BENTLEY PHARMACEUTICALS INC
Form 10-Q
May 10, 2004

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2004

OR

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

For the transition period from to

Commission File Number 1-10581

BENTLEY PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE **No. 59-1513162**

(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

Bentley Park, 2 Holland Way, Exeter, New Hampshire 03833

(Current Address of Principal Executive Offices)

Registrant s telephone number, including area code: **(603) 658-6100**

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in rule 12b-2 of the Exchange Act). YES ý NO o

The number of shares of the registrant s common stock outstanding as of May 7, 2004 was 20,600,909.

BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES

FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2004

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BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)

	March 31, 2004	December 31, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 37,812	$ 39,393
Marketable securities	1,218	1,252
Receivables, net	18,885	18,036
Inventories, net	7,439	7,106
Deferred taxes	207	213
Prepaid expenses and other	1,600	899
Total current assets	67,161	66,899
Non-current assets:		
Fixed assets, net	19,637	18,566
Drug licenses and related costs, net	13,536	13,818
Restricted cash	1,000	1,000
Other	169	180
Total non-current assets	34,342	33,564
	$ 101,503	$ 100,463
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 11,223	$ 10,154
Accrued expenses	7,774	7,103
Short-term borrowings	1,355	1,915
Current portion of long-term debt		70
Deferred income	2,272	1,956
Total current liabilities	22,624	21,198
Non-current liabilities:		
Deferred taxes	2,478	2,555
Long-term debt	358	369
Other	76	176
Total non-current liabilities	2,912	3,100
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $1.00 par value, authorized 2,000 shares, issued and outstanding, none		
	412	412

Common stock, $.02 par value, authorized 100,000 shares, issued and outstanding, 20,600 and 20,573 shares				
Stock purchase warrants (to purchase 420 and 420 shares of common stock)		333		333
Additional paid-in capital		137,072		136,850
Accumulated deficit		(65,790)		(66,599)
Accumulated other comprehensive income		3,940		5,169
Total stockholders equity		75,967		76,165
	$	101,503	$	100,463

The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these financial statements.

BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED INCOME STATEMENTS

AND STATEMENTS OF COMPREHENSIVE (LOSS) INCOME

(in thousands, except per share data)

	For the Three Months Ended March 31,	
	2004	**2003**
Revenues:		
Net product sales	$ 16,606	$ 14,235
Licensing and collaboration revenues	696	753
Total revenues	17,302	14,988
Cost of net product sales	8,196	6,121
Gross profit	9,106	8,867
Operating expenses:		
Selling and marketing	3,870	3,353
General and administrative	2,162	1,559
Research and development	995	1,018
Depreciation and amortization	406	283
Total operating expenses	7,433	6,213
Income from operations	1,673	2,654
Other income (expenses):		
Interest income	110	83
Interest expense	(53)	(54)
Income before income taxes	1,730	2,683
Provision for income taxes	921	1,151
Net income	$ 809	$ 1,532
Net income per common share:		
Basic	$ 0.04	$ 0.09
Diluted	$ 0.04	$ 0.08
Weighted average common shares outstanding:		

Basic		20,597		17,455
Diluted		22,784		20,350
Net income	$	809	$	1,532
Other comprehensive (loss) income:				
Foreign currency translation (losses) gains		(1,229)		680
Comprehensive (loss) income	$	(420)	$	2,212

The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these financial statements.

BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY

(in thousands, except per share data)

	$.02 Par Value Common Stock		Stock Purchase	Additional		Accumulated Other	
	Shares	Amount	Warrants	Paid-In Capital	Accumulated Deficit	Comprehensive Income	Total
Balance at December 31, 2003	20,573	$ 412	$ 333	$ 136,850	$ (66,599)	$ 5,169	$ 76,165
Exercise of stock options	20			122			122
Equity based compensation	7			100			100
Foreign currency translation adjustment						(1,229)	(1,229)
Net income					809		809
Balance at March 31, 2004	20,600	$ 412	$ 333	$ 137,072	$ (65,790)	$ 3,940	$ 75,967

The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these financial statements.

BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Three Months Ended March 31,	
	2004	**2003**
Cash flows from operating activities:		
Net income	$ 809	$ 1,532
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	829	500
Forgiveness of related party loans		75
Equity-based compensation expense	60	141
Other non-cash items	(55)	(152)
(Increase) decrease in assets and increase (decrease) in liabilities:		
Receivables	(1,438)	(1,248)
Inventories	(565)	599
Prepaid expenses and other current assets	(809)	(52)
Other assets	6	(42)
Accounts payable and accrued expenses	2,387	131
Deferred income	318	551
Other liabilities	(100)	(5)
Net cash provided by operating activities	1,442	2,030
Cash flows from investing activities:		
Proceeds from sale of investments	80,450	56,800
Purchase of investments	(80,395)	(56,763)
Additions to fixed assets	(2,096)	(2,268)
Additions to drug licenses and related costs	(268)	(386)
Net cash used in investing activities	(2,309)	(2,617)

(Continued on following page)

The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these financial statements.

BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS (concluded)

(in thousands)

	For the Three Months Ended March 31,	
	2004	**2003**
Cash flows from financing activities:		
Proceeds from exercise of stock options	$ 122	$ 30
Repayment of borrowings	(594)	(895)
Proceeds from borrowings	84	720
Net cash used in financing activities	(388)	(145)
Effect of exchange rate changes on cash	(326)	193
Net decrease in cash and cash equivalents	(1,581)	(539)
Cash and cash equivalents at beginning of period	39,393	26,581
Cash and cash equivalents at end of period	$ 37,812	$ 26,042
Supplemental Disclosures of Cash Flow Information		
The Company paid cash during the period for*:*		
Interest	$ 46	$ 42
Supplemental Disclosures of Non-Cash Financing and Investing Activities		
The Company has issued or is obligated to issue Common Stock in exchange for services as follows:		
Shares	7	49
Amount	$ 101	$ 391
Included in accounts payable at period-end are fixed asset and drug license purchases totaling	$ 1,619	$ 910

The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these financial statements.

BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

HISTORY AND OPERATIONS:

Bentley Pharmaceuticals, Inc. and Subsidiaries (which may be referred to as *Bentley Pharmaceuticals*, *Bentley*, *the Company*, *we*, *us* or *our*) is a U.S.-based international specialty pharmaceutical company, incorporated in the State of Delaware, focused on:

research, development and licensing/commercialization of advanced drug delivery technologies and pharmaceutical products; and

development, licensing and sales of generic and branded pharmaceutical products and the manufacturing of pharmaceuticals for others.

In our research and development activities, we have U.S. and international patents and other proprietary rights to technologies that facilitate the absorption of drugs. Our pharmaceutical product sales and licensing activities are based in Spain, where we have a significant commercial presence and manufacture and market approximately 100 pharmaceutical products through three wholly-owned Spanish subsidiaries, Laboratorios Belmac, Laboratorios Davur and Laboratorios Rimafar. These products represent various dosage strengths and product formulations of more than 30 chemical entities in four primary therapeutic areas: cardiovascular, gastrointestinal, neurological and infectious diseases. We continually add to our product portfolio in response to increasing market demand for generic and branded therapeutic agents and divest portfolio products that we consider to be redundant or that have become non-strategic. Although most of our sales of these products are currently in the Spanish market, we have recently focused on increasing our sales in other European countries and other geographic regions through strategic alliances with companies in these countries. We have a strategic alliance with Teva Pharmaceutical Industries Ltd. granting us the right to register and market in Spain more than 75 of Teva s pharmaceutical products through our sales force of approximately 150 full-time personnel located in major cities throughout Spain. In addition, our Spanish manufacturing facility produces pharmaceutical products which are marketed by pharmaceutical companies both in Spain and in other markets. We have also recently developed a strategy to introduce certain of our generic pharmaceutical products into the U.S. marketplace. Subsequent to March 31, 2004, we purchased an FDA approved manufacturing facility, located in Spain, which specializes in the manufacture of several active pharmaceutical ingredients (API). We will manufacture and market these products through our newly formed subsidiary, Bentley API.

We develop products which incorporate our drug delivery technologies and have licensed applications of our proprietary CPE-215® drug delivery technology to Auxilium Pharmaceuticals, Inc., which launched Testim , the first product incorporating our drug delivery technology, in February 2003. Testim is a gel indicated for testosterone replacement therapy which restores serum testosterone levels in men and thereby improves symptoms of health problems associated with low testosterone levels (hypogonadism), including loss of muscle mass and a decrease in sexual desire, sexual motivation and frequency of spontaneous erections. We are in discussions with other pharmaceutical and biotechnology companies to form additional strategic alliances to facilitate the development and commercialization of other products using our drug delivery technologies, including product candidates that deliver insulin to diabetic patients intranasally and treat nail fungus infections topically.

BASIS OF CONSOLIDATED FINANCIAL STATEMENTS:

The consolidated financial statements of Bentley Pharmaceuticals as of March 31, 2004 and for the three months ended March 31, 2004 and 2003, included herein, have been prepared by us, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted insofar as such information was disclosed in our consolidated financial statements for the year ended December 31, 2003. These consolidated financial statements should be read in conjunction with the summary of significant accounting policies and the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2003.

In the opinion of management, the accompanying unaudited consolidated financial statements as of March 31, 2004 and for the three months ended March 31, 2004 and 2003 are presented on a basis consistent with the audited consolidated financial statements for the year ended December 31, 2003 and contain all adjustments, consisting only of normal recurring adjustments, necessary to present fairly Bentley s financial position as of March 31, 2004 and the results of our operations and our cash flows for the three months ended March 31, 2004 and 2003. The results of operations for the three months ended March 31, 2004 should not necessarily be considered indicative of the results to be expected for the full year ending December 31, 2004.

CASH AND CASH EQUIVALENTS AND RESTRICTED CASH:

Included in *cash and cash equivalents* at March 31, 2004 and December 31, 2003 are approximately $34,344,000 and $29,156,000, respectively, of short-term investments considered to be cash equivalents, as the remaining maturity dates of such investments were three months or less when purchased.

The Company acquired intellectual property during the year ended December 31, 2003 for $1,000,000 plus future royalties on sales and licensing income. In connection with the acquisition, the Company obtained a renewable, irrevocable letter of credit in the amount of $1,000,000 in favor of the seller to guarantee future royalty payments. The $1,000,000 used to secure the letter of credit has been classified as *restricted cash* in the Consolidated Balance Sheets as of March 31, 2004 and December 31, 2003.

MARKETABLE SECURITIES:

The Company has investments in securities, with maturities of greater than three months when purchased, which are classified as available-for-sale, totaling $1,218,000 as of March 31, 2004, compared to $1,252,000 as of December 31, 2003. The Company s investments are carried at amortized cost which approximates fair value due to the short-term nature of these investments. Accordingly, no unrealized gains or losses have been recognized on these investments. Should the fair values differ significantly from the amortized costs, unrealized gains or losses would be included as a component of *other comprehensive income (loss)*.

INVENTORIES:

Inventories are stated at the lower of cost or market, cost being determined on the first in, first out (FIFO) method, and are comprised of the following (in thousands):

	March 31, 2004	December 31, 2003
Raw materials	$ 5,233	$ 5,351
Finished goods	2,278	1,829
	7,511	7,180
Less allowance for slow moving inventory	(72)	(74)
	$ 7,439	$ 7,106

FIXED ASSETS:

Fixed assets consist of the following (in thousands):

	March 31, 2004	December 31, 2003
Land	$ 1,867	$ 1,900
Buildings	8,879	9,085
Equipment	12,666	10,953
Furniture and fixtures	1,465	1,497
Leasehold improvements	44	43
	24,921	23,478
Less accumulated depreciation	(5,284)	(4,912)
	$ 19,637	$ 18,566

In order to support the Company s growth in Europe, we are adding additional capacity to our manufacturing facility through a series of improvements. During the three months ended March 31, 2004, the Company invested approximately $1,663,000 for machinery and equipment, including new high speed manufacturing and packaging equipment.

Subsequent to March 31, 2004, we purchased an FDA approved manufacturing facility, located in Spain which specializes in the manufacture of several active pharmaceutical ingredients, including methocarbamal (30 tons per annum), silver sulfadiazine (7 tons per annum), nimodipine, guaifenesin and ambroxol, for approximately $3,300,000. We will manufacture and market these products through our newly formed subsidiary, Bentley API. The 20,000 square foot facility is currently FDA approved for one product, which it sells to several customers in the United States. FDA approvals for additional products manufactured in the facility are currently pending. The facility is also certified for European Union production of API.

Depreciation expense of approximately $129,000 and $65,000 has been charged to operations as a component of *depreciation and amortization expense* in the Consolidated Income Statements for the three months ended March 31, 2004 and 2003, respectively. We have included depreciation totaling approximately $423,000 and $217,000 in *cost of net product sales* during the three months ended March 31, 2004 and 2003, respectively.

STOCKHOLDERS EQUITY:

A substantial amount of our business is conducted in Europe and is therefore influenced by fluctuations in the U.S. Dollar s value against other currencies, specifically the Euro. The exchange rate at March 31, 2004 and December 31, 2003 was .82 Euros and .80 Euros per U.S. Dollar, respectively. The weighted average exchange rate for the three months ended March 31, 2004 and

2003 was ..81 Euros and .93 Euros per U.S. Dollar, respectively. The effect of foreign currency fluctuations on long lived assets for the three months ended March 31, 2004 was a decrease of $1,229,000 and the cumulative historical effect was an increase of $3,940,000, as reflected in our Consolidated Balance Sheets as *accumulated other comprehensive income*. Although exchange rates fluctuated significantly in recent years, we do not believe that the effect of foreign currency fluctuation is material to our results of operations as the expenses related to much of our foreign currency revenues are in the same functional currency as those revenues, the Euro. However, the carrying value of assets and liabilities can be materially impacted by foreign currency translation, as can the translated amounts of revenues and expenses.

During the three months ended March 31, 2004, we issued 20,000 shares of Common Stock upon exercise of employee stock options, and approximately 8,000 shares of Common Stock as equity-based compensation in lieu of cash contributions to the Company-sponsored 401(k) retirement savings plan. Also during the three months ended March 31, 2004 we awarded our employees stock options to purchase approximately 403,000 shares of Common Stock.

LICENSING AND COLLABORATION REVENUES:

Our licensee, Auxilium Pharmaceuticals, Inc., launched its testosterone replacement gel, Testim, which utilizes our patented CPE-215 drug delivery technology, during the first quarter of 2003. Auxilium paid a $500,000 milestone payment to us during the first quarter of 2003, which we recorded as *licensing and collaboration revenues* in the Consolidated Income Statement for the three months ended March 31, 2003. In connection with the Testim product launch, we began earning royalty revenues on a percentage of Testim sales as defined in the licensing agreement with Auxilium. Royalty revenues on Testim product sales are recognized based on an estimate of Auxilium s sell-through of the Testim product based on prescriptions filled, until such time that returns from wholesalers and pharmacies can be reasonably estimated. For the three months ended March 31, 2004 and 2003, we recognized royalty revenues of $554,000 and $50,000, respectively, based on an estimate of prescriptions filled. The difference between the total amount earned from Auxilium under the royalty arrangement and the amount recognized as *licensing and collaboration revenues* is recorded as a component of *deferred income* in the Consolidated Balance Sheets. As of March 31, 2004 and December 31, 2003, deferred income from Testim royalties totaled $681,000 and $634,000, respectively. We will continue to use available market information to determine the amount and timing of royalty revenue recognition. Auxilium has recently filed an initial public offering with the SEC and has indicated in that filing, that approximately 30% of the proceeds from its offering of stock will be dedicated to furthering the commericialization of Testim.

PROVISION FOR INCOME TAXES:

As a result of reporting taxable income in Spain, we recorded provisions for foreign income taxes totaling $921,000 and $1,151,000 for the three months ended March 31, 2004 and 2003, respectively. These amounts represent 37% and 36% of the pre-tax income reported in Spain of $2,482,000 and $3,172,000 for the three months ended March 31, 2004 and 2003, respectively. No tax benefit has been recorded for U.S. losses, which totaled ($752,000) and ($489,000) for the three months ended March 31, 2004 and 2003, respectively, as future domestic operating profits cannot be reasonably assured. Accordingly, we have established a valuation allowance equal to the full amount of the U.S. deferred tax assets. The provisions for income taxes differ from the amounts computed by applying the U.S. federal income tax rate of 34% to pretax income, primarily as a result of the increase in the valuation allowance to offset U.S. deferred tax assets, certain nondeductible expenses in Spain and the higher statutory income tax rate of 35% in Spain.

Should we determine that it is more likely than not that we will realize certain of our net deferred tax assets for which we have previously provided a valuation allowance, an adjustment would be required to reduce the existing valuation allowance. In addition, we operate within multiple taxing jurisdictions and are subject to audit in those jurisdictions. These audits can involve complex issues, which may require an extended period of time for resolution. We are currently undergoing a tax review of our Spanish subsidiary, Laboratorios Belmac S.A., by the Spanish tax authorities. Certain tax contingencies exist and when probable and reasonably estimable, are provided for in the Consolidated Financial Statements. Accordingly, as of March 31, 2004, since these contingencies are not considered probable or reasonably estimable, no amounts have been provided for these contingencies. However, there is the possibility that the ultimate resolution of such issues could have an adverse effect on our results of operations.

BASIC AND DILUTED NET INCOME PER COMMON SHARE:

Basic and diluted net income per common share is based on the weighted average number of shares of common stock outstanding during each period. The dilutive effect of our outstanding stock options and stock purchase warrants, as calculated using the treasury stock method, were considered in the net income per share calculations for the three months ended March 31, 2004 and 2003.

The following is a reconciliation between basic and diluted net income per common share for the three months ended March 31, 2004 and 2003. Dilutive securities issuable for the three months ended March 31, 2004 include approximately 2,187,000 shares issuable as a result of various stock options and warrants that are outstanding and exercisable. Dilutive securities issuable for the three months ended March 31, 2003 included approximately 1,168,000 shares that were issuable as a result of Class B Warrants and approximately 1,727,000 shares that were issuable as a result of various stock options and other warrants that were outstanding at that time.

(in thousands, except per share data)

For the Three Months Ended March 31, 2004:

	Basic EPS	Effect of Dilutive Securities	Diluted EPS
Net Income	$ 809	$	$ 809
Weighted Average Common Shares Outstanding	20,597	2,187	22,784
Net Income Per Common Share	$ 0.04	$	$ 0.04

For the Three Months Ended March 31, 2003:

	Basic EPS	Effect of Dilutive Securities	Diluted EPS
Net Income	$ 1,532	$	$ 1,532
Weighted Average Common Shares Outstanding	17,455	2,895	20,350
Net Income Per Common Share	$ 0.09	$ (0.01)	$ 0.08

PROVISION FOR INCOME TAXES:

Excluded from the diluted EPS presentation, because their exercise prices were greater than the average fair value of the Common Stock in the respective periods, were warrants and options to purchase an aggregate of 642,000 and 1,011,000 shares of Common Stock, for the three months ended March 31, 2004 and 2003, respectively.

STOCK BASED COMPENSATION:

We have stock-based employee compensation plans that are described more fully in Note 11 of the Notes to Consolidated Financial Statements included in the Annual Report on Form 10-K for the year ended December 31, 2003. We account for these plans under the recognition and measurement principles of Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and related Interpretations. Options granted under these plans have exercise prices equal to or greater than the market value of the underlying Common Stock on the dates of grant, which is generally the date on which compensation is measured. In addition to these plans, we also sponsor a 401(k) retirement savings plan for eligible employees and match eligible contributions with shares of the Company s Common Stock. From time to time, at the discretion of the Compensation Committee of the Board of Directors (*the Compensation Committee*), the Company grants shares of its Common Stock to employees in lieu of cash compensation. Related stock-based employee compensation costs are reflected in the Consolidated Income Statements and Statements of Cash Flows.

General and administrative expenses for the three months ended March 31, 2004 and 2003 include $32,000 and $70,000, respectively, of non-cash equity-based compensation. Research and development expenses for the three months ended March 31, 2004 and 2003 include $28,000 and $71,000, respectively, of non-cash equity-based compensation.

The following table illustrates the effect on net income per share if we had applied the fair value recognition provisions of Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock-Based Compensation*, to stock-based employee compensation.

	For the Three Months Ended March 31,	
	2004	**2003**
Net income, as reported	$ 809	$ 1,532
Add: Stock-based employee compensation expense included in reported net income	60	141
Deduct: Total stock-based employee compensation expense determined under fair value method for all awards	(601)	(512)
Pro forma net income	$ 268	$ 1,161
Net income per common share:		
Basic - as reported	$ 0.04	$ 0.09
Basic - pro forma	$ 0.01	$ 0.07
Diluted - as reported	$ 0.04	$ 0.08
Diluted - pro forma	$ 0.01	$ 0.06

The preceding pro forma results were calculated using the Black-Scholes option pricing model with the following weighted average assumptions (results may vary depending on the assumptions applied within the model):

	For the Three Months Ended March 31,	
	2004	**2003**
Risk-free interest rate	3.2%	3.1%
Dividend yield	0.0%	0.0%
Expected life	5 years	5 years
Volatility	49.3%	50.6%
Fair value of options granted	$5.51	$3.87

Stock or other equity-based compensation for non-employees is accounted for under the fair value method as required by SFAS No. 123 and Emerging Issues Task Force (EITF) Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services* and other related interpretations.

RECLASSIFICATIONS:

Certain prior period amounts have been reclassified to conform with the current period s presentation. Such reclassifications are not material to the Consolidated Financial Statements.

NEW ACCOUNTING PRONOUNCEMENTS:

In November 2002, the EITF released Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*, which addresses certain aspects of the accounting by a vendor for arrangements under which it will perform multiple revenue-generating activities. EITF Issue No. 00-21 establishes three principles: revenue arrangements with multiple deliverables should be evaluated to determine if separate units of accounting exist; arrangement consideration should be allocated among the separate units of accounting based on their relative fair values; and revenue recognition criteria should be considered individually for each separate unit of accounting. EITF Issue No. 00-21 is effective for all revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The adoption of EITF Issue No. 00-21 in our third quarter of 2003 did not have a material effect on our financial position, results of operations or cash flows for the year ended December 31, 2003. However, the adoption of EITF Issue No. 00-21 requires the deferral and recognition over extended periods, of certain up-front fees, even if such fees or payments are non-refundable, associated with our multiple element collaboration and license agreements and of our marketing, distribution and supply agreements and may have an impact on future periods.

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

You should read the following discussion and analysis together with all financial and non-financial information appearing elsewhere in this report and with our consolidated financial statements and related notes included in our Annual Report on Form 10-K for the year ended December 31, 2003, which has been previously filed with the SEC. In addition to historical information, the following discussion and other parts of this report contain forward-looking information that involves risks and uncertainties. Our actual results could differ materially from those anticipated by such forward-looking information due to competitive factors and other risks discussed below under the caption Important Factors That May Affect Future Results .

RESULTS OF OPERATIONS:

Three Months Ended March 31, 2004 versus Three Months Ended March 31, 2003

Revenues

(in thousands)	For the Three Months Ended March 31, 2004	%	2003	%	Change $	%
Revenues:						
Net product sales	$ 16,606	96%	$ 14,235	95%	$ 2,371	17%
Licensing and collaboration revenues	696	4%	753	5%	(57)	-8%
Total revenues	$ 17,302	100%	$ 14,988	100%	$ 2,314	15%

Total revenues for the three months ended March 31, 2004 increased 15% from the same period in the prior year. However, our total revenues increased approximately 1% when expressed in constant currency. An increase in the weighted average value of the Euro, in relation to the U.S. Dollar, had the effect of increasing revenues by approximately $2,143,000, offsetting the impact of recent price reductions in Spain during the first quarter of 2004. In addition to the favorable impact of exchange rate fluctuation, the increase reflects the continued growth of our Spanish operations despite recent price reductions (the Company shipped approximately 25% more units of product in the first quarter of 2004 than in the first quarter of 2003) and, to a lesser degree, the advancement of our proprietary drug delivery programs in the U.S., as evidenced by the growing royalty stream from sales of Testim, the first marketed product incorporating our CPE-215 drug delivery technology, which was launched by our licensee in February 2003.

Our revenues are generated through our five primary sales channels (branded pharmaceuticals, generic pharmaceuticals, contract manufacturing for other pharmaceutical companies, sales outside of Spain and licensing and collaborations). See a summary of our revenues by sales channel and top-selling product lines below:

For the three months ended March 31, 2004:

(in thousands)	Sales Within Spain					
Product Line	**Branded Products**	**Generic Products**	**Contract Manu-facturing**	**Other Revenues**	**Total**	**% of Total Revenues**
Omeprazole	*$ 533*	*$ 3,288*	*$*	*$*	*$ 3,821*	*22%*
Paroxetine	*250*	*820*			*1,070*	*6%*
Simvastatin	*239*	*773*			*1,012*	*6%*
Codeisan	*903*	*-*			*903*	*5%*
Enalapril	*662*	*209*			*871*	*5%*
All other products	*1,704*	*1,693*			*3,397*	*20%*
Contract manufacturing			*2,534*		*2,534*	*15%*
Sales outside of Spain				*2,998*	*2,998*	*17%*
Licensing and collaborations				*696*	*696*	*4%*
Total Revenues	*$ 4,291*	*$ 6,783*	*$ 2,534*	*$ 3,694*	*$ 17,302*	*100%*
% of Total Revenues	*25%*	*39%*	*15%*	*21%*	*100%*	

For the three months ended March 31, 2003:

(in thousands)	Sales Within Spain					
Product Line	**Branded Products**	**Generic Products**	**Contract Manu-facturing**	**Other Revenues**	**Total**	**% of Total Revenues**
Omeprazole	*$ 1,499*	*$ 3,151*	*$*	*$*	*$ 4,650*	*31%*
Paroxetine						*0%*
Simvastatin	*372*	*796*			*1,168*	*8%*
Codeisan	*706*				*706*	*5%*
Enalapril	*505*	*457*			*962*	*6%*
All other products	*1,225*	*1,497*			*2,722*	*18%*
Contract manufacturing			*2,486*		*2,486*	*17%*
Sales outside of Spain				*1,541*	*1,541*	*10%*
Licensing and collaborations				*753*	*753*	*5%*
Total Revenues	*$ 4,307*	*$ 5,901*	*$ 2,486*	*$ 2,294*	*$ 14,988*	*100%*
% of Total Revenues	*29%*	*39%*	*17%*	*15%*	*100%*	

Spanish Operations. The core of our Spanish operations has been the efficient manufacturing and domestic marketing of branded and generic pharmaceutical products. Historically, our pharmaceutical products were sold only within Spain. However, the execution of our long-term strategic plan over the past eight years has created an opportunity for our Spanish operations to expand beyond the borders of Spain and into other European countries and other countries outside of Europe. First quarter 2004 product sales have been fueled by the introduction of our paroxetine product line, which was launched in May of 2003. Our paroxetine product line generated net sales of $1,070,000, representing

6% of our total revenues during the three months ended March 31, 2004. Revenues from our paroxetine products were second only to our omeprazole products in the first quarter of 2004, which in spite of recently reduced selling prices, comprised 22% of our total revenues in the first quarter of 2004, compared to 31% in the same quarter of the prior year.

Prices for prescription pharmaceutical products in Spain must be approved by the Ministry of Health. For several years now, the Ministry of Health has encouraged the substitution of generic-equivalent products in order to help control rising healthcare costs. In further efforts to reduce healthcare costs, the Ministry of Health had contemplated new laws and regulations that would significantly reduce the market prices of certain pharmaceutical products in Spain, including generic-equivalent drugs. In late October 2003, the Spanish government enacted a regulation that reduced the prices that the government reimburses for six of our chemical entities, including the chemical entities omeprazole, simvastatin and enalapril, which accounted for approximately 65% to 70% of revenues in the year ended December 31, 2003. These new prices were required to take effect on December 26, 2003. However, we, and some other pharmaceutical companies in Spain, strategically implemented the new prices on December 1, 2003.

Although the law required laboratories to begin selling at the new prices in December 2003, pharmacies in Spain were able to continue to sell at the old higher prices until January 31, 2004. This transition period was an attempt to reduce returns of the higher priced products by allowing the higher priced products to pass through the distribution channel to the end users. On average, our customers maintain a stock of approximately one to two months' supply of our products. As we began selling at the new lower prices on December 1, 2003, we expected the majority of our products that were labeled and stamped at the old higher prices to have cleared the distribution channel by January 31, 2004. We experienced an unforeseen level of returns totaling approximately $1,800,000 between mid February and mid March. A majority of the products returned were either expired, nearing expiration or otherwise not resalable and consequently were destroyed. As these product returns exceeded our allowance for estimated sales returns, they resulted in a reduction in total revenues of approximately $1,800,000 and a reduction in our gross profit of approximately $1,600,000 in the first quarter. Consequently our gross margins on net product sales were negatively impacted by four percentage points which contributed to a temporary decline in our margins to 51% for the three months ended March 31, 2004 compared to 57% for the three months ended March 31, 2003. Price reductions and product mix constitute the additional decrease of two percentage points in the first quarter. We expect our gross margins on product sales to be approximately 54% to 56% in the second quarter.

We have implemented several initiatives to mitigate the decline in margins. We expect to continue to increase our future sales volume through our pipeline of approximately 100 products, consisting of approximately 20 chemical entities that are not affected by the new pricing regulations. In addition, we have modified our pricing structure in efforts to increase our sales volume and market share throughout Spain. We will continue to focus on acquiring, developing and launching new products that will improve our product mix. We will also continue our efforts to increase our sales outside of Spain through additional registration, marketing, and supply agreements. Over the past several years we have made significant investments in renovating and increasing capacity in our manufacturing facility, as well as investments in new high speed, high volume equipment. Those investments are enabling us to manufacture and package larger quantities of products more efficiently and cost effectively. We anticipate that our gross margins will begin to gradually increase in the next few quarters as we continue to implement our strategy and benefit from economies of scale. See additional discussion about our gross margins below under the caption *Gross Profit*.

Branded Pharmaceutical Products

	For the Three Months Ended March 31,				Change	
(in thousands)	**2004**	**%**	**2003**	**%**	**$**	**%**
Branded Product Sales:						
Paroxetine	$ 250	*6%*	$	*	$ 250	*
Codeisan	903	*21%*	706	*16%*	197	*28%*
Enalapril	662	*15%*	505	*12%*	157	*31%*
Simvastatin	239	*6%*	372	*9%*	(133)	*-36%*
Omeprazole	533	*12%*	1,499	*35%*	(966)	*-64%*
All other branded products	1,704	*40%*	1,225	*28%*	479	*39%*
Total branded sales	$ 4,291	*100%*	$ 4,307	*100%*	$ (16)	*0%*

* Not meaningful

Sales of our branded pharmaceutical products remained relatively constant in U.S. Dollars compared to the prior year, and they accounted for 25% of total revenues during the three months ended March 31, 2004 compared to 29% of total revenues during the three months ended March 31, 2003. An increase in the weighted average value of the Euro, in relation to the U.S. Dollar, had the effect of increasing branded net product sales by approximately $562,000 in the first quarter of 2004. Most significantly, sales of our branded omeprazole and simvastatin products decreased by approximately $966,000 and $133,000, respectively, from the same quarter in the prior year as a result of the recent price reductions. Our branded omeprazole, Belmazol, for example, experienced the most severe of the price reductions, suffering on average a 61% price cut. Even in the face of these price cuts and strong generic competition, we were successful in maintaining market share and sold approximately the same number of units of Belmazol in the first quarter of 2004 as in the comparable period of the prior year. A 60% increase in unit sales of Enalapril and the launch of our branded version of paroxetine in May of 2003 helped mitigate the impact of the price cuts. Our branded enalapril continued to be a major contributor to our branded pharmaceutical revenues, even though its sales were affected by the price reductions. While we expect to continue to develop, acquire, and launch new branded products, our focus on generics and sales outside of Spain are expected to increase those revenues at a significantly higher pace than that of our branded products.

Generic Pharmaceutical Products

	For the Three Months Ended March 31,				Change	
(in thousands)	**2004**	**%**	**2003**	**%**	**$**	**%**
Generic Product Sales:						
Paroxetine	$ 820	*12%*	$	*	$ 820	*
Pentoxifylline	691	*10%*	446	*8%*	245	*55%*
Omeprazole	3,288	*49%*	3,151	*53%*	137	*4%*
Simvastatin	773	*11%*	796	*13%*	(23)	*-3%*
All other generic products	1,211	*18%*	1,508	*26%*	(297)	*-20%*
Total generic sales	$ 6,783	*100%*	$ 5,901	*100%*	$ 882	*15%*

* Not meaninningful

Sales of our generic pharmaceutical products increased by 15% during the three months ended March 31, 2004 compared to the three months ended March 31, 2003. An increase in the weighted average value of the Euro, in relation to the U.S. Dollar, had the effect of increasing generic product sales by approximately $953,000 in the first quarter of 2004. Strong sales of our generic omeprazole accounted for 49% of our generic pharmaceutical revenues in the first quarter of 2004, compared to 53% of generic revenues in the first quarter of the prior year, in spite of the recent price reductions. Sales of our generic paroxetine, which was launched in May of 2003, added approximately $820,000 to our generic sales, positioning it second only to our generic omeprazole in the first quarter, accounting for 93% of the growth in generic product sales when compared to the

comparable period of the prior year. Sales of our generic pentoxifylline increased by approximately $245,000, or approximately 55% from the same quarter in the prior year, while sales of our generic simvastatin, while higher in terms of units sold, remained relatively flat when sales are expressed in U.S. Dollars, accounting for approximately 11% of our generic pharmaceutical sales in the first quarter of 2004. We expect to continue to increase our generic drug portfolio and increase our generic drug sales in Spain as products come off patent in the future.

Contract Manufacturing

(in thousands)	For the Three Months Ended March 31, 2004	2003	Change $	Change %
Contract manufacturing	*$ 2,534*	*$ 2,486*	*$ 48*	*2%*

In addition to manufacturing our own products, our Spanish manufacturing facility supplies branded and generic products to approximately 17 entities in Spain, which market these products under their own name and with their own labeling. Revenues generated from contract manufacturing represented 15% of total revenues in the three months ended March 31, 2004, compared to 17% of total revenues in the three months ended March 31, 2003. An increase in the weighted average value of the Euro, in relation to the U.S. Dollar, had the effect of increasing contract manufacturing sales by approximately $323,000 in the first quarter of 2004. Our increased capacity and high speed, high volume equipment enables us to manufacture pharmaceutical products at relatively low costs. This competitive advantage could lead to an increase in contract manufacturing agreements throughout 2004 as other pharmaceutical companies in Spain search to find low cost alternatives to mitigate the impact of the new lower selling prices.

Sales Outside of Spain

(in thousands)	For the Three Months Ended March 31, 2004	2003	Change $	Change %
Sales outside of Spain	*$ 2,998*	*$ 1,541*	*$ 1,457*	*95%*

We have entered into license and supply agreements with more than 20 entities to sell our products outside of Spain. Sales under these supply agreements increased 95% from 10% of total revenues in the three months ended March 31, 2003 to 17% of total revenues in the three months ended March 31, 2004. The $1,457,000 increase is primarily attributable to demand for products that we manufacture and sell to customers outside of Spain. We believe that our highly efficient manufacturing processes could lead to increased sales outside of Spain as other countries around the world seek to reduce health care costs and other pharmaceutical companies outside of Spain search to find low cost manufacturing alternatives to remain competitive in their respective markets. An increase in the weighted average value of the Euro, in relation to the U.S. Dollar, had the effect of increasing sales outside of Spain by approximately $382,000 during the three months ended March 31, 2004.

Licensing and Collaboration Revenues. Licensing and collaboration revenues account for 4% of total revenues in the three months ended March 31, 2004. These revenues include royalties totaling $554,000 (compared to $50,000 in the first quarter of the prior year) from the commercialization and continuing sales of Testim, the first product incorporating our drug delivery technology, which was launched by our licensee, Auxilium, in February 2003. Testim is currently reported to capture approximately 10-11% of all new testosterone gel replacement prescriptions in the market. We have also recognized revenues totaling $142,000 during the three months ended March 31, 2004, related to product licensing activities in Europe. Licensing and collaboration revenues in the first quarter of the prior year included non-recurring one-time milestone payments of $500,000.

Gross Profit. Gross profit increased by approximately 3% in the three months ended March 31, 2004 compared to the three months ended March 31, 2003 to $9,106,000. As discussed previously, our gross margins on net product sales decreased to 51% for the three months ended March 31, 2004 from 57% during the three months ended March 31, 2003. The decrease in gross margins is the result of unexpected sales returns, which had the effect of decreasing our margins on net product sales by four percentage points. We expect our gross margins on product sales to be approximately 54% to 56% in the second quarter of 2004. The government-mandated price reductions and our current product mix, partially offset by an increase in the weighted average value of the Euro, in relation to the U.S. Dollar, of approximately $1,118,000 during the three months ended March 31, 2004, explain the balance of the gross margin reduction in the first quarter of 2004.

It is possible that our gross margins could decrease in the future as sales of higher priced products are continually replaced with sales of lower priced generic products, as a result of a change in our product mix or by additional governmental action. However, we have implemented several initiatives to mitigate the decline in margins. We expect to continue to increase our future sales volume through our pipeline of approximately 100 products, consisting of approximately 20 chemical entities that are not affected by the new pricing regulations. In addition, we have modified our pricing structure in efforts to increase our sales volume and market share throughout Spain. We will continue to focus on acquiring, developing and launching new products that will improve our product mix. We will also continue our efforts to increase our sales outside of Spain through additional registration, marketing, and supply agreements. Over the past several years we have made significant investments in renovating and increasing capacity in our manufacturing facility, as well as investments in new high speed, high volume equipment. Those investments are enabling us to manufacture and package larger quantities of products more efficiently and cost effectively. We anticipate that our gross margins will begin to gradually increase in the next few quarters as we continue to implement our strategy and benefit from economies of scale.

Selling and Marketing Expenses

(in thousands)	For the Three Months Ended March 31, 2004	2003	Change $	Change %
Selling and marketing	*$ 3,870*	*$ 3,353*	*$ 517*	*15%*

Selling and marketing expenses for the three months ended March 31, 2004 increased 15% from the same period in the prior year. The weighted average value of the Euro, in relation to the U.S. Dollar, had the effect of increasing selling and marketing expenses by approximately $490,000 in the three months ended March 31, 2004, accounting for approximately 95% of the increase. Selling and marketing expenses as a percentage of net product sales decreased slightly to 23.3% in the three months ended March 31, 2004 compared to 23.6% of net product sales in the three

months ended March 31, 2003.

General and Administrative Expenses

(in thousands)	For the Three Months Ended March 31, 2004	2003	Change $	%
General and administrative	*$ 2,162*	*$ 1,559*	*$ 603*	*39%*

General and administrative expenses for the three months ended March 31, 2004 increased 39% from the same period in the prior year. The $603,000 increase was the result of increased general and administrative activities required to support our continued growth and prepare for our anticipated future growth. These expenditures include increased costs in the current year for additional employees, outside services, occupancy costs, corporate communications, insurance, etc. General and administrative expenses as a percent of total revenues increased to approximately 12.5% in the three months ended March 31, 2004, compared to approximately 10.4% of total revenues in the three months ended March 31, 2003. General and administrative expenses would have been approximately $174,000 lower, absent the increase in the weighted average value of the Euro, in relation to the U.S. Dollar, in the three months ended March 31, 2004. This foreign currency impact accounted for almost 30% of the increase in general and administrative expenses when compared to the prior year s first quarter. We expect that our future expenditures for general and administrative expenses will continue to increase as we grow. Although we cannot reasonably estimate the costs associated with implementation of the internal control provisions of the Sarbanes-Oxley Act of 2002, we do expect to incur costs not previously experienced.

Research and Development Expenses

(in thousands)	For the Three Months Ended March 31, 2004	2003	Change $	%
Research and development	*$ 995*	*$ 1,018*	*$ (23)*	*-2%*

Research and development expenses for the three months ended March 31, 2004 decreased 2% from the same period in the prior year. We completed and reported the results of a Phase I intranasal insulin trial during the first quarter of 2004. We are scheduled to commence a study in diabetic patients as part of our clinical program for the intranasal delivery of insulin in the near future. In addition, we are currently in the planning stages of clinical programs, including bio-equivalence studies to support the eventual distribution of certain of our Spanish generic pharmaceutical products in other countries, including the U.S. We expect to continue to incur costs to conduct clinical trials and support the required regulatory submissions for our clinical programs. We also incur costs related to pre-clinical programs for product formulation and testing efforts being performed in the laboratory in our U.S. headquarters and at our facility in Zaragoza, Spain. We are using our U.S. laboratory to develop potential product applications using our drug delivery technologies. The expenditures in research and development reflect our focus on projects that are necessary for expansion of our portfolio of marketed products and clinical trials involving our drug delivery technologies. Although costs incurred in the first quarter of 2004 are consistent with those of the same quarter in the prior year and some of our cost estimates for our research and development programs are preliminary, and the specific timing is not known, our research and development expenses for the year ended December 31, 2004 could be $1,500,000 to $2,000,000 higher than in the year ended December 31, 2003.

Provision for Income Taxes

	For the Three Months Ended March 31, 2004		
(in thousands)	**Spain**	**U.S.**	**Consolidated**
Income (loss) before income taxes	*$ 2,482*	*$ (752)*	*$ 1,730*
Provision (benefit) for income taxes	*921*	*(256)*	*665*
Valuation allowance		*256*	*256*
Net provision for income taxes	*921*		*921*
Net income (loss)	*$ 1,561*	*$ (752)*	*$ 809*
Effective tax rate	*37%*	*0%*	*53%*

We recorded a provision for foreign income taxes totaling $921,000 (approximately 37% of the Spanish pretax income of $2,482,000) for the three months ended March 31, 2004 compared to a provision for foreign income taxes of $1,151,000 (approximately 36% of the Spanish pretax income of $3,172,000) in the three months ended March 31, 2003. The provision for foreign income taxes would have been approximately $128,000 lower than reported, absent the increase in the weighted average value of the Euro, in relation to the U.S. Dollar, during the three months ended March 31, 2004.

We generated additional U.S. federal net operating loss carry-forwards in the three months ended March 31, 2004 and 2003 as a result of U.S. pretax losses of ($752,000) and ($489,000), respectively. However, since we are not assured of future profitable domestic operations, we have recorded a valuation allowance for any future tax benefit of such losses in the U.S. Therefore, no tax benefit has been recognized with respect to U.S. losses reported in the three months ended March 31, 2004 or 2003.

Net Income

	For the Three Months Ended March 31,		Change	
(in thousands, except per share data)	**2004**	**2003**	**$**	**%**
Net income	*$ 809*	*$ 1,532*	*$ (723)*	*-47%*
Net income per common share:				
Basic	*$ 0.04*	*$ 0.09*	*$ (0.05)*	*-56%*
Diluted	*$ 0.04*	*$ 0.08*	*$ (0.04)*	*-50%*
Weighted average common shares outstanding:				
Basic	*20,597*	*17,455*	*3,142*	*18%*
Diluted	*22,784*	*20,350*	*2,434*	*12%*

We reported income from operations of $1,673,000 in the three months ended March 31, 2004 compared to $2,654,000 (which included a non-recurring one-time milestone payment of $500,000) in the three months ended March 31, 2003. The combination of income from operations of $1,673,000 and the non-operating items, primarily the provision for income taxes of $921,000, resulted in net income of $809,000, or $0.04

per basic common share ($0.04 per diluted common share) on 20,597,000 weighted average basic common shares outstanding (22,784,000 weighted average diluted common shares outstanding) in the current year first quarter, compared to net income

of $1,532,000, or $0.09 per basic common share ($0.08 per diluted common share) on 17,455,000 weighted average basic common shares outstanding (20,350,000 weighted average diluted common shares outstanding) in the same period of the prior year. Net income in the future could be negatively impacted as a result of the lower selling prices in Spain and anticipated increases in research and development programs that are expected to benefit future periods. However, as previously discussed, our broad-based growth strategy should mitigate the impact of these developments over time.

LIQUIDITY AND CAPITAL RESOURCES:

Total assets increased from $100,463,000 at December 31, 2003 to $101,503,000 at March 31, 2004, while stockholders equity decreased from $76,165,000 at December 31, 2003 to $75,967,000 at March 31, 2004. The decrease in stockholders equity primarily reflects the negative impact of the fluctuation of the Euro/U.S. dollar exchange rate, which totaled $1,229,000 in the current period, partially offset by net income of $809,000, and net proceeds from the exercise of stock options of approximately $122,000.

Cash, cash equivalents and marketable securities decreased by 4% or $1,615,000 from $40,645,000 at December 31, 2003 to $39,030,000 at March 31, 2004, primarily as a result of additions to fixed assets totaling $2,096,000, net repayment of borrowings of $510,000, and expenditures for drug licenses and related costs totaling $268,000, partially offset by $1,442,000 in cash provided by operating activities. Cash and cash equivalents at March 31, 2004 include approximately $34,344,000 of short-term liquid investments considered to be cash equivalents.

Receivables increased by 5% from $18,036,000 at December 31, 2003 to $18,885,000 at March 31, 2004. Receivables increased by approximately $1,438,000 in local currency, but fluctuations in foreign currency exchange rates decreased receivables reported in U.S. dollars by approximately $535,000. We have not experienced any material delinquencies on our receivables that have had a material effect on our financial position, results of operations or cash flows.

Inventories increased by approximately $333,000 from $7,106,000 at December 31, 2003 to $7,439,000 at March 31, 2004, primarily as a result of increased production during the quarter required to meet anticipated sales demand. Inventory increased by approximately $565,000 in local currency, and fluctuations in foreign currency exchange rates decreased inventories reported in U.S. dollars by approximately $232,000.

The combined total of accounts payable and accrued expenses increased from $17,257,000 at December 31, 2003 to $18,997,000 at March 31, 2004, primarily due to an increase in inventory (approximately $775,000) and income taxes payable (approximately $1,146,000), while fluctuations in foreign currency exchange rates decreased accounts payable and accrued expenses reported in U.S. dollars by approximately $593,000.

Short-term borrowings and current portion of long-term debt decreased from $1,985,000 at December 31, 2003 to $1,355,000 at March 31, 2004, primarily as a result of net repayment of short-term borrowings, payment of the current portion of long-term debt and the effect of fluctuations in foreign currency exchange rates. The weighted average interest rate on our short-term borrowings at March 31, 2004 was 3.7%.

Operating activities for the three months ended March 31, 2004 provided net cash of $1,442,000. Our future operating cash flows could be negatively impacted as a result of the recently enacted government regulations in Spain and anticipated increases in research and development programs that are expected to benefit future periods. However, as previously discussed, our broad-based growth strategy should mitigate the impact of these developments.

Investing activities, primarily capital expenditures to: (1) increase the capacity of our manufacturing facility in Spain, and (2) increase our manufacturing and packaging capabilities with new high speed equipment, along with additions to drug licenses and related costs, used net cash of $2,309,000 during the three months ended March 31, 2004.

Financing activities during the three months ended March 31, 2004 required cash totaling $388,000, and included net repayments of borrowings of approximately $510,000.

Our licensee, Auxilium Pharmaceuticals, Inc., launched its testosterone replacement gel, Testim, which utilizes our patented CPE-215 drug delivery technology, during the first quarter of 2003. Auxilium paid a $500,000 milestone payment to us during the first quarter of 2003, which we recorded as *licensing and collaboration revenues* in the Consolidated Income Statement for the three months ended March 31, 2003. In connection with the Testim product launch, we began earning royalty revenues on a percentage of Testim sales as defined in the licensing agreement with Auxilium. Royalty revenues on Testim product sales are recognized based on an estimate of Auxilium s sell-through of the Testim product based on prescriptions filled, until such time that returns from wholesalers and pharmacies can be reasonably estimated. For the three months ended March 31, 2004 and 2003, we recognized royalty revenues of $554,000 and $50,000, respectively, based on an estimate of prescriptions filled. The difference between the total amount earned from Auxilium under the royalty arrangement and the amount recognized as licensing and collaboration revenues is recorded as a component of *deferred income* in the Consolidated Balance Sheets. As of March 31, 2004 and December 31, 2003, deferred income from Testim royalties totaled $681,000 and $634,000, respectively. We will continue to use available market information to determine the amount and timing of royalty revenue recognition. Auxilium has recently filed an initial public offering with the SEC and has indicated in that filing, that approximately 30% of the proceeds from its offering of stock will be dedicated to furthering the commericialization of Testim.

Seasonality. In the past, we have experienced lower sales in the third calendar quarter and higher sales in the fourth calendar quarter due to seasonality. As we market more pharmaceutical products whose sales are seasonal, seasonality of sales may become more significant.

Effect of Inflation and Changing Prices. Neither inflation nor changing prices has materially impacted our net product sales or income from operations for the periods presented.

Liquidity. We plan to continue making improvements to our manufacturing facilities during the balance of 2004 to accommodate our continuing growth. As previously discussed, in April of 2004, we purchased an FDA approved manufacturing facility located in Spain, which specializes in the manufacture of several active pharmaceutical ingredients, for approximately $3,300,000. We estimate that capital investments of approximately $2,000,000 for the purchase of new manufacturing equipment will be required in the balance of 2004 to expand that facility. We also plan to continue improving and expanding our other manufacturing facility in Spain and plan to purchase new equipment to support our research and development activities in the U.S. We expect to invest an additional $3,000,000

in capital improvements and additions for these items during the balance of 2004. As mentioned above, we have cash, cash equivalents and short-term liquid investments totaling approximately $39,030,000 as of March 31, 2004, which is sufficient to fund our operations for the foreseeable future. Even though the Company is generating positive cash flow

from operations, (approximately $1,442,000 in the three months ended March 31, 2004), there can be no assurance that changes in our research and development plans, capital expenditures and/or acquisitions, or other events affecting our net product sales or operating expenses will not result in the earlier depletion of our funds. However, we continue to explore alternative sources for financing our business activities. In appropriate situations, which will be strategically determined, we may seek financial assistance from other sources, including contribution by others to joint ventures and other collaborative or licensing arrangements for the development, testing, manufacturing and marketing of products under development.

Critical Accounting Policies and Estimates

Our significant accounting policies are more fully described in Note 2 to our consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2003. However, certain of our accounting policies are particularly important to the portrayal of our financial position, results of operations and cash flows and require the application of significant judgment by our management; as a result they are subject to an inherent degree of uncertainty. In applying those policies, our management uses its judgment to determine the appropriate assumptions to be used in the determination of certain estimates. Those estimates are based on our historical experience, terms of existing contracts, our observance of trends in the industry, information provided by our customers and information available from other outside sources, as appropriate.

Important Factors That May Affect Future Results

This Quarterly Report on Form 10-Q contains forward-looking statements. These forward-looking statements appear principally in the section entitled Management s Discussion and Analysis of Financial Condition and Results of Operations. Forward-looking statements may appear in other sections of this report, as well. Generally, the forward-looking statements in this report include such words as expect, believe, continue, anticipate, estimate, may, will, could, opportunity, future, project, and similar expressions.

The forward-looking statements include statements about our:

- Strategic plans;
- Anticipated sources of future revenues;
- Anticipated 2004 margins and operating performance;
- Expected launch of new products;
- Anticipated expenses and spending;
- Commencement of clinical trials;
- The sufficiency of capital to fund our operations.

These forward-looking statements are based on our current expectations, beliefs, assumptions, estimates, forecasts and projections for our business and the industry and markets in which we compete. These statements are not guarantees of future performance and involve certain risks, uncertainties and assumptions that are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed in such forward-looking statements. We caution investors not to place undue reliance on the forward-looking statements contained in this report. These statements speak only as of the date of this report, and we do not undertake any obligation to update or revise them, except as required by law. The following factors, among others, create risks and uncertainties that could affect our future or other performance: expanding generic and branded drug operations,

changes in third-party reimbursement and government mandates which impact pharmaceutical pricing, development and commercialization of our products, relationships with our strategic partners, uncertainty of clinical trial results, regulatory approval process, unpredictability of patent protection, technological changes, the effects of economic conditions, risks associated with international operations, competition from other manufacturers of generic and proprietary pharmaceuticals, and difficulties in managing our growth and the other risk factors contained in the section entitled Risk Factors in our Annual Report on Form 10-K filed for the year ended December 31, 2003. As a result of these and other factors, we may experience material fluctuations in our future operating results, which could materially affect our business, financial position, and stock price.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Foreign Currency. A substantial amount of our business is conducted in Europe and is therefore influenced to the extent to which there are fluctuations in the U.S. Dollar s value against other currencies, specifically the Euro. The exchange rate at March 31, 2004 and December 31, 2003 was .82 Euros and .80 Euros per U.S. Dollar, respectively. The weighted average exchange rate for the three months ended March 31, 2004 and 2003 was .81 Euros and .93 Euros per U.S. Dollar, respectively. The effect of foreign currency fluctuations on long lived assets for the three months ended March 31, 2004 was a decrease of $1,229,000 and the cumulative historical effect was an increase of $3,940,000, as reflected in our Consolidated Balance Sheets as *accumulated other comprehensive income*. Although exchange rates have fluctuated significantly in recent years, we do not believe that the effect of foreign currency fluctuation is material to our results of operations as the expenses related to much of our foreign currency revenues are in the same functional currency as those revenues, namely the Euro. However, the carrying value of assets and liabilities can be materially impacted by foreign currency translation, as can the translated amounts of revenues and expenses. Nonetheless, we do not plan to modify our business practices at this time.

We have relied primarily upon financing activities to fund our operations in the U.S. In the event that we are required to fund U.S. operations or cash needs with funds generated in Europe, currency rate fluctuations in the future could have a significant impact on us. However, at the present time, we do not anticipate altering our business plans and practices to compensate for future currency fluctuations.

Interest Rates. The weighted average interest rate on our short-term borrowings is 3.7% and the balance outstanding is $1,355,000 as of March 31, 2004. A portion of our long-term borrowings is non-interest bearing and the balance outstanding on these borrowings at March 31, 2004 is $358,000 including imputed interest (ranging from 4.8% to 6.0%) of $80,000. The weighted average interest rate on our long-term borrowings is 5.6%. The effect of an increase in interest rates of one percentage point (one hundred basis points) to 4.7% on short-term borrowings and to an average of 6.6% on long-term borrowings would have the effect of increasing interest expense by approximately $17,000 annually.

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Item 4. Controls and Procedures

Bentley Pharmaceuticals maintains disclosure controls and procedures that are designed to ensure that information required to be disclosed in Bentley s reports that are filed with the Securities and Exchange Commission is recorded, processed and reported within the time periods required for each report and that such information is reported to Bentley s management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

As of March 31, 2004, Bentley carried out an evaluation, under the supervision of, and with the participation of Bentley s management, including the Company s Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of Bentley s disclosure controls and procedures (as defined in Exchange Act Rules 13a - 15(e) and 15d - 15(e)). Based on that evaluation, Bentley s Chief Executive Officer and Chief Financial Officer concluded that Bentley s disclosure controls and procedures are effective in timely alerting them to material information relating to Bentley (including its consolidated subsidiaries) which is required to be included in its publicly filed reports or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms. Although Bentley s management continues to evaluate the internal control structure and strengthen the Company s control procedures, particularly in connection with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, there have been no significant changes in Bentley s internal controls, or in other factors which could significantly affect internal controls since that evaluation.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

On February 4, 2002, we were notified that a legal proceeding had been commenced against us by Merck & Co. Inc. and its Spanish subsidiary, Merck Sharp & Dohme de España, S.A., alleging that we violated their patents in our production of simvastatin products and requested an injunction ordering us not to manufacture or market the products. The case was brought against our Spanish subsidiaries in the 39th First Instance Court of the City of Madrid. After a hearing on February 18, 2002, the court refused to grant the requested injunction and dismissed the case on February 25, 2002, awarding court costs and legal fees to us. Merck has appealed the award of fees. Merck re-instituted its claim against us in another proceeding brought in the 19th First Instance Court of the City of Madrid, of which we received notice on January 23, 2003. This case also alleged violation of Merck s patents in the production of simvastatin products, requested an order that we cease manufacturing the products and demanded damages during the period of manufacture. After a trial with respect to this matter held on February 19 and 20, 2004, the court, on April 8, 2004, ruled in our favor, again awarding us court costs and legal fees. Merck has subsequently appealed this ruling.

On January 10, 2004, we were notified that a legal proceeding had been commenced against us by Smith Kline Beecham PLC, Smith Kline Beecham, S.A. and GlaxoSmithKline S.A. alleging that we violate their patents in our production of paroxetine products and they requested an order requiring us to not manufacture or market the products. The case was brought against our Spanish subsidiaries in the 50th First Instance Court of the City of Madrid. This proceeding followed a preliminary injunction that the same plaintiffs attempted to bring against us in 2003, which was dismissed. We filed a response to this suit in February 2004 that included a counterclaim requesting that the court declare the asserted patent invalid. We intend to vigorously oppose this claim as we believe the claim is without merit. Our paroxetine product line was launched in 2003.

We are party to various other legal actions that arise in the ordinary course of business. We do not expect that resolution of these matters will have, individually or in the aggregate, a material adverse effect on the Company s financial position, results of operations or cash flows.

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits:

The Exhibits filed as part of this report are listed on the Exhibit Index immediately preceding the exhibits, which Exhibit Index is incorporated herein by reference.

(b) Reports on Form 8-K filed during the quarter ended March 31, 2004:

i) The Company furnished a Current Report on Form 8-K dated February 18, 2004, providing earnings guidance for the year ended December 31, 2003 and attaching a press release related thereto. (Items 7 and 12) *

ii) The Company furnished a Current Report on Form 8-K dated February 27, 2004, announcing earnings for the three months and year ended December 31, 2003 and attaching a press release related thereto. (Items 7 and 12) *

* This information shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing made by Bentley under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

SIGNATURES

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.

BENTLEY PHARMACEUTICALS, INC.
Registrant

May 10, 2004	By:	/s/ James R. Murphy James R. Murphy Chairman of the Board of Directors, President and Chief Executive Officer (Principal Executive Officer)
May 10, 2004	By:	/s/ Michael D. Price Michael D. Price Vice President, Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)

Exhibit Index

Exhibit No.	
3.1	Amended and Restated Bylaws. Filed herewith.
31.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. Filed herewith.
31.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. Filed herewith.
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Filed herewith.
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Filed herewith.