

**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 March 31, 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 (State of Incorporation)	_____ 91-1513032 (I.R.S. Employer Identification No.)
_____ 2981 Route 22, Patterson, NY (Address of principal executive offices)	_____ 12563-2335 (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 May 13, 2002.

_____ Class	_____ Outstanding
Common stock, par value \$.001	15,465,852

TABLE OF CONTENTS

PART I — FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

CONDENSED CONSOLIDATED BALANCE SHEETS

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

ITEM 2. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

PART II — OTHER INFORMATION

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

SIGNATURE

EXHIBIT INDEX

EX-10.1 ROYALTY AGREEMENT DATED SEPTEMBER 25, 1992

EX-10.2 CONFIDENTIALITY, CONSULTING AND NONCOMP...

EX-99 PAGES 23-30 OF COMPANY’S ANNUAL REPORT

PENWEST PHARMACEUTICALS CO.

TABLE OF CONTENTS

	PAGE
Part I	Financial Information
Item 1	Financial Statements (Unaudited)
	Condensed Consolidated Balance Sheets
	Condensed Consolidated Statements of Operations
	Condensed Consolidated Statements of Cash Flows
	Notes to Condensed Consolidated Financial Statements
Item 2	Management's Discussion and Analysis of Financial Condition and Results of Operations
Item 3	Quantitative and Qualitative Disclosures About Market Risk
Part II	Other Information
Item 6	Exhibits and Reports on Form 8-K
Signature	
Exhibit Index	

PART I — FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	March 31, 2002	December 31, 2001
	(Unaudited)	(Note 2)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 15,266	\$ 12,903
Marketable securities	7,268	9,609
Trade accounts receivable, net of allowance for doubtful accounts of \$226 and \$220	6,992	6,228
Inventories:		
Raw materials and other	1,495	1,558
Finished goods	6,160	6,299
	7,655	7,857
Prepaid expenses and other current assets	616	1,166
Total current assets	37,797	37,763
Fixed assets, net	14,985	15,567
Patents, net	3,854	3,545
Other assets	2,779	2,738
Total assets	<u>\$ 59,415</u>	<u>\$ 59,613</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 3,293	\$ 2,174
Accrued expenses	2,076	2,275
Accrued development costs	4,838	3,139
Taxes payable	510	448
Loan payable	2,799	2,668
Total current liabilities	13,516	10,704
Deferred income taxes	199	205
Deferred revenue	341	369
Deferred compensation	2,753	2,711
Total liabilities	16,809	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 15,450,852 shares at March 31, 2002 and 15,276,630 shares at December 31, 2001	15	15
Additional paid in capital	109,485	108,054
Accumulated deficit	(65,244)	(60,926)
Accumulated other comprehensive loss	(1,650)	(1,519)
Total shareholders' equity	42,606	45,624
Total liabilities and shareholders' equity	<u>\$ 59,415</u>	<u>\$ 59,613</u>

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 March 31,	
	2002	2001
	(Unaudited)	
Revenues		
Product sales	\$ 9,175	\$ 9,236
Royalties and licensing fees	1,138	1,703
Total revenues	10,313	10,939
Cost of product sales	6,594	6,563
Gross profit	3,719	4,376
Operating expenses		
Selling, general and administrative	3,373	2,995
Research and product development	4,589	3,323
Total operating expenses	7,962	6,318
Loss from operations	(4,243)	(1,942)
Investment income	130	40
Interest expense	58	74
Loss before income taxes	(4,171)	(1,976)
Income tax expense	147	147
Net loss	<u>\$ (4,318)</u>	<u>\$ (2,123)</u>
Basic and diluted net loss per share	<u>\$ (0.28)</u>	<u>\$ (0.17)</u>
Weighted average shares of common stock outstanding	<u>15,398</u>	<u>12,678</u>

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2002	2001
	(Unaudited)	
Net cash (used in) provided by operating activities	\$ (902)	\$ 352
Investing activities:		
Acquisitions of fixed assets, net	(146)	(93)
Intangible asset costs	(370)	(95)
Proceeds from maturities of marketable securities	2,250	—
Net cash provided by (used in) investing activities	1,734	(188)
Financing activities:		
Borrowings from credit facility	6,055	9,730
Repayments of credit facility	(5,925)	(7,147)
Issuance of common stock, net	1,431	139
Net cash provided by financing activities	1,561	2,722
Effect of exchange rate changes on cash and cash equivalents	(30)	(55)
Net increase in cash and cash equivalents	2,363	2,831
Cash and cash equivalents at beginning of period	12,903	2,204
Cash and cash equivalents at end of period	<u>\$15,266</u>	<u>\$ 5,035</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”) 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 tableting 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 period ended March 31, 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, and its inventory and general intangibles. The Revolver has an initial term of three years, 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 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 March 31, 2002 was 5.75%.

5. INCOME TAXES

The effective tax rates for the quarters ended March 31, 2002 and 2001, were expenses of 4% and 7%, 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 periods ended March 31, 2002 and 2001 are as follows:

	Three Months Ended March 31,	
	2002	2001
	(in thousands)	
Net loss	\$(4,318)	\$(2,123)
Foreign currency translation adjustments	(114)	(306)
Change in unrealized net gains on marketable securities	(17)	—
Comprehensive loss	<u>\$(4,449)</u>	<u>\$(2,429)</u>

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.

7. ISSUANCE OF COMMON STOCK

On July 11, 2001, the Company completed a private placement of 2,447,187 shares of its common stock to selected institutional investors, resulting in proceeds of approximately \$30 million, less expenses. The Company is using the net proceeds of this offering primarily for the development of drug delivery products as well as to fund the research and development of new oral drug delivery technologies.

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 tableting 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 incurred net losses since 1994. As of March 31, 2002, the Company's accumulated deficit was approximately \$65.2 million. The Company expects operating losses and negative cash flows during the remainder of 2002 and into 2003. A substantial portion of the Company's revenues to date have been generated from the 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; as well as 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 will be formulated using the Company's drug delivery 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 this area, however, is discretionary and is dependent on 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, royalties on Mylan's sales of Pfizer's 30 mg generic version of Procardia XL, 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 March 31, 2002 and 2001

Total revenues decreased by \$0.6 million or 5.7% for the first quarter ended March 31, 2002 to \$10.3 million, from \$10.9 million for the comparable quarter ended March 31, 2001. Product sales remained constant at approximately \$9.2 million for each of the quarters ended March 31, 2002 and 2001. Royalties and licensing fees decreased by \$0.6 million for the first quarter of 2002 as compared to the first quarter of 2001, primarily due to lower royalties from Mylan as a result of increased competition for generic Procardia XL. Product sales were impacted by a decline in the first quarter of 2002 as compared to the first quarter of 2001, in sales of bulk TIMERx resulting from the timing of certain customer orders. This decrease was largely offset by increased excipient product sales, reflecting greater sales of the Company's ProSolv® products primarily attributable to additional filings and approvals of customers' products containing ProSolv® in the ethical pharmaceutical market, and growth in its European excipients business.

Gross profit decreased to \$3.7 million, or 36.1% of total revenues, for the first quarter of 2002 from \$4.4 million, or 40.0% of total revenues, for the first quarter of 2001. The Company's gross profit declined primarily due to the lower royalties from Mylan noted above. Gross profit percentage on product sales decreased to 28.1% for the first quarter of 2002 from 28.9% for the first quarter of 2001. This decrease was primarily due to the lower sales in the first quarter of 2002 of bulk TIMERx, which has higher overall margins.

Selling, general and administrative expenses increased by \$0.4 million or 12.6% for the first quarter of 2002 to \$3.4 million, from \$3.0 million for the first quarter of 2001. This increase was primarily attributable to higher selling costs in Europe, including those associated with the opening of a sales office in France, increased compensation expense related to marketing and information technology, as well as higher business insurance costs.

Research and product development expenses increased by \$1.3 million or 38.1% for the first quarter of 2002 to \$4.6 million, from \$3.3 million for the first quarter of 2001. In addition to the significant costs of Phase III clinical trials for oxymorphone ER being developed with Endo, the Company increased its investment in developing new products utilizing TIMERx technology for its drug development pipeline, and in the research of new drug delivery technologies.

As of March 31, 2002, the Company had ten 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 Company's most advanced product candidate, oxymorphone ER, is currently in Phase III clinical trials. Endo is conducting these clinical trials, which are scheduled to be completed in the second quarter of 2002. Assuming the results of the clinical trials are consistent with the results of previous trials, the Company expects that Endo will submit the NDA for this product in the second half of 2002. The Company anticipates spending an additional \$7.0 million on this development and marketing 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 March 31, 2002 and 2001, were expenses of 4% and 7%, 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.

On July 11, 2001, the Company completed a private placement of 2,447,187 shares of its common stock to selected institutional investors, resulting in proceeds of approximately \$30 million, less expenses. The Company is using the net proceeds of this offering primarily for the development of drug delivery products as well as to fund the research and development of new oral drug delivery technologies.

As of March 31, 2002, the Company had cash, cash equivalents, and short-term investments of \$22.5 million. The Company had no committed sources of capital at March 31, 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, 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. It also 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 May 9, 2002, there was approximately \$3.0 million outstanding under the Revolver.

As of March 31, 2002, the Company did not have any material commitments for capital expenditures. As of March 31, 2002, the Company's trade receivables were \$7.0 million, an increase of \$0.8 million from the December 31, 2001 balance of \$6.2 million. In connection with its strategic alliance agreement with Endo, the Company expects to expend approximately an additional \$7.0 million in 2002 on the development and pre-marketing costs of oxymorphone ER.

The Company had negative cash flow from operations in the quarter ended March 31, 2002 of \$0.9 million, primarily due to the net loss in the period, partially offset by an increase of \$2.6 million in accounts payable and accrued expenses. This increase in accounts payable and accrued expenses is primarily attributable to the timing of a payment due to Endo which was not paid until April 2002. Funds expended during the first quarter of 2002 for the acquisition of fixed assets were primarily related to additions at the Company's manufacturing facility in Iowa, 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. 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 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 the first quarter of 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 discussed in the Overview to Management's Discussion and Analysis of Financial Condition and Results of Operations in this Quarterly Report and the factors set forth under "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations – Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2001, which factors are filed with this report as Exhibit 99 and incorporated herein by reference. 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.

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 \$7.3 million at March 31, 2002. These securities have contractual maturity dates of up to two years. Due to the relatively short-term maturities of these securities, management believes there is no significant market risk. At March 31, 2002, market values approximated carrying values. At March 31, 2002, the Company had approximately \$22.5 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 \$225,000.

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 March 31, 2002) on the greater of \$3.0 million or on the average outstanding balance. At March 31, 2002, there was approximately \$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 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 March 12, 2002, the Company filed a report on Form 8-K announcing its results for the fourth quarter ended December 31, 2001.

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: May 13, 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	Royalty Agreement dated September 25, 1992 between the Company and John N. Staniforth
10.2	Confidentiality, Consulting and Noncompetition Agreement dated September 25, 1992 between the Company and John N. Staniforth
99	Pages 23 through 30 of the Company's Annual Report on Form 10-K for the year ended December 31, 2001, as filed with the Securities and Exchange Commission on April 1, 2002 (which is not deemed filed except to the extent that portions thereof are expressly incorporated by reference herein)