BENTLEY PHARMACEUTICALS INC
Form 10-Q
August 06, 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 June 30, 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 August 4, 2004 was 20,787,576.

BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES

FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2004

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BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)	June 30, 2004	December 31, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 35,743	$ 39,393
Marketable securities	465	1,252
Receivables, net	23,772	18,036
Inventories, net	9,605	7,106
Deferred taxes	237	213
Prepaid expenses and other	1,857	899
Total current assets	71,679	66,899
Non-current assets:		
Fixed assets, net	23,057	18,566
Drug licenses and related costs, net	13,889	13,818
Restricted cash	1,000	1,000
Other	162	180
Total non-current assets	38,108	33,564
	$ 109,787	$ 100,463
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 14,949	$ 10,154
Accrued expenses	8,355	7,103
Short-term borrowings	1,871	1,915
Current portion of long-term debt		70
Deferred income	3,167	1,956
Total current liabilities	28,342	21,198
Non-current liabilities:		
Deferred taxes	2,353	2,555
Long-term debt	360	369
Other	75	176
Total non-current liabilities	2,788	3,100
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $1.00 par value, authorized 2,000 shares, issued and outstanding, none		
Common stock, $.02 par value, authorized 100,000 shares, issued and outstanding, 20,787 and 20,573 shares	416	412
Stock purchase warrants (to purchase 400 and 420 shares of common stock)	333	333
Additional paid-in capital	138,578	136,850
Accumulated deficit	(64,301)	(66,599)
Accumulated other comprehensive income	3,631	5,169
Total stockholders equity	78,657	76,165
	$ 109,787	$ 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 INCOME

(in thousands, except per share data)	For the Three Months Ended June 30, 2004	2003	For the Six Months Ended June 30, 2004	2003
Revenues:				
Net product sales	$ 17,407	$ 16,596	$ 34,013	$ 30,831
Licensing and collaboration revenues	1,063	158	1,759	911
Total revenues	18,470	16,754	35,772	31,742
Cost of net product sales	8,396	6,819	16,592	12,940
Gross profit	10,074	9,935	19,180	18,802
Operating expenses:				
Selling and marketing	3,851	3,626	7,721	6,979
General and administrative	2,287	1,786	4,451	3,345
Research and development	946	879	1,941	1,897
Depreciation and amortization	407	328	813	611
Total operating expenses	7,491	6,619	14,926	12,832
Income from operations	2,583	3,316	4,254	5,970
Other income (expenses):				
Interest income	132	82	242	165
Interest expense	(58)	(64)	(111)	(118)
Other, net	1,274		1,274	
Income before income taxes	3,931	3,334	5,659	6,017
Provision for income taxes	2,441	1,805	3,361	2,956
Net income	$ 1,490	$ 1,529	$ 2,298	$ 3,061
Net income per common share:				
Basic	$ 0.07	$ 0.09	$ 0.11	$ 0.17
Diluted	$ 0.07	$ 0.07	$ 0.10	$ 0.15
Weighted average common shares outstanding:				
Basic	20,644	17,534	20,620	17,495
Diluted	22,800	20,878	22,787	20,617
Net income	$ 1,490	$ 1,529	$ 2,298	$ 3,061
Other comprehensive (loss) income:				
Foreign currency translation (losses) gains	(309)	1,513	(1,538)	2,193
Comprehensive income	$ 1,181	$ 3,042	$ 760	$ 5,254

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

BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS EQUITY

(in thousands, except per share data)	$ .02 Par Value Common Stock Shares	Amount	Stock Purchase Warrants	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total
Balance at December 31, 2003	20,573	$ 412	$ 333	$ 136,850	$ (66,599)	$ 5,169	$ 76,165
Exercise of stock options	204	4		1,599			1,603
Equity based compensation	10			129			129
Foreign currency translation adjustment						(1,538)	(1,538)
Net income					2,298		2,298
Balance at June 30, 2004	20,787	$ 416	$ 333	$ 138,578	$ (64,301)	$ 3,631	$ 78,657

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

(in thousands)	For the Six Months Ended June 30, 2004	2003
Cash flows from operating activities:		
Net income	$ 2,298	$ 3,061
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	1,696	1,078
Forgiveness of related party loans		(150)
Equity-based compensation expense	129	237
Other non-cash items	(87)	1
(Increase) decrease in assets and increase (decrease) in liabilities:		
Receivables	(6,583)	(4,709)
Inventories	(2,620)	33
Prepaid expenses and other current assets	(1,119)	(134)
Other assets	9	(9)
Accounts payable and accrued expenses	6,753	3,732
Deferred income	1,347	753
Other liabilities	(256)	(7)
Net cash provided by operating activities	1,567	3,886
Cash flows from investing activities:		
Proceeds from sale of investments	149,100	114,600
Purchase of investments	(148,219)	(114,509)
Purchase of API manufacturing assets	(3,309)	
Additions to fixed assets	(3,476)	(4,131)
Additions to drug licenses and related costs	(549)	(2,054)
Net cash used in investing activities	(6,453)	(6,094)

(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 Six Months Ended June 30, 2004	2003
Cash flows from financing activities:		
Proceeds from exercise of stock options/warrants	$ 1,603	$ 962
Repayment of borrowings	(2,550)	(1,329)
Proceeds from borrowings	2,500	1,150
Increase in restricted cash		(1,000)
Net cash provided by (used in) financing activities	1,553	(217)
Effect of exchange rate changes on cash	(317)	667
Net decrease in cash and cash equivalents	(3,650)	(1,758)
Cash and cash equivalents at beginning of period	39,393	26,581
Cash and cash equivalents at end of period	$ 35,743	$ 24,823
Supplemental Disclosures of Cash Flow Information		
The Company paid cash during the period for:		
Interest	$ 106	$ 97
Foreign income taxes	$ 638	$ 847
Supplemental Disclosures of Non-Cash Financing and Investing Activities		
The Company has issued Common Stock in exchange for services as follows:		
Shares	10	55
Amount	$ 129	$ 465
Included in accounts payable at period-end are fixed asset and drug license purchases totaling	$ 1,539	$ 320

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

BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONDENSED 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 territories. In April of 2004, we purchased a manufacturing facility located in Spain which specializes in the manufacture of several active pharmaceutical ingredients (API), of which, one ingredient has been approved by the Food and Drug Administration for marketing and sale in the U.S. We are manufacturing and marketing these products through our newly formed subsidiary, Bentley API. Additionally, we have a strategic alliance with Teva Pharmaceutical Industries Ltd. granting us the right to register and market several of Teva s pharmaceutical products in Spain 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 that 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.

We are developing 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.

The Company s Common Stock began trading on the New York Stock Exchange (*NYSE)* on May 12, 2004, under the trade symbol *BNT*. Prior thereto, the Company s stock was traded on the American Stock Exchange.

BASIS OF CONSOLIDATED FINANCIAL STATEMENTS:

The consolidated financial statements of Bentley Pharmaceuticals as of June 30, 2004 and for the three and six months ended June 30, 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 June 30, 2004 and for the three and six months ended June 30, 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 June 30, 2004 and the results of its operations and cash flows for the three and six months ended June 30, 2004 and 2003. The results of operations for the three and six months ended June 30, 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 June 30, 2004 and December 31, 2003 are approximately $4,604,000 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. This irrevocable letter of credit was renewed in June of 2004 for a one year period. The $1,000,000 used to secure the letter of credit has been classified as *restricted cash* in the Consolidated Balance Sheets as of June 30, 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 $465,000 as of June 30, 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):

	June 30, 2004	December 31, 2003
Raw materials	$ 6,731	$ 5,351
Finished goods	2,940	1,829
	9,671	7,180
Less allowance for slow moving inventory	(66)	(74)
	$ 9,605	$ 7,106

FIXED ASSETS:

Fixed assets consist of the following (in thousands):

	June 30, 2004	December 31, 2003
Land	$ 2,243	$ 1,900
Buildings	9,467	9,085
Equipment	15,668	10,953
Furniture and fixtures	1,482	1,497
Leasehold improvements	42	43
	28,902	23,478
Less accumulated depreciation	(5,845)	(4,912)
	$ 23,057	$ 18,566

In April of 2004, we purchased a Spanish manufacturing facility and related machinery and equipment, used to manufacture active pharmaceutical ingredients, for approximately $3,300,000. We are manufacturing and marketing some of 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, including customers in the United States.

In order to support the Company s growth in Europe, we are adding additional capacity to our finished pharamaceutical product manufacturing facility through a series of improvements. During the six months ended June 30, 2004, the Company invested approximately $2,000,000 for machinery and equipment, including new high speed manufacturing and packaging equipment.

Depreciation expense of approximately $275,000 and $147,000 has been charged to operations as a component of *depreciation and amortization expense* in the Consolidated Income Statements for the six months ended June 30, 2004 and 2003, respectively. We have included depreciation totaling approximately $883,000 and $467,000 in *cost of net product sales* during the three months ended June 30, 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 rates at June 30, 2004 and December 31, 2003 were .83 Euros and .80 Euros per U.S. Dollar, respectively. The weighted average exchange rates for the three months ended June 30, 2004 and 2003 were .83 Euros and .88 Euros per U.S. Dollar, respectively. The weighted average exchange rates for the six months ended June 30, 2004 and 2003 were .82 Euros and .91 Euros per U.S. Dollar, respectively. The effect of foreign currency fluctuations on long lived assets for the six months ended June 30, 2004 was a decrease of $1,538,000 and the cumulative historical effect was an increase of $3,631,000, 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, the Euro, as those revenues. 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 six months ended June 30, 2004, we received proceeds of approximately $1,600,000 from the issuance of approximately 204,000 shares of Common Stock upon exercise of employee stock options. We also issued approximately 10,000 shares of Common Stock as equity-based compensation in lieu of cash contributions to the Company-sponsored 401(k) retirement savings plan. Additionally, we granted to our employees and directors stock options to purchase approximately 533,000 shares of Common Stock during the six months ended June 30, 2004.

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 and six months ended June 30, 2004 we recognized royalty revenues of $644,000 and $1,198,000, respectively, compared to $158,000 and $208,000 in the three and six months ended June 30, 2003, respectively. The difference between the total amount earned from Auxilium under the royalty arrangement and the amount recognized as a component of *licensing and collaboration revenues* is recorded as a component of *deferred income* in the Consolidated Balance Sheets. As of June 30, 2004 and December 31, 2003, deferred income from Testim royalties totaled $995,000 and $634,000, respectively. We will continue to use available market information to determine the amount and timing of royalty revenue recognition. Auxilium completed its initial public offering of its common stock on July 23, 2004. A portion of the offering proceeds were designated to be used to commercialize its products.

OTHER INCOME (EXPENSES):

In addition to interest income on our investment and cash balances and interest expense on our debt obligations, other income (expenses) for the three and six months ended June 30, 2004 includes the reversal of previously accrued tax assessments, as well as interest and penalties associated with the settlement of the tax audit of our Spanish subsidiary s tax years 1998 - 2000 (see Provision for Income Taxes footnote below). We recorded a pre-tax benefit totaling $1,467,000 ($954,000 after taxes) as a component of other income and expenses as the result of the reversal of previously accrued pharmaceutical tax assessments in Spain. These assessments had been accrued to be paid to the Spanish government as a vehicle to help reduce the impact of the rising health care costs in Spain. Due to recent changes in the pharmaceutical industry in Spain and a change in the Spanish political environment, these liabilities no longer exist. Accordingly, these accruals were reversed during the quarter ended June 30, 2004. These amounts have also been recorded in accrued expenses in the consolidated balance sheet as of June 30, 2004.

PROVISION FOR INCOME TAXES:

A tax review of our Spanish subsidiary, Laboratorios Belmac S.A. by the Spanish tax authorities for the tax years 1998, 1999 and 2000, which had commenced over a year ago, was completed in the quarter ended June 30, 2004. As a result of this audit, our subsidiary has been assessed an additional tax liability of approximately $604,000, which has been recorded as a component of *provision for income taxes*, and approximately $193,000 for related interest and penalties, which have been recorded as components of *other income and expenses*, in the consolidated income statements for the three and six months ended June 30, 2004.

As a result of reporting taxable income in Spain, we recorded provisions for foreign income taxes totaling $2,441,000 ($1,837,000 income tax expense on operations plus $604,000 recorded as a result of the tax audit of our Spanish subsidiary) and $1,805,000 for the three months ended June 30, 2004 and 2003, respectively. The effective tax rate for the three months ended June 30, 2004 is 52%, however, when the $604,000 tax audit settlement related to prior years is excluded, the effective tax rate is 39% compared to 42% in the prior year second quarter. We have recorded provisions for foreign income taxes totaling $3,361,000 ($2,757,000 income tax expense on operations plus $604,000 tax liability recorded as a result of the tax audit of our Spanish subsidiary) and $2,956,000 for the six months ended June 30, 2004 and 2003, respectively. The effective tax rate in Spain for the six months ended June 30, 2004 is 47%, however, when the $604,000 tax audit settlement related to prior years is excluded, the effective tax rate is 39% compared to 40% in the comparable six month period of the prior year.

As future domestic operating profits cannot be reasonably assured, no tax benefit has been recorded for U.S. losses, which totaled ($727,000) and ($976,000) for the three months ended June 30, 2004 and 2003, respectively, and ($1,481,000) and ($1,465,000) for the six months ended June 30, 2004 and 2003, respectively. 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 pre-tax 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. During the quarter ended June 30, 2004, we identified certain tax contingencies that we have determined are probable and reasonably estimable. Consequently, we have included a charge totaling $188,000 in the *provision for income taxes* for the quarter ended June 30, 2004 related to these contingencies.

No other potential tax contingencies were considered probable or reasonably estimable by the Company at period end. However, there is the possibility that the ultimate resolution of such potential contingencies 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 and six months ended June 30, 2004 and 2003.

The following is a reconciliation between basic and diluted net income per common share for the three and six months ended June 30, 2004 and 2003. Dilutive securities issuable for the three and six months ended June 30, 2004 include approximately 2,156,000 and 2,167,000 shares, respectively, issuable as a result of various stock options and warrants that are outstanding and exercisable. Dilutive securities issuable for the three and six months ended June 30, 2003 include approximately 1,334,000 and 1,260,000 shares, respectively, issuable as a result of exercisable Class B Warrants and approximately 2,010,000 and 1,862,000 shares, respectively, issuable as a result of various stock options and other warrants that were outstanding and exercisable at that time.

(in thousands, except per share data)

For the Three Months Ended June 30, 2004:

	Basic EPS	Effect of Dilutive Securities	Diluted EPS
Net Income	$ 1,490	$	$ 1,490
Weighted Average Common Shares Outstanding	20,644	2,156	22,800
Net Income Per Common Share	$ 0.07	$	$ 0.07

For the Three Months Ended June 30, 2003:

	Basic EPS	Effect of Dilutive Securities	Diluted EPS
Net Income	$ 1,529	$	$ 1,529
Weighted Average Common Shares Outstanding	17,534	3,344	20,878
Net Income Per Common Share	$ 0.09	$ (0.02)	$ 0.07

For the Six Months Ended June 30, 2004:

	Basic EPS	Effect of Dilutive Securities	Diluted EPS
Net Income	$ 2,298	$	$ 2,298
Weighted Average Common Shares Outstanding	20,620	2,167	22,787
Net Income Per Common Share	$ 0.11	$ (0.01)	$ 0.10

For the Six Months Ended June 30, 2003:

	Basic EPS	Effect of Dilutive Securities	Diluted EPS
Net Income	$ 3,061	$	$ 3,061
Weighted Average Common Shares Outstanding	17,495	3,122	20,617
Net Income Per Common Share	$ 0.17	$ (0.02)	$ 0.15

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 468,000 shares of Common Stock, for the three and six months ended June 30, 2004 and warrants and options to purchase an aggregate of 518,000 and 1,328,000 shares of Common Stock, for the three and six months ended June 30, 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 and six months ended June 30, 2004 include $15,000 and $47,000, respectively, of non-cash equity-based compensation. General and administrative expenses for the three and six months ended June 30, 2003 include $54,000 and $102,000, respectively, of non-cash equity-based compensation. Research and development expenses for the three and six months ended June 30, 2004 include $41,000 and $82,000, respectively, of non-cash equity-based compensation. Research and development expenses for the three and six months ended June 30, 2003 include $65,000 and $135,000, 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 June 30,		For the Six Months Ended June 30,	
	2004	2003	2004	2003
Net income, as reported	$ 1,490	$ 1,529	$ 2,298	$ 3,061
Add: Stock-based employee compensation expense included in reported net income	56	109	129	237
Deduct: Total stock-based employee compensation expense determined under fair value method for all awards	(596)	(775)	(1,720)	(1,512)
Pro forma net income	$ 950	$ 863	$ 707	$ 1,786
Net income per common share:				
Basic - as reported	$ 0.07	$ 0.09	$ 0.11	$ 0.17
Basic - pro forma	$ 0.05	$ 0.05	$ 0.03	$ 0.10
Diluted - as reported	$ 0.07	$ 0.07	$ 0.10	$ 0.15
Diluted - pro forma	$ 0.04	$ 0.04	$ 0.03	$ 0.09

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 June 30,		For the Six Months Ended June 30,	
	2004	2003	2004	2003
Risk-free interest rate	2.10%	3.62%	2.97%	3.89%
Dividend yield	0.00%	0.00%	0.00%	0.00%
Expected life	5 years	5 years	5 years	5 years
Volatility	50.49%	53.06%	49.28%	54.30%
Fair value of options granted	$ 5.70	$ 4.87	$ 6.03	$ 4.98

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

The following discussion and analysis should be read 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 Securities and Exchange Commission. 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 June 30, 2004 versus Three Months Ended June 30, 2003

Revenues

	For the Three Months Ended June 30,				Change	
(in thousands)	**2004**	**%**	**2003**	**%**	**$**	**%**
Revenues:						
Net product sales	*$ 17,407*	*94%*	*$ 16,596*	*99%*	*$ 811*	*5%*
Licensing and collaboration revenues	*1,063*	*6%*	*158*	*1%*	*905*	*573%*
Total revenues	*$ 18,470*	*100%*	*$ 16,754*	*100%*	*$ 1,716*	*10%*

Total revenues for the three months ended June 30, 2004 increased 10% from the same period in the prior year. However, our total revenues increased approximately 4% 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 $1,043,000, partially offsetting the impact of price reductions in Spain. Price reductions were mandated for certain pharmaceutical products by the Spanish government in late 2003, which we put into effect on December 1, 2003. Over the past six months we have implemented several initiatives to reduce our production costs and increase our margins on several of our products affected by the price reductions. Additionally, through strategic pricing, we have been able to increase our market share on these and other products. 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, and other licensing revenues have increased our revenues by approximately $905,000 in the three months ended June 30, 2004 over the same period in the prior year.

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). Set forth below is a summary of our revenues by sales channel and top-selling product lines:

For the three months ended June 30, 2004 (in thousands):

Product Line	Sales Within Spain: Branded Products	Sales Within Spain: Generic Products	Sales Within Spain: Contract Manu-facturing	Other Revenues	Total	% of Total Revenues
Omeprazole	*$ 647*	*$ 3,204*	*$*	*$*	*$ 3,851*	*21%*
Simvastatin	*354*	*868*			*1,222*	*7%*
Enalapril	*893*	*327*			*1,220*	*7%*
Paroxetine	*228*	*765*			*993*	*5%*
Codeisan	*608*				*608*	*3%*
All other products	*1,535*	*1,646*		*264*	*3,445*	*19%*
Contract manufacturing			*2,304*		*2,304*	*12%*
Sales outside of Spain				*3,764*	*3,764*	*20%*
Licensing and collaborations				*1,063*	*1,063*	*6%*
Total Revenues	*$ 4,265*	*$ 6,810*	*$ 2,304*	*$ 5,091*	*$ 18,470*	*100%*
% of Total Revenues	*23%*	*37%*	*12%*	*28%*	*100%*	

For the three months ended June 30, 2003 (in thousands):

Product Line	Sales Within Spain: Branded Products	Sales Within Spain: Generic Products	Sales Within Spain: Contract Manu-facturing	Other Revenues	Total	% of Total Revenues
Omeprazole	*$ 1,694*	*$ 3,431*	*$*	*$*	*$ 5,125*	*31%*
Simvastatin	*588*	*1,128*			*1,716*	*10%*
Enalapril	*743*	*460*			*1,203*	*7%*
Paroxetine		*207*			*207*	*1%*
Codeisan	*524*				*524*	*3%*
All other products	*1,236*	*1,629*			*2,865*	*17%*
Contract manufacturing			*2,607*		*2,607*	*16%*
Sales outside of Spain				*2,349*	*2,349*	*14%*
Licensing and collaborations				*158*	*158*	*1%*
Total Revenues	*$ 4,785*	*$ 6,855*	*$ 2,607*	*$ 2,507*	*$ 16,754*	*100%*
% of Total Revenues	*28%*	*41%*	*16%*	*15%*	*100%*	

Spanish Operations. The core of our Spanish operations has been the efficient manufacturing and in-country 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 into other European countries and other countries outside of Europe. The increase in second quarter 2004 product sales over the 2003 second quarter is due primarily to the introduction of our paroxetine product line, which was launched in May of 2003. Our paroxetine product line generated net sales of $993,000, representing 5% of our total revenues during the three months ended June 30, 2004, compared to 1% in the comparable period of the prior year. However, revenues from our top two selling products, omeprazole and simvastatin, comprised 28% of our total revenues in the second quarter of 2004, compared to 41% in

the same quarter of the prior year, as a result of price reductions that we implemented on December 1, 2003.

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 net product sales 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 in February and March 2004. A majority of the products returned were either expired, nearing expiration or otherwise not resalable and consequently were destroyed. These product returns exceeded our allowance for estimated sales returns at that time, which 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 of 2004. Consequently our gross margins on net product sales in that quarter were negatively impacted, resulting in a temporary decline in gross our margins to 51%, compared to 57% in the three months ended March 31, 2003. Product returns in the second quarter of 2004 decreased; product returns in April and May 2004 totaled $462,000, reducing revenues by this amount during the second quarter of 2004. Gross margins on pharmaceutical product sales excluding sales of active pharmaceutical ingredients were 53% in the second quarter of 2004. See additional discussion in the *Gross Profit* section.

Over the past six months we have implemented several initiatives which have effectively reduced our production costs on several of our products and increased our gross margins. These initiatives include the purchase of new high speed manufacturing equipment; new product launches; and increased sales volume and marketshare through strategic pricing. We expect to continue to increase our future sales volume through our pipeline of approximately 100 products. Additionally, we recently purchased a manufacturing facility, located in Spain, which specializes in the manufacture of several active pharmaceutical ingredients, and has diversified our revenue base. 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. We will also continue to make significant investments in renovating and increasing capacity in our manufacturing facilities, as well as continued investments in new high speed, high volume equipment. We anticipate that our gross margins will continue to gradually increase in the following quarters as we continue to implement our strategy and benefit from economies of scale.

Branded Pharmaceutical Products

(in thousands)	For the Three Months Ended June 30, 2004	%	2003	%	Change $	%
Branded Product Sales:						
Enalapril	$ 893	*21%*	$ 743	*16%*	$ 150	*20%*
Omeprazole	647	*15%*	1,694	*35%*	(1,047)	*-62%*
Codeisan	608	*14%*	524	*11%*	84	*16%*
All other branded products	2,117	*50%*	1,824	*38%*	293	*16%*
Total branded sales	$ 4,265	*100%*	$ 4,785	*100%*	$ (520)	*-11%*

Sales of our branded pharmaceutical products in the three months ended June 30, 2004 decreased by approximately 11% compared to the same period of the prior year, and they accounted for 23% of total revenues during the three months ended June 30, 2004 compared to 28% of total revenues during the three months ended June 30, 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 $248,000 in the second quarter of 2004. Price reductions continued to erode the sales of our branded omeprazole and simvastatin, which decreased by approximately $1,047,000 and $234,000, respectively, from the same quarter in the prior year. Our branded omeprazole, Belmazol, 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 second quarter of 2004 as in the comparable period of the prior year. Sales of our branded enalapril which experienced a 66% increase in unit volume compared to the same period of the prior year, increased 20% from the prior year second quarter in spite of price cuts, and now accounts for 21% of our branded product sales. Strong sales of our cough and cold medicine, Codeisan, and the launch of our branded version of paroxetine in May of 2003 also helped to mitigate the impact of price cuts. 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

(in thousands)	For the Three Months Ended June 30, 2004	%	2003	%	Change $	%
Generic Product Sales:						
Omeprazole	$ 3,204	*47%*	$ 3,431	*50%*	$ (227)	*-7%*
Simvastatin	868	*13%*	1,128	*16%*	(260)	*-23%*
Paroxetine	765	*11%*	207	*3%*	558	*270%*
Pentoxifylline	587	*9%*	527	*8%*	60	*11%*
All other generic products	1,386	*20%*	1,562	*23%*	(176)	*-11%*
Total generic sales	$ 6,810	*100%*	$ 6,855	*100%*	$ (45)	*-1%*

Sales of our generic pharmaceutical products remained relatively consistent during the three months ended June 30, 2004 when expressed in U.S. dollars, compared to the three months ended June 30, 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 $396,000 in the second quarter of 2004. Sales of our generic omeprazole in the second quarter of 2004, while higher in terms of units sold,

decreased by 7% in U.S. dollars when compared to the prior year and account for 47% of our generic pharmaceutical revenues in the second quarter of 2004, compared to 50% of generic revenues in the second quarter of 2003, as a result of price reductions. Similarly, sales of our generic simvastatin, while higher in terms of units sold, decreased by approximately 23% when expressed in U.S. Dollars. Sales of our generic paroxetine, which was launched in May of 2003, added approximately $558,000 to our generic sales, and continued to be a major contributor again in the second quarter of 2004 accounting for 11% of generic product sales, compared to 3% in the second quarter of the prior year. Sales of our generic pentoxifylline in the second quarter of 2004 increased by approximately $60,000, or approximately 11% from the same quarter in the prior year. 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 June 30, 2004	2003	Change $	Change %
Contract manufacturing	*$ 2,304*	*$ 2,607*	*$ (303)*	*-12%*