $5.0 million and $2.9 million, respectively (see Note 11).

Under the modified prospective transition method, prior periods are not restated for the effect of SFAS 123R. Had the Company accounted for stock-based compensation plans using the fair value based accounting method proscribed by SFAS 123R for the periods prior to 2006, the Company's net loss and net loss per share would have approximated the pro forma amounts indicated below:

| | Year Ended December 31 | |
|---|---|---|
| | 2005 | 2004 |
| | (In thousands, except per share data) | |
| Net loss — as reported | $(22,898) | $(23,785) |
| Stock-based compensation expense included in reported net loss | 2,939 | 296 |
| Stock-based compensation under fair value method | (3,652) | (3,575) |
| Net loss — pro forma after stock-based compensation under fair value method | $(23,611) | $(27,064) |
| Net loss per share, basic and diluted — as reported | $ (1.05) | $ (1.28) |
| Net loss per share, basic and diluted — pro forma after stock-based compensation under fair value method | $ (1.09) | $ (1.45) |

***Penwest Stock Option Plans***

As of December 31, 2006, 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. No additional awards have been made under the Spin-off Plan or the 1997 Plan. A total of 1,650,000 shares of common stock may be issued pursuant to Awards granted under the 2005 Plan. Such awards generally may not be granted at an exercise price that is less than the fair market value of the common stock on the date of grant, as determined by the Company's Board of Directors. Stock option awards generally vest over a one to four year period and expire no later than ten years from the date of grant. Restricted stock awards entitle recipients to acquire shares of common stock, subject to the right of the Company to purchase all or part of such shares from the recipient in the event that the conditions specified in the applicable award are not satisfied prior to the end of the applicable restriction period established for such award. Restricted stock awards currently vest over a one to four year period and are recorded at fair value, which is based on the fair market value of the common stock on the date of grant.

On June 21, 2004, the Company granted nonstatutory stock options outside of any equity compensation plan pursuant to a Nonstatutory Stock Option Agreement entered into with one of its former officers in connection with such officer's commencement of employement, providing for the purchase of 100,000 shares of its common stock at an exercise price equal to the fair market value of the common stock on the date of

grant. These options vest over a four year period, and are subject to acceleration upon the occurrence of a change in control of the Company.

On August 31, 1998, Penford Corporation ("Penford"), the Company's former parent corporation, distributed to the holders of Penford common stock all of the outstanding shares of the Company's common stock (the "Distribution"). In connection with such transaction, the Company's 1998 Spin-off Option Plan was adopted in June 1998 to provide for the grant of stock options to employees of Penwest and non-employee directors of Penford who held options to purchase Penford common stock as of the date of the Distribution and who ceased to be employees of Penford under the terms of Penford's stock option plans. As of December 31, 2006, options to purchase 1,999 shares remain outstanding under the Spin-off Plan. The Company may not grant any additional options under the Spin-off Plan.

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

The following table presents a summary of the Company's stock option activity and related information for the year ended December 31, 2006:

| | Shares | Weighted Average Exercise Price | Weighted-Average Remaining Contractual Terms in Years | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Balance at December 31, 2005 | 3,015,563 | $10.88 | | |
| Options Exercisable | 2,120,947 | $ 9.99 | | |
| Granted | 622,250 | $20.03 | | |
| Exercised | (1,202,792) | $ 8.84 | | |
| Forfeited | (167,286) | $14.10 | | |
| Expired | (1,075) | $15.93 | | |
| Balance at December 31, 2006 | 2,266,660 | $14.23 | 6.5 | $7,809,424 |
| Options Exercisable | 1,274,381 | $11.98 | 4.7 | $6,219,428 |

The weighted average fair values of options granted during 2006, 2005 and 2004 were $11.18, $6.82 and $8.12, respectively. Total cash received by the Company from the exercise of stock options during 2006 was approximately $10.6 million. The total intrinsic values of options exercised during 2006, 2005 and 2004 were approximately $14.8 million, $827,000 and $634,000, respectively. The total fair value of options which vested during 2006, 2005 and 2004 were approximately $2.7 million, $3.8 million and $2.3 million, respectively. As of December 31, 2006, there was approximately $4.4 million of unrecognized compensation cost related to stock option awards that is expected to be recognized as expense over a weighted average period of 1.1 years.

The fair values of each option grant in 2006, 2005 and 2004 were estimated using the Black-Scholes-Merton option pricing model with the following weighted average assumptions:

| | 2006 | 2005 | 2004 |
|---|---|---|---|
| Expected dividend yield | None | None | None |
| Risk free interest rate | 4.7% | 4.1% | 3.7% |
| Expected volatility | 58% | 48% | 46% |
| Expected life of options | 5.6 years | 7.5 years | 7.5 years |

The following table presents a summary of restricted stock activity for 2006:

| | Shares | Weighted-Average Grant-Date Fair Value | Aggregate Intrinsic Value |
|---|---|---|---|
| Restricted stock outstanding at December 31, 2005 | 68,000 | $11.37 | $1,308,660 |
| Granted | 24,000 | $19.41 | |
| Vested | (40,500) | $11.17 | |
| Restricted stock outstanding at December 31, 2006 | 51,500 | $15.24 | $ 853,355 |

The total fair value of restricted stock which vested and the total compensation cost recognized for restricted stock awards during 2006 were approximately $452,000 and $771,000, respectively. As of December 31, 2006, there was approximately $79,000 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 common stock at the lower of 85% of the fair market value of the shares on the first or last day of such offering period. A maximum of 228,000 shares are authorized for issuance under the Plan. There were 10,404 shares, 13,779 shares and 14,612 shares issued under the Plan during 2006, 2005 and 2004, respectively.

***Rights Agreement***

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

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

## 9. COMMITMENTS

*Leases*

Under a lease agreement signed with Joseph Rettenmaier Holding GmbH & Co. KG on February 27, 2003 (see Note 13), the Company obtained the right to occupy approximately 14,000 square feet of office and research and development space in the Patterson, New York facility until February 2008. The lease was initially rent-free (plus operating expenses) until February 27, 2005, and since that time, the Company has leased the property pursuant to three successive one-year options at monthly rent payments approximating $14,000, plus operating expenses. On March 7, 2005, the Company signed an amendment to the lease, effective February 27, 2005, increasing its leased space to approximately 15,000 square feet and bringing its monthly rent payments to approximately $15,000, plus operating expenses. On September 1, 2006, the Company signed an additional amendment to the lease, increasing its leased space to approximately 15,500 square feet and bringing its monthly rent payments to approximately $15,500, plus operating expenses. In November 2006, Penwest exercised the third of its one year renewal options, extending the current term to February 26, 2008.

In 2004, the Company signed a lease amendment to its corporate office lease in Danbury, Connecticut for approximately 21,500 square feet of office space, replacing the office space included in its lease signed in February 2003. This lease, as amended, had an initial term expiring December 30, 2006; however, in 2006, the Company exercised its first of two one year renewal options extending this lease through December 30, 2007. Monthly rent payments, including utilities, will approximate $47,000 for 2007.

As of December 31, 2006, certain of the Company's property and equipment are leased under operating leases ranging from one to two years. Rental expense under operating leases was $873,000, $848,000 and $739,000, for the years ended December 31, 2006, 2005 and 2004, respectively. Of such amounts, approximately $171,000, $198,000 and $129,000 in 2006, 2005 and 2004, 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, 2006 for noncancellable operating leases having initial lease terms of more than one year are as follows:

| | Operating Leases |
|---|---|
| | (In thousands) |
| 2007 | $765 |
| 2008 | 32 |
| 2009 | — |
| 2010 | — |
| 2011 | — |
| Thereafter | — |
| Total minimum lease payments | $797 |

## 10. INCOME TAXES

There was no provision for income taxes for 2006. The provision for income taxes for 2005 and 2004 consisted of current foreign income taxes and totaled $2,000 and $5,000, respectively.

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

| | 2006 | 2005 | 2004 |
|---|---|---|---|
| Statutory tax rate | (34)% | (34)% | (34)% |
| Valuation allowance | 34 | 34 | 34 |
| | —% | —% | —% |

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

| | 2006 | 2005 |
|---|---|---|
| | (In thousands) | |
| Inventory allowance and basis differences | $ (13) | $ (163) |
| Deferred compensation and SERP liability | (1,266) | (1,307) |
| Deferred revenue | (17) | (23) |
| Stock-based compensation | (1,830) | — |
| Tax credit carryforwards | (5,363) | (4,497) |
| Net operating loss carryforwards | (56,156) | (44,413) |
| Total deferred tax assets | (64,645) | (50,403) |
| Depreciation and amortization | 1,608 | 1,708 |
| Other | 337 | 284 |
| Total deferred tax liabilities | 1,945 | 1,992 |
| Net deferred tax asset before valuation allowance | (62,700) | (48,411) |
| Valuation allowance | 62,700 | 48,411 |
| Net deferred tax liability | $ — | $ — |

The Company made no income tax payments in 2006. The Company's income tax payments for 2005 and 2004 consisting solely of foreign income taxes, approximated $2,000 and $5,000 for 2005 and 2004, respectively.

At December 31, 2006, the Company had federal net operating loss ("NOL") carryforwards of approximately $161.3 million for income tax purposes, of which approximately $6.2 million, $8.4 million, $9.1 million, $17.7 million, $19.4 million, $13.5 million, $22.8 million, $21.8 million and $42.4 million expire in 2018, 2019, 2020, 2021, 2022, 2023, 2024, 2025 and 2026, respectively. In addition, the Company had research and development tax credit carryforwards of approximately $5.3 million of which $67,000, $359,000, $341,000, $777,000, $828,000, $858,000, $760,000, $669,000 and $650,000 expire in 2018, 2019, 2020, 2021, 2022, 2023, 2024, 2025 and 2026, respectively. The use of the NOLs, and research and development tax credit carryforwards are limited to future taxable earnings of the Company.

The exercise of non-qualified stock options and the vesting of restricted stock give rise to compensation that is included in the taxable income of the applicable employees and directors, and deducted by the Company for federal and state income tax purposes. As a result of the exercise of non-qualified stock options and the vesting of restricted stock, the Company's net operating loss carryforwards include approximately $20.8 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, 2006 a valuation allowance of $62.7 million has been recognized to offset net deferred tax assets, primarily attributable to the NOL carryforward. The change in the valuation allowance in 2006 was an increase of $14.3 million. Utilization of the operating losses are subject to a limitation in the event of an ownership change under provisions of the Internal Revenue Code.

## 11. COMPENSATION CHARGE

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

## 12. RETIREMENT PLANS AND OTHER EMPLOYEE BENEFITS

### *Savings Plan*

Company employees participate in the Penwest Pharmaceuticals Co. Savings Plan, a defined contribution plan generally covering all of its employees. Under the Plan, the Company may make quarterly employer matching contributions as defined in the Plan agreement, in an amount equal to a percentage of each participant's pre-tax contributions to the Plan up to 6% of earnings. Participants are immediately vested in their contributions, as well as any earnings thereon. Vesting in the employer contribution portion of their accounts, as well as any earnings thereon is based on years of credited service, and vest over a four-year period. The Company's expense under the Plan was $244,000, $229,000 and $206,000 for 2006, 2005 and 2004, 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 2006, 2005, or 2004.

### *Supplemental Executive Retirement Plan*

The Company has a Supplemental Executive Retirement Plan ("SERP" or the "Plan"), a nonqualified plan, which covers the former Chairman and Chief Executive Officer of Penwest, Mr. Hamachek. For 2006, 2005 and 2004, the net expense for the SERP was $122,000, $124,000 and $135,000, respectively. The Plan is unfunded and has no assets. The Company uses a measurement date of December 31 for its SERP.

On December 31, 2006, the Company adopted the recognition and disclosure provisions of SFAS No. 158, "Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans, an amendment of FASB Statements No. 87, 88, 106 and 132(R)". SFAS No. 158 requires employers to recognize the funded status (i.e. the difference between the fair value of plan assets and the projected benefit obligations) of defined benefit pension and other postretirement benefit plans as an asset or liability in its statement of financial position and to recognize changes in the funded status in the year in which the changes occur as a component of comprehensive income. In addition, SFAS No. 158 requires employers to measure the funded status of its

plans as of the date of its year-end statement of financial position and also requires additional disclosures regarding amounts included in accumulated other comprehensive income. The adjustment to accumulated other comprehensive income (loss) at adoption represents the net unrecognized actuarial gains remaining from the initial adoption of SFAS No. 87, "Employers' Accounting for Pensions", all of which were previously netted against the plan's funded status in our statement of financial position pursuant to the provisions of SFAS No. 87. These amounts will be subsequently recognized as net periodic pension cost pursuant to our historical accounting policy for amortizing such amounts. Further, actuarial gains and losses that arise in subsequent periods, and are not recognized as net periodic pension cost in the same periods, will be recognized as a component of accumulated other comprehensive income (loss). Those amounts will be subsequently recognized as a component of net periodic pension cost on the same basis as the amounts recognized in accumulated other comprehensive income (loss) at the adoption of SFAS No. 158.

The incremental effects of adopting the provisions of SFAS No. 158 for the Plan on the Company's statement of financial position at December 31, 2006 are presented in the following table. The adoption of SFAS No. 158 had no effect on the Company's statements of operations for the year ended December 31, 2006, or for any prior period presented, and it will have no effect on the Company's future operating results. Had the Company not been required to adopt SFAS No. 158 at December 31, 2006, it would have recognized a minimum pension liability pursuant to the provisions of SFAS No. 87 of $2,297,000.

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

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

The following disclosures summarize information relating to the Plan:

Change in benefit obligation:

| | 2006 | 2005 |
|---|---|---|
| | (In thousands) | |
| Benefit obligation at beginning of period | $2,168 | $2,168 |
| Interest cost | 120 | 122 |
| Actuarial (gain) loss | 50 | (21) |
| Benefits paid | (151) | (101) |
| Benefit obligation at December 31, | $2,187 | $2,168 |

Change in plan assets:

| | 2006 | 2005 |
|---|---|---|
| | (In thousands) | |
| Fair value of plan assets at beginning of year | $ — | $ — |
| Employer contributions | 151 | 101 |
| Benefit payments | (151) | (101) |
| Fair value of plan assets at end of year | $ — | $ — |

Amounts recognized in the statement of financial position consist of:

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

Amounts recognized in accumulated other comprehensive income consist of:

| | 2006 (In thousands) |
|---|---|
| Net gain | $(122) |
| Prior service cost | 12 |
| Total | $(110) |

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

| | 2006 | 2005 |
|---|---|---|
| | (In thousands) | |
| Projected benefit obligation | $2,187 | $2,168 |
| Accumulated benefit obligation | $2,187 | $2,168 |
| Plan assets at fair value | $ — | $ — |

Components of net periodic benefit cost:

| | 2006 | 2005 |
|---|---|---|
| | (In thousands) | |
| Interest cost | $120 | $123 |
| Amortization of prior service cost | 2 | 2 |
| Amortization of gains | — | (1) |
| Net periodic benefit cost | $122 | $124 |

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 2007 is approximately $2,000.

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

| | 2006 | 2005 |
|---|---|---|
| Discount rate | 5.60% | 5.75% |
| Rate of compensation increase | N/A | N/A |

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

| | 2006 | 2005 |
|---|---|---|
| Discount rate | 5.75% | 6.00% |
| 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 2007. Effective February 14, 2005, Mr. Hamachek resigned from his positions as Chairman and Chief Executive Officer (see Note 11). 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):

| | |
|---|---|
| 2007 | $151 |
| 2008 | 151 |
| 2009 | 151 |
| 2010 | 151 |
| 2011 | 151 |
| Years 2012-2016 | 752 |

***Deferred Compensation Plan***

The Company has a Deferred Compensation Plan ("DCP"), a nonqualified plan which covers Mr. Hamachek. No amounts were contributed to the DCP during 2006, 2005 and 2004. Under the DCP, the Company recognized interest expense of $68,000, $70,000 and $76,000 for 2006, 2005 and 2004, respectively. The liability for the DCP was approximately $867,000 and $942,000 as of December 31, 2006 and 2005, respectively, and is included in deferred compensation on the Company's balance sheets, including the current portion of approximately $143,000 at December 31, 2006. The Company does not fund this liability and no assets are held by the DCP. In connection with the resignation and retirement of Mr. Hamachek in February 2005 (see Note 11) under the DCP, effective in May 2005, the Company became obligated to pay Mr. Hamachek approximately $140,000 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 eight remaining annual installments (in thousands):

| | |
|---|---|
| 2007 | $143 |
| 2008 | 143 |
| 2009 | 143 |
| 2010 | 143 |
| 2011 | 143 |
| Years 2012-2014 | 429 |

The Company has two whole-life insurance policies held in a rabbi trust (the "Trust"), the cash surrender value or death benefits of which are held in trust for the SERP and DCP liabilities. The Company is entitled to borrow against or withdraw from these policies to fund the liabilities under the SERP and the DCP as provided by the terms of the Trust. In April 2006, the Company withdrew from the Trust approximately $446,000 as reimbursement for all SERP and DCP benefit payments previously made by the Company to Mr. Hamachek. In addition, effective in June 2006, Mr. Hamachek's SERP and DCP benefit payments are being made directly from the assets in the Trust. The cash surrender value of these life insurance polices totaled $2,700,000 and $3,160,000 as of December 31, 2006 and 2005, respectively. Trust assets, including $2,000 held in a money market account at December 31, 2006, 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 $685,000, $603,000 and $643,000 in 2006, 2005 and 2004, respectively.

## 13. DISCONTINUED OPERATIONS

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

## 14. LICENSING AGREEMENTS

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

***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 based on the Company's TIMERx technology. This agreement was amended and restated in April 2002, and amended in January 2007. Endo is a specialty pharmaceutical company with a market leadership position in pain management. Endo has a broad product line, including established brands such as Lidoderm®, Percodan®, Percocet® and Frova® as well as three newly launched products in 2006 including Opana ER, Opana®, and Synera™.

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

Prior to April 17, 2003, the Company shared with Endo the costs involved in the development of Opana ER. On April 17, 2003, the Company exercised its option under the terms of the Agreement and discontinued its participation in the funding of the development of Opana ER. The Company took this action because it believed that the Company's strategic focus should be on funding other products in its development pipeline. As a result of this termination of funding, Endo completed the development of Opana ER and has the right to recoup the portion of development costs incurred by Endo that otherwise would have been funded by the Company.

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

- Endo will pay the Company royalties on U.S. sales of Opana ER calculated based on a royalty rate starting at 22% of annual net sales of the product up to $150 million of annual net sales, with the royalty rate increasing, based on agreed-upon levels of annual net sales achieved, from 25% up to a maximum of 30%.
- No royalty payments will be due to the Company for the first $41 million of royalties that would otherwise have been payable beginning from the time of the product launch in July 2006.
- 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 sales thresholds.

- The Company's share of the development costs for Opana ER that it opted out of funding in April 2003 will be fixed at $28 million and will be recouped by Endo through a temporary 50% reduction in royalties. This temporary reduction in royalties will not apply until the threshold for the $41 million royalty holiday referred to above has been met.

***Mylan Pharmaceuticals Inc.***

On March 2, 2000, Mylan announced that it had signed a supply and distribution agreement with Pfizer to market a generic version of all three strengths (30 mg, 60 mg, 90 mg) of Pfizer's 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 us a royalty on all future net sales of Pfizer's generic 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 the Nifedipine XL 30 mg. Mylan's sales in the United States in 2006 of Pfizer's generic Procardia XL 30 mg totaled approximately $25.9 million. The term of the letter agreement continues until such time as Mylan permanently ceases to market generic Procardia XL. In 2006, 2005 and 2004, royalties from Mylan were approximately $3.1 million, $3.9 million and $4.8 million, respectively, or 89%, 63% and 94%, respectively, of the Company's total revenue.

***Prism Pharmaceuticals, Inc.***

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

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

## 15. CONTINGENCIES

The Company is a party to certain 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.

## 16. RELATED PARTY TRANSACTIONS

Under a Recognition and Incentive Agreement with Anand Baichwal, (as amended, the "Baichwal Agreement") the Company's Senior Vice President of Licensing and Chief Scientific Officer, the Company was obligated to pay to Dr. Baichwal on an annual basis in arrears, royalties for (i) one-half of one percent of

the Company's Net Sales (as defined in the Baichwal Agreement) of TIMERx® material (as defined in the Baichwal Agreement) to third parties, (ii) one-half of one percent of royalties received by the Company 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 such Net Sales or royalties and received by the Company. The Baichwal Agreement also contains non-competition and non-solicitation provisions that expire two years after the termination of Dr. Baichwal's employment. These royalties for Dr. Baichwal totaled approximately $16,000, $20,000, and $25,000 for 2006, 2005 and 2004, respectively. Specified provisions of the Baichwal Agreement were terminated on February 1, 2007 (see Note 17).

Under a Royalty Agreement with John N. Staniforth (the "Staniforth Agreement"), a member of the Company's Board of Directors, the Company was obligated to pay Dr. Staniforth on an annual basis in arrears one-half of one percent of the Company's Net Sales (as defined in the Staniforth Agreement) of TIMERx® material (as defined in the Staniforth Agreement) related to the products covered by the TIMERx® patents. These royalties for Dr. Staniforth totaled approximately $16,000, $20,000 and $25,000 for 2006, 2005 and 2004, respectively. The Staniforth Agreement was terminated on February 1, 2007 (See Note 17).

Dr. Staniforth also had a consulting agreement with the Company under which he was paid $80,000 per year, payable in quarterly payments. The consulting agreement was terminated by the Company in 2006.

## 17. SUBSEQUENT EVENTS

***Royalty Termination Agreements***

On February 1, 2007, the Company entered in a termination agreement with Dr. Baichwal terminating specified provisions of the Baichwal Agreement ("Termination Agreement"). Pursuant to the Termination Agreement, the Company and Dr. Baichwal agreed that the Company would have no further obligation to make any payments to Dr. Baichwal under the Recognition and Incentive Agreement except for amounts owed with respect to 2006. In consideration for such agreement, the Company agreed to pay Dr. Baichwal $770,000 in cash and to issue 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 is still an employee of Penwest.

On February 1, 2007, the Company entered in a termination agreement with Dr. Staniforth terminating the Staniforth Agreement ("Termination Agreement"). Pursuant to the Termination Agreement, the Company and Dr. Staniforth agreed that the Company would have no further obligation to make any payments to Dr. Staniforth under the Royalty Agreement except for amounts owed with respect to 2006. In consideration for such agreement, the Company agreed to pay Dr. Staniforth $770,000 in cash and to issue 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 on the Board of Penwest.

The Termination Agreements entered into with Drs. Baichwal and Staniforth were approved by the Company's Board of Directors.

***Credit Facility***

On March 13, 2007, the Company entered into a $24.0 million senior secured credit facility ("Credit Facility") with Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services Inc. The Credit Facility consists of: (i) a $12.0 million term loan advanced upon the closing of the Credit Facility and (ii) a $12.0 million term loan that the Company may access until September 15, 2008, subject to conditions specified in the agreement. Under the agreement, the Company may not access this second amount unless the Company's market capitalization at the time of the advance request is greater than $250 million. In connection with this 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's generic version of Procardia XL 30mg, if the Company pledges such royalty payments to another lender; and up to $3,000,000 of equipment

which the Company may, at its election, pledge to another lender in connection with an equipment financing facility separate from this credit facility. In addition, the Company is precluded from paying cash dividends to its shareholders during the term of the agreement. Each loan has a term of 42 months from the date of advance with interest-only payments for the first nine months, but in any event, not beyond September 30, 2008; interest plus monthly principal payments equal to 1.67% of the loan amount for the period from the end of the interest-only period through December 2008; and interest plus straight line amortization payments with respect to the remaining principal balance for the remainder of the term.

Amounts outstanding under the Credit Facility bear interest at an annual rate of one month LIBOR at the time of the advance, plus 5%, which rate will be fixed for the term of the applicable loan. At the time of final payment of each loan under the Credit Facility, the Company will pay an exit fee of 3.0% of the original principal loan amount. 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 March 13, 2007, the interest rate on the Credit Facility was 10.32% and $12.0 million was outstanding.

## 18. QUARTERLY FINANCIAL DATA (UNAUDITED)

Summarized quarterly financial data for the years ended December 31, 2006 and 2005 is as follows:

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

| | Quarter Ended | | | |
|---|---|---|---|---|
| | Mar. 31, 2005 (a) (Unaudited) | June 30, 2005 (b) (Unaudited) | Sept. 30, 2005 (c) (Unaudited) | Dec. 31, 2005 (Unaudited) |
| | | (In thousands, except per share data) | | |
| Total revenues | $ 982 | $ 1,296 | $ 3,004 | $ 931 |
| Gross profit | 974 | 1,282 | 2,996 | 922 |
| Net loss | $(8,947) | $(5,686) | $(2,986) | $(5,279) |
| Net loss per share | $ (0.41) | $ (0.26) | $ (0.14) | $ (0.24) |

(a) During the first quarter of 2005, the Company recorded a $3.0 million compensation charge in connection with a Severance and Settlement Agreement and Release it entered into with Tod Hamachek, Penwest's former Chairman and Chief Executive Officer, upon his resignation in February 2005. Such charge is reflected in selling, general and administrative expense.

(b) During the second quarter of 2005, the Company recorded a write-off of inventory of approximately $395,000 relating primarily to a change in specifications for TIMERx. The Company also recognized impairment losses of $118,000 related to patents covering PW2101, a beta blocker intended for the treatment of hypertension and angina, which the Company determined no longer had value. Such charges are reflected in research and product development expense.

(c) During the third quarter of 2005, the Company recognized $2.25 million of licensing revenue under its agreement with Prism, which was terminated in July 2005. Such revenue is reflected in royalties and licensing fees.

## SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS

## PENWEST PHARMACEUTICALS CO.
## DECEMBER 31, 2006

| | 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, 2006 | | | | | |
| Inventory Allowances | $208 | $ — | $— | $208(a) | $ — |
| Year ended December 31, 2005 | | | | | |
| Inventory Allowances | $ 85 | $497 | $— | $374(a) | $208 |
| Year ended December 31, 2004 | | | | | |
| Inventory Allowances | $ 82 | $ 75 | $— | $ 72(a) | $ 85 |

(a) Disposals of unrecoverable inventory costs.

# Corporate Directory and Shareholder Information

## Officers

**Jennifer L. Good**
President and
Chief Executive Officer

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

**Paul F. Hayes**
Vice President,
Strategic Marketing

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

**Thomas R. Sciascia, M.D.**
Senior Vice President,
Clinical Development and
Regulatory Affairs and
Chief Medical Officer

## Board Committees

**Audit Committee**
Anne M. VanLent, Chair
Peter F. Drake
Rolf H. Henel

**Compensation Committee**
Rolf H. Henel, Chair
Paul E. Freiman
Peter F. Drake

**Nominating and Governance Committee**
Paul E. Freiman, Chair
Anne M. VanLent
Rolf H. Henel

## 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

## Shareholder Information

Our common stock, $.001 par value, is listed with and trades on the Nasdaq Global Market under the symbol "PPCO." The high and low sale prices of our common stock during 2006 and 2005 are set forth below. These prices reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

| Period 2006 | High | Low |
|---|---|---|
| Quarter Ended March 31 | $23.70 | $19.00 |
| Quarter Ended June 30 | $23.10 | $15.73 |
| Quarter Ended September 30 | $22.74 | $16.20 |
| Quarter Ended December 31 | $19.35 | $15.67 |

| Period 2005 | High | Low |
|---|---|---|
| Quarter Ended March 31 | $12.91 | $ 9.75 |
| Quarter Ended June 30 | $13.80 | $10.29 |
| Quarter Ended September 30 | $17.59 | $10.20 |
| Quarter Ended December 31 | $20.00 | $15.02 |

On March 9, 2007, there were 655 shareholders of record.

We have never paid cash dividends on our common stock. We presently intend to retain earnings, if any, for use in the operation of our business, and are precluded from paying any cash dividends under the terms of our senior secured credit facility. See "Sources of Liquidity" under the caption "Liquidity and Capital Resources" in "Item 7 — Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Form 10-K for the year ended December 31, 2006.

**Annual Meeting**
11:00 a.m., June 13, 2007
39 Old Ridgebury Road
Danbury, Connecticut

**Form 10-K**
The Company files an annual report with the SEC on Form 10-K, pursuant to the Securities Exchange Act of 1934. Shareholders may obtain a copy of this report without charge by written request to Penwest Pharmaceuticals Co., Attention: Corporate Secretary, 39 Old Ridgebury Road, Suite 11, Danbury, Connecticut 06810-5120, or view the 10-K in its entirety on our website.

**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

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

**Transfer Agent & Registrar**
Mellon Investor Services LLC
480 Washington Blvd.
Jersey City, NJ 07310-1900
WEB: www.melloninvestor.com

TOLL FREE number:
1-800-288-9541
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 the Company's actual results to differ materially from those indicated by forward-looking statements contained in this report and presented elsewhere by management from time to time. These factors include the factors discussed under the caption "Risk Factors" in Penwest's Annual Report on Form 10-K for the year ended December 31, 2006.

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