

---

---

UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

**Form 10-Q**

- ☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2003

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 No. 000-23467

**Penwest Pharmaceuticals Co.**

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

**Washington**

*(State of Incorporation)*

**39 Old Ridgebury Road, Suite 11,  
Danbury, Connecticut**

*(Address of principal executive offices)*

**91-1513032**

*(I.R.S. Employer Identification No.)*

**06810-5120**

*(Zip Code)*

**(877) 736-9378**

*(Registrant's telephone number, including area code.)*

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes ☒ No ☐

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of August 7, 2003.

<u>Class</u>	<u>Outstanding</u>
Common stock, par value \$.001	18,167,311

---

---

**PENWEST PHARMACEUTICALS CO.**  
**TABLE OF CONTENTS**

	<u>Page</u>
<b>PART I — FINANCIAL INFORMATION</b>	
Item 1. Condensed Consolidated Financial Statements (Unaudited) .....	2
Condensed Consolidated Balance Sheets .....	2
Condensed Consolidated Statements of Operations .....	3
Condensed Consolidated Statements of Cash Flows .....	5
Notes to Condensed Consolidated Financial Statements .....	6
Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations	12
Item 3. Quantitative and Qualitative Disclosures About Market Risk .....	27
Item 4. Controls and Procedures .....	27
<b>PART II — OTHER INFORMATION</b>	
Item 4. Submission of Matters to a Vote of Security Holders .....	28
Item 6. Exhibits and Reports on Form 8-K .....	28
Signature .....	29
Exhibit Index .....	30

## PART I — FINANCIAL INFORMATION

### Item 1. Financial Statements

#### PENWEST PHARMACEUTICALS CO. CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2003	December 31, 2002
	(Unaudited)	(Note 2)
	(In thousands, except share amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents . . . . .	\$ 15,639	\$ 1,629
Marketable securities . . . . .	10,193	2,057
Trade accounts receivable . . . . .	1,250	1,078
Inventories:		
Raw materials and other . . . . .	372	149
Finished goods . . . . .	370	312
	742	461
Prepaid expenses and other current assets . . . . .	756	1,902
Deferred transaction costs . . . . .	—	1,741
Note receivable . . . . .	1,250	—
Assets held for sale . . . . .	—	33,143
Total current assets . . . . .	29,830	42,011
Fixed assets, net . . . . .	2,759	2,406
Intangible assets, net . . . . .	3,230	2,947
Other assets . . . . .	2,938	2,856
Total assets . . . . .	<u>\$ 38,757</u>	<u>\$ 50,220</u>
Current liabilities:		
Accounts payable . . . . .	\$ 726	\$ 880
Accrued expenses . . . . .	1,806	2,886
Accrued development costs . . . . .	2,817	2,785
Taxes payable . . . . .	349	258
Loans and notes payable . . . . .	—	5,693
Deferred revenue . . . . .	—	150
Liabilities held for sale . . . . .	—	3,004
Total current liabilities . . . . .	5,698	15,656
Deferred income taxes . . . . .	118	118
Deferred revenue . . . . .	121	134
Deferred compensation . . . . .	2,938	2,889
Total liabilities . . . . .	8,875	18,797
Shareholders' equity:		
Preferred stock, par value \$.001, authorized 1,000,000 shares, none outstanding . . . . .	—	—
Common stock, par value \$.001, authorized 39,000,000 shares, issued and outstanding 15,632,809 shares at June 30, 2003 and 15,506,259 shares at December 31, 2002 . . . . .	16	16
Additional paid in capital . . . . .	110,991	110,000
Accumulated deficit . . . . .	(81,134)	(78,025)
Accumulated other comprehensive income (loss) . . . . .	9	(568)
Total shareholders' equity . . . . .	29,882	31,423
Total liabilities and shareholders' equity . . . . .	<u>\$ 38,757</u>	<u>\$ 50,220</u>

See accompanying notes to condensed consolidated financial statements.

**PENWEST PHARMACEUTICALS CO.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

	Three Months Ended June 30,	
	2003	2002
	(Unaudited) (In thousands, except per share data)	
Revenues		
Product sales . . . . .	\$ 230	\$ 75
Royalties and licensing fees . . . . .	<u>1,019</u>	<u>1,193</u>
Total revenues . . . . .	1,249	1,268
Cost of revenues . . . . .	<u>63</u>	<u>35</u>
Gross profit . . . . .	1,186	1,233
Operating expenses		
Selling, general and administrative . . . . .	3,226	1,954
Research and product development . . . . .	<u>5,559</u>	<u>5,353</u>
Total operating expenses . . . . .	<u>8,785</u>	<u>7,307</u>
Operating loss from continuing operations . . . . .	(7,599)	(6,074)
Investment income . . . . .	79	112
Interest expense . . . . .	<u>2</u>	<u>62</u>
Loss from continuing operations before income taxes . . . . .	(7,522)	(6,024)
Income tax expense . . . . .	<u>—</u>	<u>—</u>
Loss from continuing operations . . . . .	(7,522)	(6,024)
Earnings from discontinued operations, net of tax expense of \$80 . . . . .	—	706
Working capital adjustment on sale of discontinued operations, net of tax benefit of \$11 . . . . .	<u>(83)</u>	<u>—</u>
Net loss . . . . .	<u><u>\$(7,605)</u></u>	<u><u>\$(5,318)</u></u>
Basic and diluted (loss) earnings per common share:		
Continuing operations . . . . .	\$ (0.48)	\$ (0.39)
Discontinued operations . . . . .	<u>(0.01)</u>	<u>0.05</u>
Net loss per common share . . . . .	<u><u>\$ (0.49)</u></u>	<u><u>\$ (0.34)</u></u>
Weighted average shares of common stock outstanding . . . . .	<u>15,572</u>	<u>15,466</u>

See accompanying notes to condensed consolidated financial statements.

**PENWEST PHARMACEUTICALS CO.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

	Six Months Ended June 30,	
	2003	2002
	(Unaudited) (In thousands, except per share data)	
Revenues		
Product sales . . . . .	\$ 455	\$ 150
Royalties and licensing fees . . . . .	1,966	2,233
Total revenues . . . . .	2,421	2,383
Cost of revenues . . . . .	144	61
Gross profit . . . . .	2,277	2,322
Operating expenses		
Selling, general and administrative . . . . .	5,530	3,483
Research and product development . . . . .	9,142	9,804
Total operating expenses . . . . .	14,672	13,287
Operating loss from continuing operations . . . . .	(12,395)	(10,965)
Investment income . . . . .	120	242
Interest expense . . . . .	34	120
Loss from continuing operations before income taxes . . . . .	(12,309)	(10,843)
Income tax expense . . . . .	—	—
Loss from continuing operations . . . . .	(12,309)	(10,843)
Earnings from discontinued operations, net of tax expense of \$26 and \$221 . . . . .	177	1,207
Gain on sale of discontinued operations, net of tax expense of \$51 . . . . .	9,497	—
Net loss . . . . .	<u>\$ (2,635)</u>	<u>\$ (9,636)</u>
Basic and diluted (loss) earnings per common share:		
Continuing operations . . . . .	\$ (0.79)	\$ (0.70)
Discontinued operations . . . . .	0.62	0.08
Net loss per common share . . . . .	<u>\$ (0.17)</u>	<u>\$ (0.62)</u>
Weighted average shares of common stock outstanding . . . . .	<u>15,540</u>	<u>15,432</u>

See accompanying notes to condensed consolidated financial statements.

**PENWEST PHARMACEUTICALS CO.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Six Months Ended June 30,	
	2003	2002
	(Unaudited) (In thousands)	
Net cash used in operating activities:		
Net loss .....	\$ (2,635)	\$ (9,636)
Less earnings from discontinued operations, net of tax .....	(177)	(1,207)
Less gain on sale of discontinued operations, net of tax .....	(9,497)	—
Loss from continuing operations .....	(12,309)	(10,843)
Adjustments to reconcile loss from continuing operations to net cash used in continuing operations operating activities .....	225	1,421
Net cash used in continuing operations operating activities .....	(12,084)	(9,422)
Net cash provided by discontinued operations operating activities .....	874	225
Net cash used in operating activities .....	(11,210)	(9,197)
Investing activities:		
Proceeds from sale of discontinued operations, net of transaction costs paid of \$1,351 .....	36,900	—
Acquisitions of fixed assets, net .....	(635)	(103)
Intangible asset costs .....	(386)	(357)
Proceeds from maturities of marketable securities .....	1,000	3,250
Purchases of marketable securities .....	(9,035)	—
Net cash provided by continuing operations investing activities .....	27,844	2,790
Net cash used in discontinued operations investing activities .....	(97)	(308)
Net cash provided by investing activities .....	27,747	2,482
Financing activities:		
Proceeds from loans .....	1,354	12,284
Repayments of loans .....	(7,047)	(12,115)
Issuance of common stock, net .....	885	1,715
Net cash provided by discontinued operations .....	2,249	—
Net cash (used in) provided by financing activities .....	(2,559)	1,884
Effect of exchange rate changes on cash and cash equivalents of discontinued operations .....	32	(30)
Net increase (decrease) in cash and cash equivalents .....	14,010	(4,861)
Cash and cash equivalents at beginning of period .....	1,629	11,530
Cash and cash equivalents at end of period .....	<u>\$ 15,639</u>	<u>\$ 6,669</u>

See accompanying notes to condensed consolidated financial statements.

**PENWEST PHARMACEUTICALS CO.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(Unaudited)**

**1. Business**

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

Prior to February 27, 2003, Penwest also developed, manufactured and distributed branded pharmaceutical excipients, which are the inactive ingredients in tablets and capsules, primarily consisting of binders, disintegrants and lubricants. On February 27, 2003, Penwest sold substantially all of the assets used in the Company’s excipient business (the “Asset Sale”) to subsidiaries and affiliates of Josef Rettenmaier Holding GmbH & Co. KG. The Company received \$39.5 million in cash and a promissory note for \$2.25 million in consideration for the excipient business. The Company used approximately \$5.5 million of proceeds of the sale of its excipient business to repay debt (see Note 5) and intends to use the balance of the proceeds to expand its drug delivery business. Commencing in the first quarter of 2003, the Company has reported the operating results of the excipient business as a discontinued operation (see Note 8).

The Company is subject to the risks and uncertainties associated with a drug delivery company actively engaged in research and development. These risks and uncertainties include, but are not limited to, a history of net losses, technological changes, dependence on collaborators and key personnel, the successful completion of development efforts and of obtaining regulatory approval, the successful commercialization of TIMERx controlled release products, compliance with government regulations, patent infringement litigation, competition from current and potential competitors, some with greater resources than the Company and a requirement for additional funding.

**2. Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments considered necessary for a fair presentation for the interim periods presented have been included. All such adjustments are of a normal recurring nature. Operating results for the three and six month periods ended June 30, 2003 are not necessarily indicative of the results that may be expected for the year ending December 31, 2003. For further information, refer to the consolidated financial statements and footnotes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2002.

During the quarter ended March 31, 2003, the Company recorded an impairment loss of approximately \$214,000, net of accumulated depreciation, relating to equipment of its excipient business. The impaired equipment primarily related to a pulp shredding transfer system which did not function as planned, resulting in the eventual abandonment of the related project and full write-down of its carrying value. This impairment loss is included in earnings from discontinued operations in the six months ended June 30, 2003 condensed consolidated statements of operations.

As a result of the Asset Sale, the operating results of the excipient business have been presented as discontinued operations in the condensed consolidated statements of operations for the three and six month periods ended June 30, 2003 and 2002 (see Note 8). In order to conform to the current period presentation, certain reclassifications have been made in the prior period financial statements.

The balance sheet at December 31, 2002, presented with reclassifications made for the Asset Sale, has been derived from the audited financial statements at that date but does not include all of the information and

**PENWEST PHARMACEUTICALS CO.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

footnotes required by accounting principles generally accepted in the United States for complete financial statements.

**3. Summary of Significant Accounting Policies**

***Revenue Recognition***

Revenues from product sales are recognized when title transfers and customer acceptance provisions have lapsed, provided collections of the related accounts receivable are probable. Revenue received from non-refundable upfront licensing fees are recognized ratably over the development period of the collaboration agreement, when this period involves development risk associated with the incomplete stage of a product's development or over the estimated or contractual licensing and supply term when there exists an obligation to supply inventory for manufacture. Non-refundable milestone fees received for the development funding of a product are partially recognized upon receipt based on the Company's proportionate development efforts achieved to date relative to the total expected development efforts and the remainder is generally recognized ratably over the remaining expected development period. The proportionate development efforts achieved are measured by estimating the percentage of work completed that is required of the Company in the development effort for the product. This estimate is primarily derived from the underlying project plans and timelines, developed by qualified personnel who work closely on such projects. 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 bios-studies, clinical development and regulatory matters. Other contractual fees received in connection with a collaborator's launch of a product are also recognized ratably over the estimated or contractual licensing and supply term. Product royalty fees are recognized when earned.

***Stock Options***

The Company adopted the disclosure provisions of Statement of Financial Accounting Standards ("SFAS") No. 148, "Accounting for Stock-Based Compensation — Transition and Disclosure," which amends SFAS No. 123, "Accounting for Stock-Based Compensation," in 2002. SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation, which was originally provided under SFAS No. 123. The Statement also improves the timeliness of disclosures by requiring the information to be included in interim as well as annual financial statements. The adoption of these disclosure provisions had no impact on the Company's 2003 consolidated results of operations, financial position or cash flows.

At June 30, 2003, the Company maintained two stock-based employee compensation plans. The Company accounts for these employee stock compensation plans in accordance with the intrinsic value-based method prescribed by Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees." During the quarter ended June 30, 2003, the Company recorded \$106,000 in compensation expense (no related tax effect) in connection with the acceleration of the vesting date of certain stock options. No other stock-based employee compensation expense is reflected in net loss as all options granted under these plans had an exercise price equal to the fair market value of the underlying common stock on the date of grant.

Consistent with the method described in SFAS No. 123, if compensation expense for the Company's plans had been determined based on the fair value at the grant dates for awards under its plans, net loss and



# PENWEST PHARMACEUTICALS CO.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

loss per share would have been increased to the pro forma amounts indicated below (in thousands, except per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2003	2002	2003	2002
	(Unaudited)		(Unaudited)	
Net loss — as reported .....	\$(7,605)	\$(5,318)	\$(2,635)	\$(9,636)
Net loss — pro forma .....	\$(7,636)	\$(5,464)	\$(4,003)	\$(10,842)
Net loss per share, basic and diluted — as reported	\$ (0.49)	\$ (0.34)	\$ (0.17)	\$ (0.62)
Net loss per share, basic and diluted — pro forma ..	\$ (0.49)	\$ (0.35)	\$ (0.26)	\$ (0.70)

### 4. Recent Accounting Pronouncements

In November 2002, the Emerging Issues Task Force (“EITF”) finalized its tentative consensus on EITF Issue 00-21, “Revenue Arrangements with Multiple Deliverables,” which provides guidance on the timing and method of revenue recognition for arrangements that include the delivery of more than one product or service. EITF 00-21 is effective prospectively for arrangements entered into in fiscal periods beginning after June 15, 2003. The adoption of EITF 00-21 is not expected to have a material effect on the Company’s financial position or results of operations.

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

### 5. Loans and Notes Payable

#### *Credit Facilities*

On January 17, 2001, the Company completed arrangements for a revolving line of credit (“Revolver”) with a financial institution. Under the terms of the Revolver, the Company could borrow up to \$10.0 million (“Line of Credit”) as determined by a formula based on the Company’s Eligible Accounts Receivable and Eligible Saleable Inventory, as defined in the agreement. Under the formula, generally 85% of the Company’s U.S. and Canadian receivables, as well as generally 60% of the Company’s U.S. saleable inventories, were included in the borrowing base. Amounts outstanding under the Revolver were collateralized by the Company’s U.S. and Canadian accounts receivable, and its inventory and general intangibles. The Revolver had an initial term of three years, and provided for annual renewals thereafter. On February 27, 2003, the Company paid off the outstanding balance of \$3.3 million and terminated the Revolver in connection with the Asset Sale (see Note 8).

#### *Note Payable to AstraZeneca AB*

On October 25, 2002, the Company entered into an agreement with AstraZeneca AB to acquire from AstraZeneca AB assets related to the excipient product, Pruv, including trademarks and other intellectual property, for a total purchase price of \$3 million. Pursuant to this agreement, the Company issued a note to AstraZeneca AB in the principal amount of \$2.25 million. Under the agreement, the note required the Company to pay all indebtedness outstanding under the note upon the closing of the Asset Sale. As a result, the note was paid in full in February 2003 in connection with the Asset Sale (see Note 8).

#### *Business Insurance Premium Financing*

On September 24, 2002, the Company entered into a Premium Finance Agreement (the “Finance Agreement”) through which it financed approximated \$1.1 million of premiums payable in connection with the annual renewal of its general business insurance. Under the Finance Agreement, Penwest was required to

## PENWEST PHARMACEUTICALS CO.

### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

repay the amount financed in equal monthly installments through June 2003, plus interest at a rate of 3.11% per annum. In addition, the Company assigned, as a security interest, any and all unearned premiums or other amounts which may become payable to the Company under the insurance policies. The amount financed under the Finance Agreement was paid in full in May 2003.

#### 6. Income Taxes

For continuing operations, the effective tax rates for the quarters and six months ended June 30, 2003 and 2002, were zero. The effective tax rates are higher than the federal statutory rate of a 34% benefit due to valuation allowances recorded to offset deferred tax assets relating to the Company's net operating losses.

In the quarter ended June 30, 2003, the Company recorded a working capital adjustment to the gain on sale of discontinued operations of \$83,000 (expense), which is net of a tax benefit of \$11,000. The gain on sale of discontinued operations of approximately \$9.5 million, recorded in the six months ended June 30, 2003, is net of tax expense of \$51,000, or less than 1% of the pretax gain. The tax expense is lower than the federal statutory rate of 34% primarily due to net operating losses which offset the gain. In addition, earnings from discontinued operations of \$177,000 and \$1,207,000, respectively, for the six months ended June 30, 2003 and June 30, 2002, are net of tax expenses of \$26,000 and \$221,000, respectively, or 13% and 15% of pretax earnings, respectively. These tax expenses, which include foreign taxes, are lower than the federal statutory rate of 34% primarily due to overall U.S. net operating losses which offset the U.S. earnings of the discontinued operation (see Note 8).

#### 7. Comprehensive Loss

The components of comprehensive loss for the three and six months ended June 30, 2003 and 2002 are as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2003	2002	2003	2002
	(Unaudited)		(Unaudited)	
Net loss .....	\$ (7,605)	\$ (5,318)	\$ (2,635)	\$ (9,636)
Foreign currency translation adjustments .....	—	722	109	608
Change in unrealized net gains on marketable securities .....	(6)	26	(6)	9
Comprehensive loss .....	<u>\$ (7,611)</u>	<u>\$ (4,570)</u>	<u>\$ (2,532)</u>	<u>\$ (9,019)</u>

Accumulated other comprehensive income (loss) equals the cumulative translation adjustment and unrealized net gains on marketable securities which are the only components of other comprehensive loss included in the Company's financial statements. Effective on the date of the Asset Sale, accumulated other comprehensive income (loss) is comprised solely of unrealized net gains and losses on marketable securities.

#### 8. Discontinued Operations

On February 27, 2003, Penwest sold substantially all of the assets (the "Assets") used in the Company's excipient business to subsidiaries and affiliates of Josef Rettenmaier Holding GmbH & Co. KG ("Rettenmaier") for \$41.75 million, plus the assumption of specified liabilities, subject to a working capital adjustment. The Assets of the excipient business were sold to Rettenmaier, either directly or through the sale of the outstanding capital stock of the three subsidiaries of Penwest that did business in the UK, Germany and Finland. 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 in April 2003 and \$1.25 million due May 25, 2004.

## PENWEST PHARMACEUTICALS CO.

### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

In the first quarter of 2003, the Company recorded a gain on the Asset Sale of approximately \$9.6 million, net of taxes of \$62,000, and has reported the operating results of the excipient business as a discontinued operation in accordance with SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." In the second quarter of 2003, the Company recorded an expense of \$83,000 for the working capital adjustment, net of a tax benefit of \$11,000, for a total gain of \$9.5 million, net of tax expense of \$51,000 for the six months ended June 30, 2003. The net carrying amount of the assets and liabilities on the date of the Asset Sale was approximately \$29.5 million. The approximate carrying values of the major classes were: property, plant and equipment of \$11.4 million; inventory of \$8.3 million; receivables of \$6.0 million; and intangible assets of \$4.3 million offset by other net liabilities. The Company has presented its December 31, 2002 balance sheet in the consolidated financial statements to reflect the assets and liabilities of the excipient business separately as assets held for sale and liabilities held for sale. The gain on the Asset Sale is net of transaction related costs totaling \$3.1 million, primarily consisting of professional and advisory fees. As of December 31, 2002, these costs approximated \$1.7 million and were reflected as deferred transaction costs on the condensed consolidated balance sheet. Revenues and pretax profits for the excipient business approximated \$6.1 million and \$203,000, respectively, for the period January 1, 2003 through the Asset Sale date of February 27, 2003, and approximated \$9.0 million and \$786,000, respectively, and \$18.2 million and \$1.4 million, respectively, for the quarter and six months ended June 30, 2002.

Prior to the sale of the excipient business, the Company owned its office, laboratory and warehouse facility in Patterson, New York, as well as a facility in Cedar Rapids, Iowa, where it manufactured pharmaceutical excipients. As part of the Asset Sale, the Company transferred these properties and assigned its lease of a pharmaceutical excipient manufacturing facility in Nastola, Finland to Rettenmaier. Under a lease agreement signed with Rettenmaier on February 27, 2003, the Company has the right to occupy approximately 14,000 square feet of office and research and development space in the Patterson facility until February 2008, initially on a rent-free basis (plus operating expenses) for two years and then pursuant to three successive one-year options at monthly rent payments approximating \$14,000, plus operating expenses. In addition, in February 2003, the Company signed a lease agreement for approximately 11,000 square feet of office space in Danbury, Connecticut. This lease has an initial term expiring January 31, 2006, with renewal options through December 30, 2006, and requires that monthly base rents of approximately \$20,000 be paid through the initial lease term. The Company moved its corporate offices to Danbury, Connecticut on March 31, 2003.

#### 9. Licensing Agreements

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

In September 1997, the Company entered into a strategic alliance agreement with Endo Pharmaceuticals, Inc. with respect to the development of an extended release formulation of oxymorphone a narcotic analgesic for the treatment of moderate to severe pain based on the Company's TIMERx technology. This agreement was amended and restated in April 2002. Endo is a fully integrated specialty pharmaceutical company with a market leadership in pain management. Endo has a broad product line including 20 branded products that include the established brands such as Percodan®, Percocet®, and Lidoderm®. Endo is registered with the U.S. Drug Enforcement Administration as a developer, manufacturer and marketer of controlled narcotic substances.

Under the strategic alliance agreement, the responsibilities of the Company and Endo with respect to the oxymorphone product are determined by a committee comprised of an equal number of members from each of the Company and Endo (the "Alliance Committee"). During the development of the product, the Company formulated oxymorphone ER and Endo conducted all clinical studies and prepared and filed all regulatory applications. The Company has agreed to manufacture and supply TIMERx material to Endo, and Endo has

## PENWEST PHARMACEUTICALS CO.

### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

agreed to manufacture and market oxymorphone ER in the United States. The manufacture and marketing outside of the United States may be conducted by the Company, Endo or a third party, as determined by the Alliance Committee.

Prior to March 17, 2003, the Company and Endo shared the costs involved in the development of oxymorphone ER. On March 17, 2003, the Company gave Endo notice that it was discontinuing its participation in the funding of the development and marketing of oxymorphone ER effective April 17, 2003. As a result of this termination, Endo has the right to complete the development of oxymorphone ER and recoup the portion of development costs incurred by Endo that otherwise would have been funded by Penwest. Endo may recoup such development costs through a temporary adjustment in the royalty rate payable to Penwest that will return to its pre-adjustment level once Endo has recovered such costs. The parties have agreed that the party marketing oxymorphone ER will pay the other party royalties initially equal to 50% of the net realization (as defined in the agreement). This percentage will decrease if the aggregate U.S. net realization exceeds pre-determined thresholds. In general, the royalty payable by the marketing party to the other party will not drop below 40%. However, the royalty will be reduced by one-third in limited circumstances, including termination of the agreement based on uncured material breaches of the agreement by the royalty receiving party and certain bankruptcy and insolvency events involving the royalty receiving party. Under the agreement, Endo will purchase formulated TIMERx material for use in oxymorphone ER exclusively from the Company at specified prices, such prices will be reflected in the determination of net profits.

On March 2, 2000, Mylan announced that it had signed a supply and distribution agreement with Pfizer to market a generic version of all three strengths (30 mg, 60 mg, 90 mg) of Pfizer's Procardia XL. In connection with that agreement, Mylan decided not to market Nifedipine XL and agreed to pay Penwest a royalty on all future net sales of the 30 mg strength of Pfizer's generic Procardia XL. The royalty percentage was comparable to the percentage called for in Penwest's original agreement with Mylan for Nifedipine XL. Mylan has retained the marketing rights to the 30 mg strength of Nifedipine XL. Mylan's sales in the United States in 2002 of the 30 mg dosage strength version of Pfizer's generic Procardia XL totaled approximately \$34.9 million. The term of this agreement continues until such time as Mylan permanently ceases to market generic Procardia XL.

#### 10. Subsequent Events

On August 5 and August 6, 2003, the Company completed the sale of a total of 2,507,762 shares of common stock through a private placement to selected institutional investors, resulting in gross proceeds to the Company of \$52.7 million, less fees and expenses estimated to be approximately \$3.3 million. In addition, the Company has granted the institutional investors additional rights to purchase up to an additional 501,552 shares of common stock at \$26.00 per share. These additional investment rights will become exercisable 90 days after the closing date or, if earlier, upon the effectiveness of a registration statement for the resale of the common stock issued to the investors, and will expire 60 trading days after the effectiveness of such registration statement. The Company intends to use the net proceeds to fund the research, development, marketing and commercialization of its products and technologies, and for general corporate purposes.

## **Item 2. *Management's Discussion and Analysis of Financial Condition and Results of Operations***

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

### **Overview**

Penwest develops pharmaceutical products based on innovative oral drug delivery technologies. The foundation of Penwest's technology platform is TIMERx, an extended release delivery system that is adaptable to soluble and insoluble drugs, and that is flexible for a variety of controlled release profiles. The Company has also developed two additional oral drug delivery systems, Geminex and SyncroDose. Geminex is a dual drug delivery system that is designed to provide independent release of different active ingredients contained in a drug, and SyncroDose is a chronotherapeutic drug delivery system that is designed to release the active ingredient of a drug at the desired site and time in the body.

Penwest's product portfolio includes four products utilizing its proprietary controlled release drug delivery technology that were developed with collaborators and have been approved in various countries. In addition, the Company has a number of product candidates in its drug development pipeline. The most advanced of these is oxymorphone ER, an extended release formulation of oxymorphone incorporating TIMERx technology. The Company is developing oxymorphone ER with Endo. The FDA accepted for filing a new drug application, or NDA, submitted by Endo for oxymorphone ER in February 2003, and the FDA is currently reviewing the application. On March 17, 2003, the Company exercised its right under the oxymorphone ER agreement and gave Endo notice that it was discontinuing its participation in the funding of the development and marketing of oxymorphone ER, effective April 17, 2003.

Prior to February 27, 2003, Penwest also developed, manufactured and distributed branded pharmaceutical excipients, which are the inactive ingredients in tablets and capsules, primarily consisting of binders, disintegrants and lubricants. On February 27, 2003, Penwest sold substantially all of the assets used in the Company's excipient business to subsidiaries and affiliates of Josef Rettenmaier Holding GmbH & Co. KG (the "Asset Sale"). The Company received \$39.5 million in cash and a promissory note for \$2.25 million in consideration for the excipient business. The Company received \$1.0 million of the \$2.25 million promissory note in April 2003 with the balance due in May 2004. The Company intends to use the proceeds of the sale of its excipient business to expand its drug delivery business. Commencing in the first quarter of 2003, the Company reported the operating results of the excipients business as a discontinued operation.

On August 5 and August 6, 2003, the Company completed the sale of a total of 2,507,762 shares of common stock through a private placement to selected institutional investors (the "Private Placement"), resulting in gross proceeds to the Company of \$52.7 million, less fees and expenses estimated to be approximately \$3.3 million. In addition, the Company has granted the institutional investors additional rights to purchase up to an additional 501,552 shares of common stock at \$26.00 per share. These additional investment rights will become exercisable 90 days after the closing date or, if earlier, upon the effectiveness of a registration statement for the resale of the common stock issued to the investors, and will expire 60 trading days after the effectiveness of such registration statement. The Company intends to use the net proceeds to fund the research, development, marketing and commercialization of its products and technologies, and for general corporate purposes.

The Company has incurred net losses since 1994. As of June 30, 2003, the Company's accumulated deficit was approximately \$81.1 million. The Company expects operating losses and negative cash flows to continue until substantial sales of products commercialized utilizing TIMERx technology occur. A substantial portion of the Company's revenues through February 27, 2003 were generated from sales of the Company's pharmaceutical excipient product line. The Company expects that the balance of its revenues for 2003 will be generated primarily from Mylan royalties and shipments of bulk TIMERx. The Company's future profitability will depend on several factors, including the successful commercialization of TIMERx controlled release



products, including in particular oxymorphone ER; the Company's ability to use net proceeds from the Asset Sale and the Private Placement to expand its drug development product pipeline; royalties from Mylan's sales of Pfizer's 30 mg generic version of Procardia XL; and the level of the Company's investment in research and development activities.

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

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

The Company's results of operations may fluctuate from quarter to quarter depending on the amount and timing of royalties on Mylan's sales of Pfizer's 30 mg generic version of Procardia XL, volume and timing of orders of formulated bulk TIMERx, and on variations in payments under the Company's collaborative agreements, including payments upon the achievement of specified milestones. The Company's quarterly operating results may also fluctuate depending on other factors, including variations in gross margins of the Company's products, the mix of product sales and royalty revenues, competition and regulatory actions.

### **Critical Accounting Policies and Estimates**

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

### **Results of Operations — Continuing Operations**

#### ***Quarters Ended June 30, 2003 and 2002***

Total revenues for both the second quarter of 2003 and the second quarter of 2002 were \$1.2 million. Sales of formulated bulk TIMERx increased to \$230,000 for the quarter ended June 30, 2003 from \$75,000 for the quarter ended June 30, 2002. The increase in these product sales was primarily due to the timing of shipments of formulated bulk TIMERx to customers. Royalties and licensing fees decreased by \$174,000 for

the second quarter of 2003 to \$1.0 million from \$1.2 million in the second quarter of 2002, primarily due to lower royalties from Mylan attributable to Mylan's decreased sales of Pfizer's 30 mg generic version of Procardia XL, due to increased generic competition.

Selling, general and administrative expenses increased by \$1.2 million to \$3.2 million for the second quarter of 2003 from \$2.0 million in the second quarter of 2002. The increase in selling, general and administrative expenses was primarily due to the Company's marketing costs for oxymorphone ER which increased in preparation for product launch, an increase in premiums for business insurance, increased professional fees associated with business development and accounting services, and increased personnel costs primarily associated with the expansion of the business development and marketing teams. The increase also reflects certain selling, general and administrative overhead expenses being fully absorbed in continuing operations during the quarter ended June 30, 2003, that were previously allocated between continuing operations and discontinuing operations for the quarter ended June 30, 2002. The second quarter of 2003 only includes expenses for oxymorphone ER through April 17, 2003. No selling, general and administrative expenses related to oxymorphone are expected to be incurred during the remainder of 2003, unless the Company resumes its participation in the funding of the development and marketing of oxymorphone ER.

Research and product development expenses increased by \$206,000 to \$5.6 million for the second quarter of 2003 as compared to \$5.4 million in the second quarter of 2002. The Company incurred costs of approximately \$635,000 on the development of oxymorphone ER in the second quarter of 2003. This was a decrease of approximately \$2.3 million from the second quarter of 2002 due to lower development costs on oxymorphone ER as clinical activity declined in the second quarter of 2003 as a result of the submission of the NDA for oxymorphone ER in December 2002, as well as the fact that the Company only funded these research and development expenses through April 17, 2003. Notwithstanding this decrease relating to oxymorphone ER, total research and development expenses increased during the period as the Company conducted clinical trials of several product candidates utilizing TIMERx technology. The majority of the increase in spending was due to the scale-up and preparation for clinical trials for the Company's hypertension product, PW2101 which began dosing in July 2003. The Company believes these trials will be the final clinical trials for PW2101 before submission to the FDA for approval. Completion of clinical trials and commercialization of these product candidates may take several years, and the length of time can vary substantially according to the type, complexity and novelty of a product candidate.

The most advanced of the Company's product candidates is oxymorphone ER, which the Company is developing with Endo. Endo, which is responsible for conducting the clinical trials and seeking regulatory approval of the product, completed the clinical trials for this product in 2002 and the FDA accepted for filing the NDA for oxymorphone ER in February 2003. No research and development expenses are expected to be incurred with respect to oxymorphone ER after April 17, 2003, unless the Company resumes its participation in the funding of the development and marketing of oxymorphone ER.

There can be no assurance that any of the Company's products will be successfully developed, will receive regulatory approval, or will be successfully commercialized.

For continuing operations, the effective tax rates for the quarters ended June 30, 2003 and 2002 were zero. The effective tax rates are higher than the federal statutory rate of a 34% benefit due to valuation allowances recorded to offset deferred tax assets relating to the Company's net operating losses.

#### ***Six Months Ended June 30, 2003 and 2002***

Total revenues for the six months ended June 30, 2003 and June 30, 2002 were \$2.4 million. Product sales increased by \$305,000 to \$455,000 for the six months ended June 30, 2003 compared to \$150,000 for the six months ended June 30, 2002. The increase in product sales was primarily due to the timing of shipments of formulated bulk TIMERx to customers. Royalties and licensing revenues decreased by \$267,000 to approximately \$2.0 million for the first six months of 2003 as compared to approximately \$2.2 million in the comparable period in 2002, primarily due to lower royalties from Mylan, attributable to Mylan's decreased sales of Pfizer's 30 mg generic version of Procardia XL, due to increased generic competition.

Selling, general and administrative expenses increased \$2.0 million to approximately \$5.5 million for the six months ended June 30, 2003, from \$3.5 million for the six months ended June 30, 2002. This increase is primarily attributable to an increase in the Company's share of marketing expenses on oxymorphone ER, and increases in the cost of business insurance, increased professional fees associated with business development and accounting services, and increased personnel costs primarily associated with the expansion of the business development and marketing teams. The increase also reflects certain selling, general and administrative overhead expenses that were incurred subsequent to February 27, 2003, the date of the Asset Sale, being fully absorbed in continuing operations for the six months ended June 30, 2003, that were previously allocated between continuing operations and discontinuing operations for the six months ended June 30, 2002. The six months ended June 30, 2003 only include expenses for oxymorphone ER through April 17, 2003. No selling, general and administrative expenses related to oxymorphone are expected to be incurred during the remainder of 2003, unless the Company resumes its participation in the funding of the development and marketing of oxymorphone ER.

Research and development expenses during the six months ended June 30, 2003 were \$9.1 million, compared to \$9.8 million for the comparable period of 2002. This lower spending is primarily related to a decrease in the development costs of oxymorphone ER in 2003 compared to the comparable period of 2002, when several clinical trials were underway and the Company was participating in the development costs for the full six months. This decrease was partially offset by increased development costs on other products in the Company's development pipeline, primarily on the Company's hypertension product, PW2101.

For continuing operations, the effective tax rates for the six months ended June 30, 2003 and 2002 were zero. The effective tax rates are higher than the federal statutory rate of a 34% benefit, due to valuation allowances recorded to offset deferred tax assets relating to the Company's net operating losses.

The gain on sale of discontinued operations of approximately \$9.5 million, recorded in the six months ended June 30, 2003, is net of tax expense of \$51,000, or less than 1% of the pretax gain. The tax expense is lower than the federal statutory rate of 34% primarily due to net operating losses which offset the gain. In addition, earnings from discontinued operations of \$177,000 and \$1,207,000, respectively, for the six months ended June 30, 2003 and June 30, 2002, are net of tax expenses of \$26,000 and \$221,000, respectively, or 13% and 15% of pretax earnings, respectively. These tax expenses, which include foreign taxes, are lower than the federal statutory rate of 34% primarily due to overall U.S. net operating losses which offset the U.S. earnings of the discontinued operation.

### **Liquidity and Capital Resources**

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

The Company is a party to an agreement with Endo with respect to the development of oxymorphone ER. On April 17, 2003, the Company discontinued its participation in the funding of the development and marketing of oxymorphone ER. Accordingly, the Company anticipates its research and development and selling, and general and administrative expenses with respect to oxymorphone ER will decrease significantly in 2003 after the first quarter, unless the Company resumes its participation in the funding of the development and marketing of oxymorphone ER. The Company anticipates using the funds that otherwise would have been expended on oxymorphone ER to increase its investment in the development of additional products utilizing TIMERx technologies and in research and development involving new drug delivery technologies.

On February 27, 2003, the Company completed the sale of its excipient business to Rettenmaier. As a result of the Asset Sale, the Company had approximately \$35 million of net cash proceeds available after the closing, which the Company plans to use to fund development of products in its pipeline as well as the rest of



the Company's operations. However, as a result of the Asset Sale, the Company no longer derives cash flow from the sale of excipients. A portion of the proceeds from the sale of the excipient business was used to pay the \$3.3 million of outstanding borrowings under the Company's line of credit, which was terminated on February 27, 2003. In addition, the Company used the proceeds from the Asset Sale to repay in full a \$2.25 million note payable to AstraZeneca AB, incurred in connection with the Company's acquisition of certain intellectual property related to the excipient business.

On August 5 and August 6, 2003, the Company sold 2,507,762 shares of common stock through the Private Placement to selected institutional investors, resulting in gross proceeds to the Company of \$52.7 million, less fees and expenses estimated to be approximately \$3.3 million. In addition, the Company has granted the institutional investors additional rights to purchase up to an additional 501,552 shares of common stock at \$26.00 per share. These additional investment rights will become exercisable 90 days after the closing date or, if earlier, upon the effectiveness of a registration statement for the resale of the common stock issued to these investors, and will expire 60 trading days after the effectiveness of such registration statement.

As of June 30, 2003, the Company had cash, cash equivalents, and short-term investments of \$25.8 million, which excludes net cash proceeds of \$49.4 million from the Private Placement. The Company has no committed sources of capital other than Rettenmaier's commitment to repay the Company pursuant to promissory notes, of which \$1.0 million was received in April 2003 and \$1.25 million is due in May 2004, in connection with the sale of the excipient business.

The Company had negative cash flow from operations for the six months ended June 30, 2003 of \$11.2 million, primarily due to a loss from continuing operations of \$12.3 million in the period. The Company had negative cash flow from operations for the six months ended June 30, 2002 of \$9.2 million, primarily due to the loss from continuing operations of \$10.8 million in the period. Investing activities provided \$27.7 million in cash for the six months ended June 30, 2003, primarily reflecting the Company's receipt of cash proceeds from the Asset Sale of \$36.9 million, net of transaction costs paid of \$1.4 million. The Company used \$2.6 million of cash for financing activities, primarily with respect to the repayment of approximately \$5.5 million in loans in connection with the Asset Sale, offset by net cash provided by discontinued operations of approximately \$2.2 million. The Company expects that its cash flow in 2003 will differ from its cash flow during 2002 and 2001 because the Company will no longer derive revenues from sales of its excipient products nor will it incur expenses in connection with its excipient business, except for the related revenues and expenses during the period ended February 26, 2003.

The Company anticipates that its existing capital resources, including the proceeds from the Private Placement, and anticipated internally generated funds from the sale of formulated bulk TIMERx, royalties from Mylan and other payments from collaborators, will be sufficient to fund our operations for the foreseeable future if oxymorphone ER is approved by the FDA during 2004.

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

- the ongoing costs under the Company's other collaboration agreements;
- whether oxymorphone ER is approved on a timely basis or at all;
- whether the Company resumes its participation in the funding of the development and marketing of oxymorphone ER;
- the structure of any future collaborative or development agreements;
- the progress of the Company's collaborative and independent development projects and funding obligations with respect to the projects and the related costs to the Company of clinical studies for its products;
- the costs and timing of adding drug development capabilities;
- royalties received from Mylan;

- the timing and amount of payments received under existing and possible future collaborative agreements, in particular oxymorphone ER; and
- the prosecution, defense and enforcement of potential patent claims and other intellectual property rights.

In addition, if the Company's existing resources are insufficient to satisfy its need for capital due to a delay in the approval for oxymorphone ER, lower than expected revenues from oxymorphone ER or otherwise, or if the Company acquires additional product candidates or technologies, the Company may need to sell additional equity or debt securities or seek additional financing through other arrangements. Any sale of additional equity or debt securities may result in additional dilution to the Company's shareholders, and the Company cannot be certain that additional public or private financing will be available in amounts or on terms acceptable to the Company, if at all. If the Company is unable to obtain this additional financing, the Company may be required to delay, reduce the scope of, or eliminate one or more of its planned research, development and commercialization activities, which could harm its financial condition and operating results.

### Contractual Obligations

The Company's major outstanding contractual cash obligations relate to its operating leases, primarily for facilities, and a consulting agreement for an implementation project relating to its information system. Below is a table summarizing the Company's contractual obligations and non-cancelable commercial commitments, including operating leases having initial lease terms of more than one year, as of June 30, 2003 (in thousands):

	<u>Total</u>	<u>Less than One Year</u>	<u>1-3 Years</u>	<u>4-5 Years</u>	<u>After 5 Years</u>
Operating Leases .....	\$ 700	\$283	\$417	\$ —	\$ —
Other .....	<u>580</u>	<u>580</u>	<u>—</u>	<u>—</u>	<u>—</u>
Total .....	<u>\$1,280</u>	<u>\$863</u>	<u>\$417</u>	<u>\$ —</u>	<u>\$ —</u>

### Net Operating Loss Carryforwards

At June 30, 2003, the Company had federal net operating loss ("NOL") carryforwards of approximately \$60.6 million for income tax purposes, of which approximately \$6.2 million, \$8.4 million, \$9.1 million, \$17.8 million and \$19.1 million expire in 2018, 2019, 2020, 2021 and 2022, respectively. In addition, the Company had research and development tax credit carryforwards of approximately \$1.4 million of which \$299,000; \$306,000 and \$777,000 expire in 2019, 2020, and 2021, respectively. The use of the NOLs and research and development tax credit carryforwards are limited to future taxable earnings of the Company. Due to the degree of uncertainty related to the ultimate realization of such carryforwards, at June 30, 2003, a valuation allowance of approximately \$23.3 million has been recognized to offset net deferred tax assets, primarily attributable to the NOL carryforward. Utilization of the operating losses may be subject to a limitation due to the ownership change provisions of the Internal Revenue Code. The Company expects to use approximately \$1.4 million of NOL carryforwards (in addition to current year losses) to offset the Company's taxable capital gains and ordinary income from the sale of the excipient business.

### Forward Looking Statements

This annual report contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. All statements, other than statements of historical facts, included or incorporated in this report regarding our strategy, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words "believes," "anticipates," "estimates," "plans," "expects," "intends," "may," "projects," "will," and "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. In addition, any forward-looking

statements represent our estimates only as of the date this annual report is filed with the SEC and should not be relied upon as representing our estimates as of any subsequent date. We do not assume any obligation to update any forward-looking statements.

## **Risk Factors**

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

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

We have incurred net losses since 1994, including net losses of \$17.1 million, \$16.0 million and \$8.8 million, during 2002, 2001, and 2000, respectively. For the six months ended June 30, 2003, we had a loss from continuing operations of \$12.3 million, which was partially offset by income from discontinued operations of \$177,000 and a gain on the sale of the excipient business of \$9.5 million. This resulted in an overall net loss for the six months ended June 30, 2003 of \$2.6 million. As of June 30, 2003, our accumulated deficit was approximately \$81.1 million.

We expect net losses to continue until substantial sales of products commercialized utilizing TIMERx technology occur. If we are unable to successfully develop and commercialize these products, or generate substantial sales from these products, we may never achieve profitability.

A substantial portion of our revenues since 1994 has been generated from the sales of our pharmaceutical excipients. Our net losses in 2000, 2001 and 2002 were reduced as a result of the operating results of our excipient business. Effective February 27, 2003, we no longer generate any revenues from the sales of excipient products and our business depends exclusively on our drug delivery business.

Our future profitability will depend on several factors, including:

- the successful commercialization of TIMERx controlled release products, including in particular oxymorphone ER, a narcotic analgesic for the treatment of moderate to severe pain, being developed with Endo;
- our ability to use the net proceeds from the sale of our excipient business and the net proceeds from the Private Placements to fund the research, development, marketing and commercialization of our products and technologies;
- royalties from Mylan's sales of Pfizer's 30 mg generic version of Procardia XL; and
- the level of investment in research and development activities.

Our strategy includes a significant commitment to spending on research and development targeted at identifying and developing modified release products which can be formulated using our TIMERx and other drug delivery technologies. We also expect to expend significant resources on the development of new drug delivery technologies, both internally and through in-licenses or acquisition. Our spending in the area of new technology, however, is discretionary and is subject to the availability of appropriate opportunities and funding.

### ***We are dependent on collaborators to conduct clinical trials, obtain regulatory approvals for, and manufacture, market, and sell our TIMERx controlled release products***

Many of our TIMERx controlled release products have been or are being developed and commercialized in collaboration with pharmaceutical companies. Under these collaborations, depending on the structure of the collaboration, we are dependent on our collaborators to fund some portion of development, to conduct clinical trials, obtain regulatory approvals for, and manufacture, market and sell products utilizing our TIMERx controlled release technology. For instance, we are dependent on Endo to obtain the regulatory approvals required to market oxymorphone ER and will be dependent on Endo to manufacture and market oxymorphone ER in the United States. We are also dependent on Sanofi and Leiras to manufacture and market

Slofedipine XL and Cystrin CR, respectively. In addition, we are dependent on Mylan with respect to the marketing and sale of the 30 mg strength of Pfizer's generic version of Procardia XL.

Our collaborators may not devote the resources necessary or may otherwise be unable to complete development and commercialization of these potential products. Our existing collaborations are subject to termination on short notice under certain circumstances including, for example, if the collaborator determines that the product in development is not likely to be successfully developed or not likely to receive regulatory approval, if we breach the agreement or upon a bankruptcy event.

If we cannot maintain our existing collaborations or establish new collaborations, we would be required to terminate the commercialization of products or undertake commercialization activities at our own expense. Moreover, we have limited experience in conducting full-scale clinical trials, preparing and submitting regulatory applications and manufacturing, marketing and selling the pharmaceutical products. We may not be successful in performing these activities.

Our existing collaborations and any future collaborations with third parties may not be scientifically or commercially successful.

Factors that may affect the success of our collaborations include the following:

- our collaborators may be pursuing alternative technologies or developing alternative products, either on their own or in collaboration with others, that may be competitive with the product as to which they are collaborating with us, which could affect our collaborator's commitment to the collaboration with us;
- reductions in marketing or sales efforts or a discontinuation of marketing or sales of our products by our collaborators would reduce our revenues, which may be based on a percentage of net sales by the collaborator;
- our collaborators may terminate their collaborations with us, which could make it difficult for us to attract new collaborators or adversely affect our perception in the business and financial communities; and
- our collaborators may pursue higher priority programs or change the focus of their development programs, which could affect the collaborator's commitment to us.

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

The pharmaceutical industry is highly competitive and is affected by new technologies, governmental regulations, health care legislation, availability of financing, litigation and other factors. Many of our competitors have longer operating histories and greater financial, marketing, legal and other resources than we do and than certain of our collaborators do.

We face competition from numerous public and private companies and their extended release technologies, including Johnson & Johnson's oral osmotic pump (OROS®) technology, multiparticulate systems marketed by Elan, Biovail and KV Pharmaceuticals, traditional matrix systems marketed by SkyePharma, plc and other controlled release technologies marketed or under development by Andrx Corporation, among others.

Our TIMERx products in development will face competition from products with the same indication as the TIMERx products being developed by Penwest. For instance, we expect extended release oxymorphone ER will face competition from Purdue Pharma's OxyContin® and Duragesic® marketed by Johnson and Johnson.

In addition to developing controlled release versions of immediate release products, we also selectively develop generic versions of branded controlled release products. The success of generic versions of branded controlled release products based on our TIMERx technology will depend, in large part, on the intensity of competition from the branded controlled release product, other generic versions of the branded controlled

release product and other drugs and technologies that compete with the branded controlled release product, as well as the timing of product approval.

The generic drug industry is characterized by frequent litigation between generic drug companies and branded drug companies. Those companies with significant financial resources will be better able to bring and defend any such litigation.

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

In order to obtain regulatory approvals for the commercial sale of our potential products, including controlled release versions of immediate release drug, we or our collaborators will be required to complete clinical trials in humans to demonstrate the safety and efficacy of the products. We or our collaborators may not be able to obtain authority from the FDA or other regulatory agencies to commence or complete these clinical trials.

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

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

We and our collaborators may not be able to successfully complete any clinical trial of a potential product within any specified time period. In some cases, we may not be able to complete the trial at all. Moreover, clinical trials may not show any potential product to be safe or efficacious. Thus, the FDA and other regulatory authorities may not approve any of our potential products for any indication.

Our business, financial condition, or results of operations could be materially adversely affected if:

- we or our collaborators are unable to complete a clinical trial of one of our potential products;
- the results of any clinical trial are unfavorable; or
- the time or cost of completing the trial exceeds our expectations.

***We may not obtain regulatory approval; the approval process can be time-consuming and expensive***

We are not able to market any of our products in the United States, Europe or in any other jurisdiction without marketing approval from the United States Food and Drug Administration, or FDA, the European Agency for the Evaluation of Medicinal Products, or an equivalent foreign regulatory agency. The regulatory process to obtain market approval for a new drug takes many years and requires the expenditure of substantial resources. We have had only limited experience in preparing applications and obtaining regulatory approvals.

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

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

We also have a number of TIMERx products in our development pipeline. The most advanced of these is oxycodone ER, which we are developing with Endo. In February 2003, the FDA accepted for filing an NDA for oxycodone ER and the FDA is currently reviewing that application.



We may encounter delays or rejections during any stage of the regulatory approval process based upon the failure of clinical data to demonstrate compliance with, or upon the failure of the product to meet, the FDA's requirements for safety, efficacy and quality; and those requirements may become more stringent due to changes in regulatory agency policy or the adoption of new regulations. After submission of a marketing application, in the form of an NDA or an Abbreviated New Drug Application, or ANDA, the FDA may deny the application, may require additional testing or data and/or may require post marketing testing and surveillance to monitor the safety or efficacy of a product. While the U.S. Food, Drug and Cosmetic Act, or FDCA, provides for a 180-day review period, the FDA commonly takes one to two years to grant final approval to a marketing application.

Further, the terms of approval of any marketing application, including the labeling content, may be more restrictive than we desire and could affect the marketability of products incorporating our controlled release technology.

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

Other products containing our TIMERx controlled release technology require the filing of an NDA. A full NDA must include complete reports of preclinical, clinical and other studies to prove adequately that the product is safe and effective, which involves, among other things, full clinical testing, and as a result requires the expenditure of substantial resources. In certain cases involving controlled release versions of FDA-approved immediate release drugs, we may be able to rely on existing publicly available safety and efficacy data to support an NDA for controlled release products under Section 505(b)(2) of the FDCA when such data exists for an approved immediate release version of the same chemical entity. However, we can provide no assurance that the FDA will accept such section 505(b)(2) NDA, or that we will be able to obtain publicly available data that is useful. The section 505(b)(2) NDA process is a highly uncertain avenue to approval because the FDA's policies on section 505(b)(2) NDAs have not yet been fully developed. There can be no assurance that the FDA will approve an application submitted under section 505(b)(2) in a timely manner or at all.

The FDA also has the authority to revoke or suspend approvals of previously approved products for cause, to debar companies and individuals from participating in the drug-approval process, to request recalls of allegedly volatile products, to seize allegedly volatile products, to obtain injunctions to close manufacturing plants allegedly not operating in conformity with current Good Manufacturing Practices and to stop shipments of allegedly volatile products. The FDA may seek to impose pre-clearance requirements on products currently being marketed without FDA approval, and there can be no assurance that the Company or its third-party manufacturers or collaborators will be able to obtain approval for such products within the time period specified by the FDA.

***Even if we obtain marketing approval, our products will be subject to ongoing regulatory review***

If regulatory approval of a product is granted, such approval may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for costly post-marketing follow-up studies. As to products for which marketing approval is obtained, the manufacturer of the product and the manufacturing facilities will be subject to continual review and periodic inspections by the FDA and other regulatory authorities. The subsequent discovery of previously unknown problems with the product, manufacturer or facility may result in restrictions on the product or manufacturer, including withdrawal of the product from the market.

If we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

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

As of June 30, 2003, the Company had cash, cash equivalents, and short-term investments of \$25.8 million, which includes the net cash proceeds from the sale of the Company's excipient business. In addition, in August 2003, the Company received \$52.7 million less fees and expenses estimated to be approximately \$3.3 million, from the Private Placement. The Company has no committed sources of capital other than Rettenmaier's commitment to repay the Company pursuant to promissory notes, of which \$1.0 million was received in April 2003 and \$1.25 million is due in May 2004, in connection with the sale of the excipient business.

We anticipate that our existing capital resources, including the proceeds from the Private Placement, anticipated internally generated funds from the sale of formulated bulk TIMERx, royalties from Mylan and other payments from collaborators, and an anticipated launch of oxymorphone ER in 2004 will enable us to fund our currently planned operations, including the planned increase in our drug development and commercialization efforts, without having to raise additional capital for the foreseeable future.

We have had negative cash flows and net losses since 1994. See "We have not been profitable and expect to continue to incur substantial losses" for a discussion of our risk of continued losses. We expect negative cash flows from operations to continue until substantial sales of products commercialized utilizing TIMERx technology occur, particularly because we expect our operating expenses to continue to increase in the future, including our research and development expenses, as our product development efforts accelerate.

The proceeds from the sale of our excipient business provided us with significant funding, but we have lost the positive cash flows generated by our excipient business.

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

- the ongoing costs under the Company's other collaboration agreements;
- whether oxymorphone ER is approved on a timely basis, or at all;
- whether the Company resumes its participation in the funding of the development and marketing of oxymorphone ER;
- the structure of any future collaborative or development agreements;
- the progress of the Company's collaborative and independent development projects and funding obligations with respect to the projects and the related costs to the Company of clinical studies for its products;
- the costs and timing of adding drug development capabilities;
- royalties received from Mylan;
- the timing and amount of payments received under existing and possible future collaborative agreements, in particular oxymorphone ER; and
- the prosecution, defense and enforcement of potential patent claims and other intellectual property rights.

If we determine to seek additional funding, we may do so through collaborative agreements or research and development arrangements and public or private financings. Additional financing may not be available to us on acceptable terms, if at all.

If we raise additional funds by issuing equity securities, further dilution to our then existing shareholders will result. In addition, the terms of the financing may adversely affect the holdings or the rights of such shareholders.

Any sale of additional equity or debt securities may result in additional dilution to the Company's shareholders, and the Company cannot be certain that additional public or private financing will be available in amounts or on terms acceptable to the Company, if at all. If the Company is unable to obtain this additional financing, the Company may be required to delay, reduce the scope of, or eliminate one or more of its planned research, development and commercialization activities, which could harm its financial condition and operating results.

***Our controlled release products that are generic versions of branded controlled release products that are covered by one or more patents may be subject to litigation***

We expect to file or have our collaborators file ANDAs for our controlled release products under development that are generic versions of branded controlled release products that are covered by one or more patents. It is likely that the owners of the patents covering the brand name product or the sponsors of the NDA with respect to the branded product will sue or undertake regulatory initiatives to preserve marketing exclusivity, as Pfizer did with respect to our generic version of Procardia XL that we developed with Mylan. Any significant delay in obtaining FDA approval to market our product candidates as a result of litigation, as well as the expense of such litigation, whether or not we or our collaborators are successful, could have a material adverse effect on our business, financial condition and results of operations.

***The market may not be receptive to products incorporating our drug delivery technologies***

The commercial success of products incorporating our extended release technology that are approved for marketing by the FDA and other regulatory authorities will depend upon their acceptance by the medical community and third party payors as clinically useful, cost-effective and safe. No product based on our TIMERx or other extended release technology is marketed in the United States, so there can be no assurance as to market acceptance.

Other factors that we believe could materially affect market acceptance of these products include:

- the timing of the receipt of marketing approvals and the countries in which such approvals are obtained;
- the safety and efficacy of the product as compared to competitive products; and
- the cost-effectiveness of the product and the ability to receive third party reimbursement.

***Our success depends on our protecting our patents and patented rights***

Our success depends in significant part on our ability to develop patentable products, to obtain patent protection for our products, both in the United States and in other countries, and to enforce these patents. The patent positions of pharmaceutical firms, including us, are generally uncertain and involve complex legal and factual questions. As a result, patents may not issue from any patent applications that we own or license. If patents do issue, the claims allowed may not be sufficiently broad to protect our technology. In addition, issued patents that we own or license may be challenged, invalidated or circumvented. Our patents also may not afford us protection against competitors with similar technology.

Our success also depends on our not infringing patents issued to competitors or others. We are aware of patents and patent applications belonging to competitors and others that may require us to alter our products or processes, pay licensing fees or cease certain activities.

We may not be able to obtain a license to any technology owned by a third party that we require to manufacture or market one or more products. Even if we can obtain a license, the financial and other terms may be disadvantageous.

Our success also depends on our maintaining the confidentiality of our trade secrets and patented know-how. We seek to protect such information by entering into confidentiality agreements with employees, consultants, licensees and pharmaceutical companies. These agreements may be breached by such parties. We



may not be able to obtain an adequate, or perhaps, any remedy to such a breach. In addition, our trade secrets may otherwise become known or be independently developed by our competitors.

***We may become involved in patent litigation or other intellectual property proceedings relating to our products or processes which could result in liability for damage or stop our development and commercialization efforts***

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

- We or our collaborators may initiate litigation or other proceedings against third parties to enforce our patent rights.
- We or our collaborators may initiate litigation or other proceedings against third parties to seek to invalidate the patents held by such third parties or to obtain a judgment that our products or processes do not infringe such third parties' patents.
- If our competitors file patent applications that claim technology also claimed by us, we or our collaborators may participate in interference or opposition proceedings to determine the priority of invention.
- If third parties initiate litigation claiming that our processes or products infringe their patent or other intellectual property rights, we and our collaborators will need to defend against such proceedings.

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

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

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

We lack commercial scale facilities to manufacture our TIMERx material or any products we may develop in accordance with current GMP requirements prescribed by the FDA. We currently rely on Draxis Pharma, Inc. for the bulk manufacture of our TIMERx material for delivery to our collaborators under a contract that expires in September 2004. The agreement shall be automatically renewed for successive one-year periods, unless either party gives notice of its intent not to renew the contract, at least six months prior to the end of the then-current term.

There are a limited number of manufacturers that operate under GMP regulations capable of manufacturing our TIMERx material. Although the Company has qualified alternate suppliers with respect to these gums, if our current manufacturer is unable to manufacture the TIMERx material in the required quantities, on a timely basis or at all, we may be unable to obtain alternative contract manufacturing, or obtain such manufacturing on commercially reasonable terms.

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

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

We have limited experience in manufacturing TIMERx material on a commercial scale and no facilities or equipment to do so. If we determine to develop our own manufacturing capabilities, we will need to recruit qualified personnel and build or lease the requisite facilities and equipment. We may not be able to successfully develop our own manufacturing capabilities. Moreover, it may be very costly and time consuming for us to develop such capabilities.

The manufacture of any of our products is subject to regulation by the FDA and comparable agencies in foreign countries. Any delay in complying or failure to comply with such manufacturing requirements could materially adversely affect the marketing of our products and our business, financial condition and results of operations.

***We are dependent upon a limited number of suppliers for the gums used in our TIMERx material***

Our drug delivery systems are based a hydrophilic matrix combining a heterodispersed mixture primarily composed of two polysaccharides, xanthan and locust bean gums, in the presence of dextrose. These gums are also used in our Geminex and SyncroDose drug delivery systems. We purchase these gums from a sole source supplier. We have qualified alternate suppliers with respect to such materials, but we can provide no assurance that interruptions in supplies will not occur in the future or that we will not have to obtain substitute suppliers. Any interruption in these supplies could have a material adverse effect on our ability to manufacture bulk TIMERx for delivery to our collaborators.

***If we or our collaborators fail to obtain an adequate level of reimbursement by third party payors for our controlled release products, they may not be able to successfully commercialize controlled release products in certain markets***

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

The generic versions of controlled release products being developed by us and our collaborators may be assigned an AB rating if the FDA considers the product to be therapeutically equivalent to the branded controlled release drug. Failure to obtain an AB rating from the FDA would indicate that for certain purposes the drug would not be deemed to be therapeutically equivalent, would not be fully substitutable for the branded controlled release drug and would not be relied upon by Medicaid and Medicare formularies for reimbursement.

In both the U.S. and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system. Further proposals are likely. The potential for adoption of these proposals may affect our ability to raise capital, obtain additional collaborative partners and market our products.

If we or our collaborators obtain marketing approvals for our products, we expect to experience pricing pressure due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals. We may not be able to sell our products profitably if reimbursement is unavailable or limited in scope or amount.

***We will be exposed to product liability claims and may not be able to obtain adequate product liability insurance***

Our business exposes us to potential product liability risks which are inherent in the testing, manufacturing, marketing and sale of pharmaceutical products. Product liability claims might be made by consumers, health care providers, pharmaceutical companies, or others that sell our products. These claims may be made even with respect to those products that are manufactured in licensed and regulated facilities or that otherwise possess regulatory approval for commercial sale.

We are currently covered by primary product liability insurance in the amount of \$1 million per occurrence and \$2.0 million annually in the aggregate on a claims-made basis and by umbrella liability insurance in excess of \$25.0 million which can also be used for product liability insurance. This coverage may not be adequate to cover any product liability claims. Product liability coverage is expensive. In the future, we may not be able to maintain or obtain such product liability insurance at a reasonable cost or in sufficient amounts to protect us against losses due to liability claims. Any claims that are not covered by product liability insurance could have a material adverse effect on our business, financial condition and results of operations.

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

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

### **Item 3. *Quantitative and Qualitative Disclosures About Market Risk***

#### **Market Risk and Risk Management Policies**

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

The primary objectives for the Company's investment portfolio are liquidity and safety of principal. Investments are made to achieve the highest rate of return to the Company, consistent with these two objectives. The Company's investment policy limits investments to certain types of instruments issued by institutions with investment grade credit ratings and places restrictions on maturities and concentration by issuer. Marketable securities primarily consist of corporate debt, certificates of deposit and U.S. Government Agency-backed notes, and approximated \$10.1 million at June 30, 2003. These securities have contractual maturity dates of up to twenty months. Due to the relatively short-term maturities of these securities, management believes there is no significant market risk. At June 30, 2003, market values approximated carrying values. At June 30, 2003, the Company had approximately \$25.8 million in cash, cash equivalents and investments in marketable securities, and accordingly, a sustained decrease in the rate of interest earned of 1% would cause a decrease in the annual amount of interest earned of up to approximately \$258,000.

#### **Item 4. *Controls and Procedures***

The Company's management, with the participation of the Company's chief executive officer and chief financial officer, evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of June 30, 2003. Based on this evaluation, the Company's chief executive officer and chief financial officer concluded that, as of June 30, 2003, the Company's disclosure controls and procedures were (1) designed to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to the Company's chief executive officer and chief financial officer by others within those entities, particularly during the period in which this report was being prepared and (2) effective, in that they provide reasonable assurance that information required to be disclosed by the 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.

No change in the Company's internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended June 30, 2003 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

## PART II — OTHER INFORMATION

### Item 4. *Submission of Matters to a Vote of Security Holders*

At the Company's Annual Meeting of Shareholders held on June 4, 2003, the following proposals were adopted by the vote specified below:

- a. Election of Class III directors for a term of three years:

	<u>For</u>	<u>Withhold</u>
Tod R. Hamachek .....	12,432,439	1,317,043
Robert J. Hennessey .....	13,732,197	17,285
Dr. John N. Staniforth .....	12,561,883	1,187,599

The following directors did not stand for reelection as their terms in office continued after the Annual Meeting: Paul E. Freiman, Jere E. Goyan, Rolf H. Henel and Anne M. VanLent.

- b. Ratification of the selection of Ernst & Young LLP as independent auditors of the Company for the current year:

<u>For</u>	<u>Against</u>	<u>Abstain</u>	<u>Broker Non-Votes</u>
13,710,366	21,336	17,780	NONE

### Item 6. *Exhibits and Reports on Form 8-K*

- a. *Exhibits.*

See exhibit index below for a list of the exhibits filed as part of this Quarterly Report on Form 10-Q, which exhibit index is incorporated herein by reference.

- b. *Reports on Form 8-K.*

On May 12, 2003, the Company filed a report on Form 8-K announcing its results for the first quarter ended March 31, 2003.

## SIGNATURE

Pursuant to the requirements 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  
*Senior Vice President, Finance and Chief Financial  
Officer (Principal Financial Officer)*

Date: August 12, 2003

## EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of The Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of The Sarbanes-Oxley Act of 2002
32.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of The Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of The Sarbanes-Oxley Act of 2002