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, 2002

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	91-1513032
(State of Incorporation)	(I.R.S. Employer Identification No.)
2981 Route 22, Patterson, NY	12563-2335
(Address of principal executive offices)	(Zip Code)

(845) 878-3414
(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 the number of shares outstanding of each of the issuer's classes of common stock, as of August 9, 2002.

Class	Outstanding
Common stock, par value $.001	15,485,670

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PART I — FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

PENWEST PHARMACEUTICALS CO.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share amounts)

	June 30, 2002	December 31, 2001
	(Unaudited)	(Note 2)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 8,697	$ 12,903
Marketable securities	6,281	9,609
Trade accounts receivable, net of allowance for doubtful accounts of $214 at June 30, 2002 and $220 at December 31, 2001	7,283	6,228
Inventories:		
Raw materials and other	1,611	1,558
Finished goods	6,600	6,299
	8,211	7,857
Prepaid expenses and other current assets	679	1,166
Total current assets	31,151	37,763
Fixed assets, net	14,420	15,567
Patents, net	3,929	3,545
Other assets	2,808	2,738
Total assets	$ 52,308	$ 59,613
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,548	$ 2,174
Accrued expenses	1,772	2,275
Accrued development costs	3,110	3,139
Taxes payable	393	448
Loan payable	2,838	2,668
Total current liabilities	10,661	10,704
Deferred income taxes	205	205
Deferred revenue	323	369
Deferred compensation	2,798	2,711
Total liabilities	13,987	13,989
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 15,480,670 shares at June 30, 2002 and 15,276,630 shares at December 31, 2001	16	15
Additional paid in capital	109,769	108,054
Accumulated deficit	(70,562)	(60,926)
Accumulated other comprehensive loss	(902)	(1,519)
Total shareholders' equity	38,321	45,624
Total liabilities and shareholders' equity	$ 52,308	$ 59,613

See accompanying notes to condensed consolidated financial statements.

PENWEST PHARMACEUTICALS CO.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	Three Months Ended June 30,	
	2002	2001
	(Unaudited)	
Revenues		
Product sales	$ 8,943	$ 8,378
Royalties and licensing fees	1,318	1,137
Total revenues	10,261	9,515
Cost of product sales	6,230	5,817
Gross profit	4,031	3,698
Operating expenses		
Selling, general and administrative	3,776	3,742
Research and product development	5,540	2,960
Total operating expenses	9,316	6,702
Loss from operations	(5,285)	(3,004)
Investment income	112	20
Interest expense	62	78
Loss before income taxes	(5,235)	(3,062)
Income tax expense	83	104
Net loss	$ (5,318)	$ (3,166)
Basic and diluted net loss per share	$ (0.34)	$ (0.25)
Weighted average shares of common stock outstanding	15,466	12,700

	Six Months Ended June 30,	
	2002	2001
	(Unaudited)	
Revenues		
Product sales	$18,118	$17,614
Royalties and licensing fees	2,456	2,840
Total revenues	20,574	20,454
Cost of product sales	12,824	12,380
Gross profit	7,750	8,074
Operating expenses		
Selling, general and administrative	7,149	6,737
Research and product development	10,129	6,283
Total operating expenses	17,278	13,020
Loss from operations	(9,528)	(4,946)
Investment income	242	60
Interest expense	120	152
Loss before income taxes	(9,406)	(5,038)
Income tax expense	230	251

Net loss	$ (9,636)	$ (5,289)
Basic and diluted net loss per share	$ (0.62)	$ (0.42)
Weighted average shares of common stock outstanding	15,432	12,689

See accompanying notes to condensed consolidated financial statements.

PENWEST PHARMACEUTICALS CO.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Six Months Ended June 30,	
	2002	**2001**
	(Unaudited)	
Net cash used in operating activities	$ (8,703)	$ (3,405)
Investing activities:		
Acquisitions of fixed assets, net	(259)	(252)
Intangible asset costs	(509)	(411)
Proceeds from maturities of marketable securities	3,250	—
Net cash provided by (used in) investing activities	2,482	(663)
Financing activities:		
Borrowings from credit facility	12,284	17,558
Repayments of credit facility	(12,115)	(14,845)
Issuance of common stock, net	1,714	357
Net cash provided by financing activities	1,883	3,070
Effect of exchange rate changes on cash and cash equivalents	132	(60)
Net decrease in cash and cash equivalents	(4,206)	(1,058)
Cash and cash equivalents at beginning of period	12,903	2,204
Cash and cash equivalents at end of period	$ 8,697	$ 1,146

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") is engaged in the development of pharmaceutical products based on novel oral drug delivery technologies. The Company is also a leader in the development, manufacture, and distribution of branded pharmaceutical excipients which are the inactive ingredients in tablets and capsules. Based on its fundamental expertise in tabletting ingredients, the Company has developed its proprietary TIMERx® controlled release drug delivery technology, which is applicable to a broad range of orally administered drugs, and ProSolv®, a high functionality excipient based on co-processing technology, which, among other things, improves the performance characteristics of tablets. The Company has manufacturing facilities in Iowa and Finland and has customers primarily throughout North America and Europe.

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

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-month and six-month periods ended June 30, 2002 are not necessarily indicative of the results that may be expected for the year ending December 31, 2002. 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, 2001.

The balance sheet at December 31, 2001 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

Certain prior year amounts have been reclassified to conform with the current year's presentation. These reclassifications had no effect on previously reported results of operations.

3. RECENT ACCOUNTING PRONOUNCEMENTS

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

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

4. CREDIT FACILITY

On January 17, 2001, the Company completed arrangements for a revolving line of credit ("Revolver") with a financial institution. Under the terms of the Revolver, the Company may borrow up to $10.0 million ("Line of Credit") as determined by a formula based on the Company's Eligible Accounts Receivable and Eligible Saleable Inventory, as defined in the agreement. Under the formula, generally 85% of the Company's U.S. and Canadian receivables, as well as generally 60% of the Company's U.S. saleable inventories, are included in the borrowing base. Amounts outstanding under the Revolver are collateralized by the Company's U.S. and Canadian accounts receivable, the Company's inventory and general intangibles. The Revolver has an initial term of three years, ending in January 2004, and provides for annual renewals thereafter.

The Revolver bears interest at a specified bank's prime rate plus 1% per annum, on the greater of $3.0 million or on the average outstanding balance. The Revolver also requires that fees be paid of 0.5% per annum on unused portions of the Line of Credit and provides for early termination fees of up to 0.75% in the event the Company terminates the Revolver prior to the end of the initial term.

The Revolver contains covenants, including the requirement that the Company maintain at all times, certain minimum levels of tangible net worth as defined, at varying specified amounts during the initial term of the agreement, and restrictions on the incurrence of additional indebtedness and the payment of dividends. The Revolver includes a lockbox requirement under the control of the lender, whereby collections of certain trade receivables are used to immediately reduce the balance of the Revolver.

The interest rate on the Revolver at June 30, 2002 was 5.75%.

5. INCOME TAXES

The effective tax rates for the quarters ended June 30, 2002 and 2001, were expenses of 2% and 3%, respectively. The effective tax rates for the six months ended June 30, 2002 and 2001 were expenses of 2% and 5%, respectively. The effective tax rates are higher than the federal statutory rate of a 34% benefit, due primarily to valuation allowances recorded to offset deferred tax assets relating to the Company's net operating losses, and state and foreign income taxes.

6. COMPREHENSIVE LOSS

The components of comprehensive loss for the three-month and six-month periods ended June 30, 2002 and 2001 are as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2002	2001	2002	2001
	(unaudited)		(unaudited)	
Net loss	$(5,318)	$(3,166)	$(9,636)	$(5,289)
Foreign currency translation adjustments	722	(111)	608	(417)
Change in unrealized net gains on marketable securities	26	—	9	—
Comprehensive loss	$(4,570)	$(3,277)	$(9,019)	$(5,706)

Accumulated other comprehensive 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.

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 "Certain Factors That May Affect Future Results."

OVERVIEW

Penwest is engaged in the development of pharmaceutical products based on novel oral drug delivery technologies. The Company is also a leader in the development, manufacture, and distribution of branded pharmaceutical excipients which are the inactive ingredients in tablets and capsules. Based on its fundamental expertise in tabletting ingredients, the Company has developed its proprietary TIMERx® controlled release drug delivery technology, which is applicable to a broad range of orally administered drugs, and its ProSolv® line of products, high functionality excipients based on co-processing technology, which, among other things, improve the performance characteristics of tablets.

The Company has incurred net losses since 1994. As of June 30, 2002, the Company's accumulated deficit was approximately $70.6 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 to date have been generated from sales of the Company's pharmaceutical excipients. The Company's future profitability will depend on several factors, including the successful commercialization of TIMERx controlled release products, including in particular oxymorphone ER, a narcotic analgesic for the treatment of moderate to severe pain, being developed with Endo Pharmaceuticals Inc.; royalties from Mylan Pharmaceuticals, Inc.'s sales of Pfizer, Inc.'s 30 mg generic version of Procardia XL; sales growth of the Company's pharmaceutical excipients products; royalties received on third parties' sales of products containing ProSolv; 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 extended 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 in predetermined percentages, but does not generally receive milestone payments. There can be no assurance that the Company's controlled release product development efforts will be successfully completed, that required regulatory approvals will be obtained or that approved products will be successfully manufactured or marketed.

The Company's business is conducted internationally and may be affected by fluctuations in currency exchange rates, as well as by governmental controls and other risks associated with international sales (such as export licenses, collectibility of accounts receivable, trade restrictions, and changes in tariffs). The Company's international subsidiaries transact a substantial portion of their sales and purchases in European currencies other than their functional currency, which can result in the Company having gains or losses from currency exchange rate fluctuations. The Company does not use derivatives to hedge the impact of fluctuations in foreign currencies.

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

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our discussion and analysis of our financial condition and results of operations are based upon our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. 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, allowance for doubtful accounts, inventory, deferred taxes, valuation allowance, and impairment of intangible assets. Actual results could differ materially from these estimates. For a more detailed explanation of the judgments made in these areas, refer to our Annual Report on Form 10-K for the year ended December 31, 2001.

RESULTS OF OPERATIONS

Quarters Ended June 30, 2002 and 2001

Total revenues increased by $746,000 or 7.8% for the second quarter ended June 30, 2002 to $10.3 million, from $9.5 million for the comparable quarter ended June 30, 2001. Product sales increased by 6.7% to $8.9 million for the quarter ended June 30, 2002 from $8.4 million for the quarter ended June 30, 2001. The increase in product sales reflects increased sales of the Company's ProSolv® products primarily attributable to additional approvals of customers' products containing ProSolv® in the ethical pharmaceutical market, and growth in the Company's European excipients business as a whole. This increase was offset slightly by lower sales of formulated bulk TIMERx. Royalties and licensing fees increased by $181,000 for the second quarter of 2002 to $1.3 million from $1.1 million in the second quarter of 2001, primarily due to higher royalties from Mylan attributable to increased sales of Pfizer's 30 mg generic version of Procardia XL, as well as higher royalties from the licensing of ProSolv®.

Gross profit increased to $4.0 million, or 39.3% of total revenues, for the second quarter of 2002 from $3.7 million, or 38.9% of total revenues, for the second quarter of 2001. The Company's gross profit increased primarily due to increased excipient sales, and higher royalties from Mylan and from the licensing of ProSolv, as noted above, but was partially offset by decreased sales of formulated bulk TIMERx. Gross profit percentage on product sales decreased to 30.3% for the second quarter of 2002 from 30.6% for the second quarter of 2001. This decrease was primarily attributable to lower sales in the second quarter of 2002 of formulated bulk TIMERx, which has higher overall margins than the Company's excipient products.

Selling, general and administrative expenses were essentially flat at approximately $3.8 million for the second quarter of 2002 and 2001.

Research and product development expenses increased by $2.6 million or 87.2% for the second quarter of 2002 to $5.5 million, from $3.0 million for the second quarter of 2001. In addition to the significant costs of Phase III clinical trials for oxymorphone ER being developed with Endo which were incurred in the second quarter, the Company increased its investment in the development of new products utilizing TIMERx technology and in the research of new drug delivery technologies.

As of June 30, 2002, the Company had several product candidates utilizing TIMERx technology in various stages of clinical trials. Completion of clinical trials and commercialization of these product candidates may take several years and the length of time can vary substantially according to the type, complexity, and novelty of a product candidate.

The most advanced of these product candidates is oxymorphone ER, which the Company is developing with Endo. Endo, which is conducting the clinical trials of the product, completed the pivotal Phase III clinical trial of the product in July 2002. Assuming favorable results of the ongoing clinical trials and that all other FDA requirements for filing are met, the Company expects that Endo will submit the NDA with the FDA for this product in the second half of 2002. The Company anticipates spending an additional $2.5 million on the oxymorphone program during the remainder of 2002.

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.

The effective tax rates for the quarters ended June 30, 2002 and 2001, were expenses of 2% and 3%, respectively. The effective tax rates are higher than the federal statutory rate of a 34% benefit, due primarily to valuation allowances recorded to offset deferred tax assets relating to the Company's net operating losses, and state and foreign income taxes.

Six Months Ended June 30, 2002 and 2001

Total revenues increased 0.6% for the six months ended June 30, 2002 to $20.6 million from $20.5 million for the six months ended June 30, 2001. Product sales increased by 2.9% to $18.1 million for the six months ended June 30, 2002 compared to $17.6 million for the six months ended June 30, 2001. The increase in product sales was due to increased sales of excipient products, primarily in Europe, and was partially offset by lower revenues on sales of formulated bulk TIMERx. Royalties and licensing revenues decreased by $384,000 to $2.5 million for the first six months of 2002 as compared to $2.8 million in the comparable period in 2001, primarily due to lower royalties from Mylan as a result of increased competition for Mylan's generic Procardia XL from another generic version of Procardia XL.

Gross profit decreased to $7.8 million, or 37.7% of total revenues, for the first six months of 2002 from $8.1 million, or 39.5% of total revenues, for the first six months of 2001. This decrease was primarily due to lower royalties from Mylan as noted above.

Selling, general and administrative expenses increased by 6.1% for the first six months of 2002, to $7.1 million as compared with $6.7 million for the first six months of 2001. The increase was primarily due to increased compensation expense due to hiring additional drug delivery personnel, increased costs for the Company's annual report, and increased business insurance costs.

Research and product development expenses increased by 61.2% for the first six months of 2002 to $10.1 million from $6.3 million for the first six months of 2001. This increase was primarily due to the Company's share of the costs of clinical trials for oxymorphone ER being developed with Endo and the Company's increased investment in the development of new products utilizing TIMERx technology and in the research of new drug delivery technologies.

The effective tax rates for the first six months of 2002 and 2001 were expenses of 2% and 5%, respectively. The effective tax rates are higher than the federal statutory rate of a 34% benefit, due primarily to valuation allowances recorded to offset deferred tax assets relating to the Company's net operating losses, and state and foreign income taxes.

LIQUIDITY AND CAPITAL RESOURCES

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

As of June 30, 2002, the Company had cash, cash equivalents, and short-term investments of $15.0 million. The Company had no committed sources of capital at June 30, 2002 other than the Company's revolving line of credit ("Revolver") with CIT Group/Business Credit, Inc. Under the Revolver, generally 85% of the Company's U.S. and Canadian receivables, as well as generally 60% of the Company's U.S. saleable inventories, are included in the borrowing base. Amounts outstanding under the Revolver are collateralized by the Company's U.S. and Canadian accounts receivable, and its inventory and general intangibles. The Revolver has an initial term of three years ending January 2004, and provides for annual renewals thereafter. The Revolver bears interest at a specified bank's prime rate plus 1% per annum, on the greater of $3.0 million or on the average outstanding balance. The Revolver also requires that fees be paid of 0.5% per annum on unused portions of the Line of Credit and provides for early termination fees of up to 0.75% in the event the Company terminates the Revolver prior to the end of the initial term. The Revolver contains covenants, including the requirement that the Company maintain at all times, certain minimum levels of tangible net worth as defined, at varying specified amounts during the initial term of the agreement, and restrictions on the incurrence of additional indebtedness and the payment of dividends. The Revolver includes a lockbox requirement under the control of the lender, whereby collections of certain trade receivables are used to immediately reduce the balance of the Revolver. Under the terms of the Revolver, the Company may borrow up to $10.0 million ("Line of Credit") as determined by a formula based on the Company's Eligible Accounts Receivable and Eligible Saleable Inventory, as defined in the agreement. As of August 9, 2002, there was approximately $3.0 million outstanding under the Revolver.

As of June 30, 2002, the Company did not have any material commitments for capital expenditures. As of June 30, 2002, the Company's trade receivables were $7.3 million, an increase of $1.1 million from the $6.2 million in trade receivables at December 31, 2001. This increase was primarily due to higher sales of excipient products as well as increased royalties for the quarter. In connection with its strategic alliance agreement with Endo, the Company expects to expend approximately an additional $2.5 million in 2002 on the development and pre-marketing costs of oxymorphone ER.

The Company had negative cash flow from operations for the six months ended June 30, 2002 of $8.7 million, primarily due to the

net loss in the period. Funds expended during the first six months of 2002 for the acquisition of fixed assets were primarily related to additions at the Company's manufacturing facility in Iowa, laboratory equipment for drug development activities, and information technology associated with the Company strengthening its technology infrastructure to prepare for increasing drug development activities. Funds expended for intangible assets include costs to secure patents on technology developed by the Company and to secure trademarks.

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

The Company anticipates that its existing capital resources, including funds available under the Revolver as well as anticipated internally generated funds from the sale of excipients and formulated bulk TIMERx, royalties from Mylan and other payments from collaborators, will enable the Company to maintain currently planned operations through mid 2003. The Company may need to raise additional funds to maintain its operations beyond such date. The Company may seek to obtain additional funds through transactions relating to its business lines and/or debt or equity financings. The additional financing may not be available to the Company on acceptable terms, if at all. If adequate funds are not available, Penwest may be required to (i) significantly curtail its product commercialization efforts, including terminating existing collaborative agreements; (ii) obtain funds through arrangements with collaborators or others on adverse terms to Penwest that may require Penwest to relinquish rights to certain of its technologies, product candidates, or products which Penwest would otherwise pursue on its own or that would significantly dilute the Company's stockholders; (iii) significantly scale back or terminate operations and/or; (iv) seek relief under applicable bankruptcy laws.

CERTAIN FACTORS THAT MAY AFFECT FUTURE RESULTS

This Quarterly Report on Form 10-Q contains or incorporates forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical facts, included or incorporated in this report regarding our strategy, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words "believes," "anticipates," "estimates," "plans," "expects," "intends," "may," "projects," "will," and "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. There are a number of important factors that could cause actual results or events to differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. These important factors include the factors set forth below. In addition, any forward-looking statements represent Penwest's estimates only as of the date this Quarterly Report is first filed with the Securities and Exchange Commission and should not be relied upon as representing Penwest's estimates as of any subsequent date. We do not assume any obligation to update any forward-looking statements.

RISK FACTORS

WE HAVE NOT BEEN PROFITABLE

We have incurred net losses since 1994, including net losses of approximately $9.6 million for the first six months of 2002 and of $15.9 million, $8.8 million, and $7.7 million, during 2001, 2000, and 1999, respectively. As of June 30, 2002, our accumulated deficit was approximately $70.6 million. The Company expects net losses to continue until substantial sales of products commercialized utilizing TIMERx technology occur. A substantial portion of our revenues have been generated from the sales of our pharmaceutical excipients. Our future profitability will depend on several factors, including:

- the successful commercialization of TIMERx controlled release products, including in particular oxymorphone ER, a narcotic analgesic for the treatment of moderate to severe pain, being developed with Endo Pharmaceuticals Inc.;
- royalties from Mylan's sales of Pfizer's 30mg generic version of Procardia XL;
- royalties received on third parties' sales of products containing ProSolv;
- sales growth of our pharmaceutical excipient products; and
- the level of investment in research and development activities.

WE ARE DEPENDENT ON COLLABORATORS TO CONDUCT FULL-SCALE BIOEQUIVALENCE STUDIES AND CLINICAL TRIALS, OBTAIN REGULATORY APPROVALS FOR, AND MANUFACTURE, MARKET, AND SELL OUR TIMERx CONTROLLED RELEASE PRODUCTS

Certain of our TIMERx controlled release products we develop and commercialize in collaboration with pharmaceutical companies. We are parties to collaborative agreements with third parties relating to most of our current products. Under these collaborations, depending on the structure of the collaboration, we are dependent on our collaborators to fund some portion of development, to conduct full-scale bioequivalence studies and clinical trials, obtain regulatory approvals for, and manufacture, market and sell products utilizing our TIMERx controlled release technology. We are also dependent on Mylan with respect to the marketing and sale of the 30 mg strength of Pfizer's generic version of Procardia XL. Our collaborators may not devote the resources necessary or may otherwise be unable to complete development and commercialization of these potential products. Our existing collaborations are subject to termination without cause on short notice under certain circumstances.

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

Our existing collaborations and any future collaborations with third parties may not be scientifically or commercially successful. Factors that may affect the success of our collaborations include the following:

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

WE FACE SIGNIFICANT COMPETITION, WHICH MAY RESULT IN OTHERS DISCOVERING, DEVELOPING OR COMMERCIALIZING PRODUCTS BEFORE OR MORE SUCCESSFULLY THAN WE DO

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

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

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

In addition to developing controlled release versions of immediate release products, we concentrated a significant portion of our initial development efforts on generic versions of branded controlled release products. The success of generic versions of branded controlled release products based on our TIMERx technology will depend, in large part, on the intensity of competition from the

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

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

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

WE REQUIRE ADDITIONAL FUNDING

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

- the structure of any future collaborative or development agreements;
- the progress of our collaborative and independent development projects and funding obligations with respect to the projects;
- revenues from our excipients products;
- the costs to us of clinical studies for our products;
- the costs and timing of adding drug development capabilities;
- royalties received from Mylan;
- royalties from sales of TIMERx products;
- the timing and amount of payments received under existing and possible future collaborative agreements; and
- the prosecution, defense and enforcement of patent claims and other intellectual property rights.

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

Additional financing may not be available to Penwest on acceptable terms, if at all. If adequate funds are not available, Penwest may be required to (i) significantly curtail its product commercialization efforts, including terminating existing collaborative agreements; (ii) obtain funds through arrangements with collaborators or others on adverse terms to Penwest that may require Penwest to relinquish rights to certain of its technologies, product candidates, or products which Penwest would otherwise pursue on its own or that would significantly dilute the Company's stockholders; (iii) significantly scale back or terminate operations and/or; (iv) seek relief under applicable bankruptcy laws.

IF OUR CLINICAL TRIALS ARE NOT SUCCESSFUL OR TAKE LONGER TO COMPLETE THAN WE EXPECT, WE MAY NOT BE ABLE TO DEVELOP AND COMMERCIALIZE CERTAIN OF OUR PRODUCTS

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

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

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

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

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

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

WE MAY NOT OBTAIN REGULATORY APPROVAL; THE APPROVAL PROCESS CAN BE TIME-CONSUMING AND EXPENSIVE

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

We may encounter delays or rejections during any stage of the regulatory approval process based upon the failure of clinical data to demonstrate compliance with, or upon the failure of the product to meet, the FDA's requirements for safety, efficacy and quality; and those requirements may become more stringent due to changes in regulatory agency policy or the adoption of new regulations. After submission of a marketing application, in the form of an NDA or an ANDA, the FDA may deny the application, may require additional testing or data and/or may require postmarketing testing and surveillance to monitor the safety or efficacy of a product. While the U.S. Food, Drug and Cosmetic Act, or FDCA, provides for a 180-day review period, the FDA commonly takes one to two years to grant final approval to a marketing application (NDA or ANDA). Further, the terms of approval of any marketing application, including the labeling content, may be more restrictive than we desire and could affect the marketability of products incorporating our controlled release technology.

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

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

The FDA also has the authority to revoke or suspend approvals of previously approved products for cause, to debar companies and individuals from participating in the drug-approval process, to request recalls of allegedly violative products, to seize allegedly volative products, to obtain injunctions to close manufacturing plants allegedly not operating in conformity with current Good Manufacturing Practices and to stop shipments of allegedly violative products. The FDA may seek to impose pre-clearance

requirements on products currently being marketed without FDA approval, and there can be no assurance that the Company or its third-party manufacturers or collaborators will be able to obtain approval for such products within the time period specified by the FDA.

EVEN IF WE OBTAIN MARKETING APPROVAL, OUR PRODUCTS WILL BE SUBJECT TO ONGOING REGULATORY REVIEW

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

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

OUR CONTROLLED RELEASE PRODUCTS THAT ARE GENERIC VERSIONS OF BRANDED CONTROLLED RELEASE PRODUCTS THAT ARE COVERED BY ONE OR MORE PATENTS MAY BE SUBJECT TO LITIGATION

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

THE MARKET MAY NOT BE RECEPTIVE TO PRODUCTS INCORPORATING OUR TIMERx CONTROLLED RELEASE TECHNOLOGY

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

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

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

OUR SUCCESS DEPENDS ON OUR PROTECTING OUR PATENTS AND PATENTED RIGHTS

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

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

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

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

WE MAY BECOME INVOLVED IN PATENT LITIGATION OR OTHER INTELLECTUAL PROPERTY PROCEEDINGS RELATING TO OUR PRODUCTS OR PROCESSES WHICH COULD RESULT IN LIABILITY FOR DAMAGE OR STOP OUR DEVELOPMENT AND COMMERCIALIZATION EFFORTS

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

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

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

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

WE HAVE ONLY LIMITED MANUFACTURING CAPABILITIES AND WILL BE DEPENDENT ON THIRD PARTY MANUFACTURERS

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

There are a limited number of manufacturers that operate under GMP regulations capable of manufacturing our TIMERx material. We have not yet qualified a second source of supply. In the event that our current manufacturer is unable to manufacture the TIMERx material in the required quantities, on a timely basis or at all, we may be unable to obtain alternative contract manufacturing, or obtain such manufacturing on commercially reasonable terms.

If our third party manufacturer fails to perform its obligations, we may be adversely affected in a number of ways, including:

- our collaborators may not be able to meet commercial demands for our products on a timely basis;

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

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

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

WE ARE DEPENDENT UPON A LIMITED NUMBER OF SUPPLIERS FOR THE GUMS USED IN OUR TIMERx MATERIAL AND UPON A LIMITED NUMBER OF SUPPLIERS FOR THE WOOD PULP USED IN THE MANUFACTURE OF OUR EXCIPIENTS

Our TIMERx drug delivery system is a hydrophilic matrix combining primarily two polysaccharides, xanthan and locust bean gums, in the presence of dextrose. We purchase these gums from a sole source supplier. Emcocel and Prosolv, our two largest selling excipients, are manufactured from a specialty grade of wood pulp. We have qualified alternate suppliers with respect to such materials, but we can provide no assurance that interruptions in supplies will not occur in the future or that we will not have to obtain substitute suppliers. Any interruption in these supplies could have a material adverse effect on our ability to manufacture bulk TIMERx for delivery to our collaborators or to manufacture these excipients.

IF OUR COLLABORATORS FAIL TO OBTAIN AN ADEQUATE LEVEL OF REIMBURSEMENT BY THIRD PARTY PAYORS FOR OUR CONTROLLED RELEASE PRODUCTS, THEY MAY NOT BE ABLE TO SUCCESSFULLY COMMERCIALIZE CONTROLLED RELEASE PRODUCTS IN CERTAIN MARKETS

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

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

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

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

WE WILL BE EXPOSED TO PRODUCT LIABILITY CLAIMS AND MAY NOT BE ABLE TO OBTAIN ADEQUATE PRODUCT LIABILITY INSURANCE

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

We are currently covered by primary product liability insurance in the amount of $1 million per occurrence and $2 million annually in the aggregate on a claims-made basis and by umbrella liability insurance in excess of $25 million which can also be used for product liability insurance. This coverage may not be adequate to cover any product liability claims. Product liability coverage is expensive. In the future, we may not be able to maintain or obtain such product liability insurance at a reasonable cost or in sufficient amounts to protect us against losses due to liability claims. Any claims that are not covered by product liability insurance could have a material adverse effect on our business, financial condition and results of operations.

THE MARKET PRICE OF OUR COMMON STOCK MAY BE VOLATILE

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

CERTAIN PROVISIONS OF OUR CERTIFICATE OF INCORPORATION AND BYLAWS AND OF WASHINGTON LAW, AS WELL AS THE RIGHTS AGREEMENT TO WHICH WE ARE A PARTY, MAKE A TAKEOVER OF PENWEST MORE DIFFICULT

Provisions of our Certificate of Incorporation, our Bylaws and Washington law, as well as the Rights Agreement to which we are a party, may have the effect of deterring hostile takeovers or delaying or preventing changes in control or management of our company, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interest.

ITEM 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, including changes in interest rates and foreign currency exchange rates. The Company's interest rate risk primarily relates to its investments in marketable securities and its revolving line of credit which bears interest at variable rates. The Company's foreign currency exchange risk primarily relates to its international subsidiaries. The Company does not use derivatives to hedge the impact of fluctuations in foreign currencies or interest rates.

The primary objectives for the Company's investment portfolio are liquidity and safety of principal. Investments are made to achieve the highest rate of return to the Company, consistent with these two objectives. The Company's investment policy limits investments to certain types of instruments issued by institutions with investment grade credit ratings and places restrictions on maturities and concentration by issuer. Marketable securities consist of corporate debt and approximated $6.3 million at June 30, 2002. These securities have contractual maturity dates of up to fourteen months. Due to the relatively short-term maturities of these securities, management believes there is no significant market risk. At June 30, 2002, market values approximated carrying values. At June 30, 2002, the Company had approximately $15.0 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 $150,000.

The Company has a revolving line of credit with a financial institution which bears interest at a specified bank's prime rate plus 1% per annum (5.75% at June 30, 2002) on the greater of $3.0 million or on the average outstanding balance. At June 30, 2002, there was $2.8 million outstanding under the line and, accordingly, a sustained increase in the interest rate of 1% would cause increased annual interest expense of approximately $30,000.

The Company's international subsidiaries transact a substantial portion of their sales and purchases in European currencies other than their functional currency, which can result in the Company having gains or losses from currency exchange rate fluctuations. Where practical, the Company seeks to manage expected local currency revenues in relation to local currency costs, and manage local currency assets in relation to local currency liabilities. The Company does not believe that the potential exposure is significant in light of the size of the Company and its business. The effect of an immediate 10% change in exchange rates would not have a material effect on the Company's results of operations, financial position or cash flows.

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 5, 2002, the following proposals were adopted by the vote specified below:

a. Election of Class II directors for a term of three years:

	For	Withhold
Jere E. Goyan	12,255,968	412,613
Anne M. VanLent	12,254,629	413,952

The following directors did not stand for reelection as their terms in office continued after the Annual Meeting: Paul E. Freiman, Tod R. Hamachek, Rolf H. Henel, Robert J. Hennessey, N. Stewart Rogers, and John N. Staniforth.

b. Approval of an amendment to the Company's 1997 Equity Incentive Plan to increase the number of shares of Common Stock that may be issued thereunder from 2,660,000 shares to 3,410,000 shares:

For	Against	Abstain	Broker Non-Votes
8,853,117	3,694,948	120,516	None

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

For	Against	Abstain	Broker Non-Votes
11,462,742	1,154,932	50,907	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 7, 2002, the Company filed a report on Form 8-K announcing its results for the first quarter ended March 31, 2002.

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.

Date: August 12, 2002

PENWEST PHARMACEUTICALS CO.
/s/ Jennifer L. Good

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

EXHIBIT INDEX

Exhibit Number	Description
*10.1	Amended and Restated Strategic Alliance Agreement, dated as of April 2, 2002, by and between Endo Pharmaceuticals Holdings Inc. and the Company
99.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of The Sarbanes-Oxley Act of 2002

* Confidential treatment requested for certain portions of this Exhibit pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.