

BENTLEY PHARMACEUTICALS INC  
Form 10-Q  
August 06, 2004

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

**FORM 10-Q**

(Mark One)

**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

**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**  
(State or other jurisdiction of  
incorporation or organization)

**No. 59-1513162**  
(I.R.S. Employer  
Identification No.)

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

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(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  NO

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

The number of shares of the registrant's common stock outstanding as of August 4, 2004 was 20,787,576.

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**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
<b>ASSETS</b>		
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
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
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,		For the Six Months Ended June 30,	
	2004	2003	2004	2003
<b>Revenues:</b>				
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
<b>Operating expenses:</b>				
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
<b>Other income (expenses):</b>				
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
<b>Net income per common share:</b>				
Basic	\$ 0.07	\$ 0.09	\$ 0.11	\$ 0.17
Diluted	\$ 0.07	\$ 0.07	\$ 0.10	\$ 0.15
<b>Weighted average common shares outstanding:</b>				
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
<b>Other comprehensive (loss) income:</b>				
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		Stock Purchase Warrants	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total
	Shares	Amount					
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
<b>Cash flows from financing activities:</b>		
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)
<b>Net cash provided by (used in) financing activities</b>	<b>1,553</b>	<b>(217)</b>
Effect of exchange rate changes on cash	(317)	667
<b>Net decrease in cash and cash equivalents</b>	<b>(3,650)</b>	<b>(1,758)</b>
Cash and cash equivalents at beginning of period	39,393	26,581
Cash and cash equivalents at end of period	\$ 35,743	\$ 24,823
<b>Supplemental Disclosures of Cash Flow Information</b>		
The Company paid cash during the period for:		
Interest	\$ 106	\$ 97
Foreign income taxes	\$ 638	\$ 847
<b>Supplemental Disclosures of Non-Cash Financing and Investing Activities</b>		
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.



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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)*.

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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 pharmaceutical 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

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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.

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	For the Three Months Ended June 30,				For the Six Months Ended June 30,			
	2004	2003	2004	2003	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

(in thousands)	For the Three Months Ended June 30,				Change	
	2004	%	2003	%	\$	%
<i>Revenues:</i>						
<i>Net product sales</i>	\$ 17,407	94%	\$ 16,596	99%	\$ 811	5%
<i>Licensing and collaboration revenues</i>	1,063	6%	158	1%	905	573%
<i>Total revenues</i>	\$ 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:





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

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

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

Product Line	Sales Within Spain				Total	% of Total Revenues
	Branded Products	Generic Products	Contract Manufacturing	Other Revenues		
<i>Omeprazole</i>	\$ 1,694	\$ 3,431	\$	\$	\$ 5,125	31%
<i>Simvastatin</i>	588	1,128			1,716	10%
<i>Enalapril</i>	743	460			1,203	7%
<i>Paroxetine</i>		207			207	1%
<i>Codeisan</i>	524				524	3%
<i>All other products</i>	1,236	1,629			2,865	17%
<i>Contract manufacturing</i>			2,607		2,607	16%
<i>Sales outside of Spain</i>				2,349	2,349	14%
<i>Licensing and collaborations</i>				158	158	1%
<b>Total Revenues</b>	<b>\$ 4,785</b>	<b>\$ 6,855</b>	<b>\$ 2,607</b>	<b>\$ 2,507</b>	<b>\$ 16,754</b>	<b>100%</b>
<i>% of Total Revenues</i>	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,				Change	
	2004	%	2003	%	\$	%
<i>Branded Product Sales:</i>						
<i>Enalapril</i>	\$ 893	21%	\$ 743	16%	\$ 150	20%
<i>Omeprazole</i>	647	15%	1,694	35%	(1,047)	-62%
<i>Codeisan</i>	608	14%	524	11%	84	16%
<i>All other branded products</i>	2,117	50%	1,824	38%	293	16%
<i>Total branded sales</i>	\$ 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,				Change	
	2004	%	2003	%	\$	%
<i>Generic Product Sales:</i>						
<i>Omeprazole</i>	\$ 3,204	47%	\$ 3,431	50%	\$ (227)	-7%
<i>Simvastatin</i>	868	13%	1,128	16%	(260)	-23%
<i>Paroxetine</i>	765	11%	207	3%	558	270%
<i>Pentoxifylline</i>	587	9%	527	8%	60	11%
<i>All other generic products</i>	1,386	20%	1,562	23%	(176)	-11%
<i>Total generic sales</i>	\$ 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,				Change	
	2004	2003	\$	\$	%	
<i>Contract manufacturing</i>	\$ 2,304	\$ 2,607	\$	(303)		-12%

In addition to manufacturing our own products, our Spanish manufacturing facility supplies branded and generic products to approximately 20 entities in Spain, which market these products under their own names and with their own labeling. Revenues generated from contract manufacturing represented 12% of total revenues in the three months ended June 30, 2004, compared to 16% of total revenues in 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 contract manufacturing sales by approximately \$134,000 in the second quarter of 2004.

#### Sales Outside of Spain

(in thousands)	For the Three Months Ended June 30,				Change	
	2004	2003	\$	\$	%	
<i>Sales outside of Spain</i>	\$ 3,764	\$ 2,349	\$	1,415		60%

We have entered into license and supply agreements with more than 25 entities to sell our products outside of Spain. Sales under these supply agreements increased 60% from 14% of total revenues in the three months ended June 30, 2003 to 20% of total revenues in the three months ended June 30, 2004. The \$1,415,000 increase is attributable to increased demand for products that we are able to manufacture at relatively low costs and sell to customers in other countries around the world as they search to find low cost manufacturing alternatives to remain competitive in their respective markets. 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 for cost savings alternatives. 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 \$219,000 during the three months ended June 30, 2004 compared to the second quarter of 2003.

*Licensing and Collaboration Revenues.* Licensing and collaboration revenues accounted for 6% of total revenues in the three months ended June 30, 2004. These revenues include royalties totaling \$644,000 (compared to \$158,000 in the second 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 \$419,000 during the three months ended June 30, 2004, related to product licensing activities in Europe.

*Gross Profit.* Gross profit increased by approximately \$139,000, or 1%, in the three months ended June 30, 2004 when compared to the three months ended June 30, 2003, while our gross margins on net product sales have decreased from 59% in the three months ended June 30, 2003 to 52% in the three months ended June 30, 2004 (53% gross margins on sales of pharmaceutical products, excluding sales of active pharmaceutical ingredients). As discussed previously, our gross margins on net product sales have been negatively impacted by the December 2003 price reductions in Spain. Product returns in April and May 2004 totaled \$462,000, reducing revenues by this amount during the second quarter of 2004. We performed a detailed analysis in the second quarter of the current year in order to identify all potential returns related to the December 2003 price reductions. We are confident that we have captured the majority of such returns, as evidenced by a decrease in product returns in June and July 2004 to levels consistent with our historical experience and budgeted amounts.

Over the past six months we have implemented several initiatives to reduce our production costs on several of our products and increase 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. While it is possible that our gross margins could decrease 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, we expect the effect of our many initiatives will mitigate these exposures. 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.

#### Selling and Marketing Expenses

(in thousands)	For the Three Months Ended June 30,		Change	
	2004	2003	\$	%
<i>Selling and marketing</i>	\$ 3,851	\$ 3,626	\$ 225	6%

Selling and marketing expenses for the three months ended June 30, 2004 increased 6% 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 \$216,000 in the three months ended June 30, 2004, accounting for approximately 96% of the increase. Selling and marketing expenses as a percentage of net product sales remained constant at 22% in the three months ended June 30, 2004, compared to the three months ended June 30, 2003.

#### General and Administrative Expenses

(in thousands)	For the Three Months Ended June 30,		Change	
	2004	2003	\$	%
<i>General and administrative</i>	\$ 2,287	\$ 1,786	\$ 501	28%



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General and administrative expenses for the three months ended June 30, 2004 increased 28% from the same period in the prior year. The \$501,000 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, insurance and other costs to support the growth of our organization. General and administrative expenses as a percent of total revenues increased to approximately 12% in the three months ended June 30, 2004, compared to approximately 11% of total revenues in the three months ended June 30, 2003. General and administrative expenses would have been approximately \$77,000 lower, absent the increase in the weighted average value of the Euro, in relation to the U.S. Dollar, in the three months ended June 30, 2004. This foreign currency impact accounted for almost 15% of the increase in general and administrative expenses when compared to the prior year's second 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 total costs associated with implementation of the internal control provisions of the Sarbanes-Oxley Act of 2002, we have incurred over \$100,000 of external costs to date.

#### Research and Development Expenses

(in thousands)	For the Three Months Ended June 30,		Change	
	2004	2003	\$	%
Research and development	\$ 946	\$ 879	\$ 67	8%

Research and development expenses for the three months ended June 30, 2004 increased 8% from the same period in the prior year. In the first quarter of 2004, we completed and reported the results of a Phase I intranasal insulin trial. We recently commenced Phase II studies of our clinical program for the intranasal delivery of insulin. In addition, we have initiated certain clinical programs to support the eventual distribution of certain of our Spanish generic pharmaceutical products in other countries, including the U.S., and are in the planning stages of certain other clinical programs. 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 facilities in 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. Some of our cost estimates for our research and development programs are preliminary, and the specific timing is not known; however, based upon our most recent information, we estimate that our research and development expenses for the year ended December 31, 2004 could be approximately \$500,000 to \$1,000,000 higher than in the year ending December 31, 2003.

#### Other Income (Expenses)

(in thousands)	For the Three Months Ended June 30,		Change	
	2004	2003	\$	%
Other income (expenses)	\$ 1,348	\$ 18	\$ 1,330	*

\* Not meaningful

Other income (expenses) for the three months ended June 30, 2004 increased by \$1,330,000 from the same period in the prior year. The increase is primarily due to the reversal of previously accrued tax assessments totaling \$1,467,000, partially offset by interest and penalties totaling \$193,000 associated with the settlement of the tax audit of our Spanish subsidiary (see *Provision for Income Taxes*). 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.

Provision for Income Taxes

(in thousands)	For the Three Months Ended June 30, 2004		
	Spain	U.S.	Consolidated
Income (loss) before income taxes	\$ 4,658	\$ (727)	\$ 3,931
Provision (benefit) for income taxes	1,837	(247)	1,590
Tax liability, 1998 - 2000 audit	604		604
Total provision (benefit) for income taxes	2,441	(247)	2,194
Valuation allowance		247	247
Net provision for income taxes	2,441		2,441
Net income (loss)	\$ 2,217	\$ (727)	\$ 1,490
Effective tax rate	52%	0%	62%

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 statement for the three 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 in Spain 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. The provision for foreign income taxes would have been approximately \$137,000 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 June 30, 2004.

We generated additional U.S. federal net operating loss carry-forwards in the three months ended June 30, 2004 and 2003 as a result of U.S. pre-tax losses of (\$727,000) and (\$976,000), respectively. As future domestic operating profits cannot be reasonably assured, no tax benefit has been recorded for U.S. losses. Accordingly, we have established a valuation allowance equal to the full amount of the U.S. deferred tax assets.

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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 related to these contingencies in the *provision for income taxes* for the quarter ended June 30, 2004. No other potential tax contingencies were considered probable and/or reasonably estimable by Bentley 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.

### Net Income

(in thousands, except per share data)	For the Three Months Ended June 30,		Change	
	2004	2003	\$	%
<i>Net income</i>	\$ 1,490	\$ 1,529	\$ (39)	-3%
<i>Net income per common share:</i>				
<i>Basic</i>	\$ 0.07	\$ 0.09	\$ (0.02)	-22%
<i>Diluted</i>	\$ 0.07	\$ 0.07		0%
<i>Weighted average common shares outstanding:</i>				
<i>Basic</i>	20,644	17,534	3,110	18%
<i>Diluted</i>	22,800	20,878	1,922	9%

We reported income from operations of \$2,583,000 in the three months ended June 30, 2004 compared to \$3,316,000 in the three months ended June 30, 2003. The combination of income from operations of \$2,583,000 and the non-operating items, primarily the provision for income taxes of \$2,441,000 and the reversal of previously accrued tax assessments totaling \$1,467,000 resulted in net income of \$1,490,000, or \$0.07 per basic common share (\$0.07 per diluted common share) on 20,644,000 weighted average basic common shares outstanding (22,800,000 weighted average diluted common shares outstanding) in the three months ended June 30, 2004, compared to net income of \$1,529,000, or \$0.09 per basic common share (\$0.07 per diluted common share) on 17,534,000 weighted average basic common shares outstanding (20,878,000 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.

**Six Months Ended June 30, 2004 versus Six Months Ended June 30, 2003**Revenues

(in thousands)	For the Six Months Ended June 30,				Change	
	2004	%	2003	%	\$	%
<i>Revenues:</i>						
<i>Net product sales</i>	\$ 34,013	95%	\$ 30,831	97%	\$ 3,182	10%
<i>Licensing and collaboration revenues</i>	1,759	5%	911	3%	848	93%
<i>Total revenues</i>	\$ 35,772	100%	\$ 31,742	100%	\$ 4,030	13%

Total revenues for the six months ended June 30, 2004 increased 13% from the same six month period in the prior year. However, our total revenues increased approximately 2% 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 \$3,526,000, partially offsetting the impact of price reductions in Spain. Price reductions were mandated for certain pharmaceutical products by the Spanish government which we put into effect on December 1, 2003. The advancement of our proprietary drug delivery programs in the U.S., as evidenced by the growing royalty stream from sales of Testim, and other licensing revenues have increased our year to date 2004 revenues by approximately \$848,000 when compared to the same period in the prior year.

Set forth below is a summary of our revenues by sales channel and top-selling product lines as generated through our five primary sales channels:

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

Product Line	Sales Within Spain				Total	% of Total Revenues
	Branded Products	Generic Products	Contract Manufacturing	Other Revenues		
<i>Omeprazole</i>	\$ 1,180	\$ 6,492	\$	\$	\$ 7,672	21%
<i>Simvastatin</i>	593	1,641			2,234	6%
<i>Enalapril</i>	1,555	535			2,090	6%
<i>Paroxetine</i>	478	1,584			2,062	6%
<i>Codeisan</i>	1,511				1,511	4%
<i>All other products</i>	3,244	3,336		265	6,845	19%
<i>Contract manufacturing</i>			4,837		4,837	14%
<i>Sales outside of Spain</i>				6,762	6,762	19%
<i>Licensing and collaborations</i>				1,759	1,759	5%
<i>Total Revenues</i>	\$ 8,561	\$ 13,588	\$ 4,837	\$ 8,786	\$ 35,772	100%
<i>% of Total Revenues</i>	24%	38%	13%	25%	100%	





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

Product Line	Sales Within Spain				Total	% of Total Revenues
	Branded Products	Generic Products	Contract Manufacturing	Other Revenues		
<i>Omeprazole</i>	\$ 3,193	\$ 6,582	\$	\$	\$ 9,775	31%
<i>Simvastatin</i>	961	1,924			2,885	9%
<i>Enalapril</i>	1,248	916			2,164	7%
<i>Paroxetine</i>		207			207	1%
<i>Codeisan</i>	1,230				1,230	4%
<i>All other products</i>	2,459	3,127			5,586	17%
<i>Contract manufacturing</i>			5,094		5,094	16%
<i>Sales outside of Spain</i>				3,890	3,890	12%
<i>Licensing and collaborations</i>				911	911	3%
<i>Total Revenues</i>	\$ 9,091	\$ 12,756	\$ 5,094	\$ 4,801	\$ 31,742	100%
<i>% of Total Revenues</i>	29%	40%	16%	15%	100%	

*Spanish Operations.* The increase in product sales for the first half of 2004 over the first half of 2003 was primarily due to the introduction of our paroxetine product line, which was launched in May of 2003. Our paroxetine product line generated net sales of \$2,062,000, representing 6% of our total revenues during the six months ended June 30, 2004 and 46% of our growth. In spite of reduced selling prices, revenues from our omeprazole products in the first half of 2004 comprised 21% of our year to date 2004 revenues, compared to 31% in the same period of the prior year.

Product returns totaled \$1,800,000 in the first quarter of 2004. Product returns in the second quarter of 2004 decreased; returns in April and May 2004 totaled \$462,000 and served to reduce revenues by the same amount during the second quarter. These returns resulted in gross margins of 51% in the six months ended June 30, 2004. See additional discussion in the *Gross Profit* section.

#### Branded Pharmaceutical Products

(in thousands)	For the Six Months Ended June 30,				Change	
	2004	%	2003	%	\$	%
<i>Branded Product Sales:</i>						
<i>Enalapril</i>	\$ 1,555	18%	\$ 1,248	14%	\$ 307	25%
<i>Codeisan</i>	1,511	18%	1,230	13%	281	23%
<i>Omeprazole</i>	1,180	14%	3,193	35%	(2,013)	-63%
<i>All other branded products</i>	4,315	50%	3,420	38%	895	26%
<i>Total branded sales</i>	\$ 8,561	100%	\$ 9,091	100%	\$ (530)	-6%

Sales of our branded pharmaceutical products decreased by approximately 6% in U.S. Dollars compared to the prior year, and they accounted for 24% of total revenues during the six months ended June 30, 2004 compared to 29% of total revenues during the six 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 \$862,000 in the first half of 2004. Price reductions continued to negatively impact our branded product sales. Most

significantly, sales of our branded omeprazole and simvastatin products decreased by

approximately \$2,013,000 and \$368,000, respectively, from the same period in the prior year, as a result of price reductions effected in December 2003. 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 half of 2004 as in the comparable period of the prior year. Sales of our branded enalapril, which experienced a 62% increase in unit volume compared to the same period of the prior year, increased 25% from the prior year in spite of price cuts, and now accounts for 18% of our year to date 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 Six Months Ended June 30,				Change	
	2004	%	2003	%	\$	%
<i>Generic Product Sales:</i>						
<i>Omeprazole</i>	\$ 6,492	48%	\$ 6,582	51%	\$ (90)	-1%
<i>Simvastatin</i>	1,641	12%	1,924	15%	(283)	-15%
<i>Paroxetine</i>	1,584	12%	207	2%	1,377	665%
<i>Pentoxifylline</i>	1,278	9%	973	8%	305	31%
<i>Trimetazidine</i>	927	7%	226	2%	701	310%
<i>All other generic products</i>	1,666	12%	2,844	22%	(1,178)	-41%
<i>Total generic sales</i>	\$ 13,588	100%	\$ 12,756	100%	\$ 832	7%

Sales of our generic pharmaceutical products increased by 7% during the six months ended June 30, 2004 compared to the six 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 \$1,368,000 in the first half of 2004. Consistent sales volume of our generic omeprazole, accounted for 48% of our generic pharmaceutical revenues in the six months ended June 30, 2004, compared to 51% of generic revenues in the comparable period of the prior year, in spite of price reductions. However, sales of our generic simvastatin which experienced a 22% increase in unit volume, decreased by approximately 15%, when expressed in U.S. Dollars as a result of price reductions. Our generic paroxetine, which was launched in May of 2003, added approximately \$1,377,000 to our generic sales over the prior year, positioning it third behind our generic omeprazole and simvastatin products in the six months ended June 30, 2004. Sales of our generic pentoxifylline increased by approximately \$305,000, or approximately 31% from the comparable period of the prior year, while sales of our generic trimetazidine increased approximately \$701,000. Trimetazidine has quickly become a major contributor to our generic pharmaceutical sales in the first half 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 Six Months Ended June 30,				Change	
	2004		2003		\$	%
<i>Contract manufacturing</i>	\$ 4,837		\$ 5,094		\$ (257)	-5%

Revenues generated from contract manufacturing represented 14% of total revenues in the six months ended June 30, 2004, compared to 16% of total revenues in the six 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 contract manufacturing sales by approximately \$487,000 in the first half of 2004.

#### Sales Outside of Spain

(in thousands)	For the Six Months Ended June 30,		Change	
	2004	2003	\$	%
Sales outside of Spain	\$ 6,762	\$ 3,890	\$ 2,872	74%

Sales under our supply agreements increased 74% from 12% of total revenues in the six months ended June 30, 2003 to 19% of total revenues in the six months ended June 30, 2004. The \$2,872,000 increase is attributable to increased demand for products that we are able to manufacture at relatively low costs and sell to customers in other countries around the world as they 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 \$681,000 during the six months ended June 30, 2004.

*Licensing and Collaboration Revenues.* Licensing and collaboration revenues accounted for 5% of total revenues in the six months ended June 30, 2004. These revenues include royalties totaling \$1,198,000 (compared to \$208,000 in the first half of the prior year) from the commercialization and continuing sales of Testim. Licensing and collaboration revenues in the first half of the prior year included a one-time milestone payment of \$500,000. We have also recognized revenues totaling \$561,000 during the six months ended June 30, 2004, related to product licensing activities in Europe.

*Gross Profit.* Gross profit increased by approximately \$378,000, or 2%, in the six months ended June 30, 2004 when compared to the six months ended June 30, 2003, while our gross margins on net product sales have decreased from 58% in the six months ended June 30, 2003 to 51% in the six months ended June 30, 2004 (52% gross margins on sales of pharmaceutical products, excluding sales of active pharmaceutical ingredients). Product returns in the six months ended June 30, 2004 totaled \$2,262,000, reducing revenues by this amount during the six months ended June 30, 2004.

#### Selling and Marketing Expenses

(in thousands)	For the Six Months Ended June 30,		Change	
	2004	2003	\$	%
Selling and marketing	\$ 7,721	\$ 6,979	\$ 742	11%

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Selling and marketing expenses for the six months ended June 30, 2004 increased 11% 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 \$766,000 in the six months ended June 30, 2004, indicating that selling and marketing expenses actually decreased in local currency. Selling and marketing expenses as a percentage of net product sales in the six months ended June 30, 2004 remained consistent with the same period of the prior year at 23%.

General and Administrative Expenses

(in thousands)	For the Six Months Ended June 30,			Change	
	2004	2003		\$	%
<i>General and administrative</i>	\$ 4,451	\$ 3,345	\$	1,106	33%

General and administrative expenses for the six months ended June 30, 2004 increased 33% from the same period in the prior year. The \$1,106,000 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, insurance and other costs to support the growth of our organization. General and administrative expenses as a percent of total revenues increased to approximately 12% in the six months ended June 30, 2004, compared to approximately 11% of total revenues in the six months ended June 30, 2003. General and administrative expenses would have been approximately \$272,000 lower, absent the increase in the weighted average value of the Euro, in relation to the U.S. Dollar, in the six months ended June 30, 2004. This foreign currency impact accounted for almost 25% of the increase in general and administrative expenses when compared to the first half of the prior year.

Research and Development Expenses

(in thousands)	For the Six Months Ended June 30,			Change	
	2004	2003		\$	%
<i>Research and development</i>	\$ 1,941	\$ 1,897	\$	44	2%

Research and development expenses for the six months ended June 30, 2004 increased 2% from the same period in the prior year. In the first quarter of 2004, we completed and reported the results of a Phase I intranasal insulin trial. We recently commenced Phase II studies of our clinical program for the intranasal delivery of insulin. In addition, we have initiated certain clinical programs to support the eventual distribution of certain of our Spanish generic pharmaceutical products in other countries, including the U.S., and are in the planning stages of certain other clinical programs. 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 facilities in 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. Some of our cost estimates for our research and development programs are preliminary, and the specific timing is not known; however, based upon our most recent information, we estimate that our research and development expenses for the year ending December 31, 2004 could be approximately \$500,000 to \$1,000,000 higher than in the year ended December 31, 2003.

Other Income (Expenses)

(in thousands)	For the Six Months Ended June 30,			Change	%
	2004	2003		\$	
<i>Other income (expenses)</i>	\$ 1,405	\$ 47	\$	1,358	*

\* *Not meaningful*

Other income (expenses) for the six months ended June 30, 2004 increased by \$1,358,000 from the same period in the prior year. The increase is primarily due to the reversal of previously accrued tax assessments totaling \$1,467,000, partially offset by interest and penalties totaling \$193,000 associated with the settlement of the tax audit of our Spanish subsidiary (see *Provision for Income Taxes*). 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.

Provision for Income Taxes

(in thousands)	For the Six Months Ended June 30, 2004		
	Spain	U.S.	Consolidated
<i>Income (loss) before income taxes</i>	\$ 7,140	\$ (1,481)	\$ 5,659
<i>Provision (benefit) for income taxes</i>	2,757	504	3,261
<i>Tax liability, 1998 - 2000 audit</i>	604		604
<i>Total provision (benefit) for income taxes</i>	3,361	504	3,865
<i>Valuation allowance</i>		(504)	(504)
<i>Net provision for income taxes</i>	3,361		3,361
<i>Net income (loss)</i>	\$ 3,779	\$ (1,481)	\$ 2,298
<i>Effective tax rate</i>	47%	0%	59%

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.

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We have recorded provisions for foreign income taxes totaling \$3,361,000 (\$2,757,000 income tax expense on operations plus \$604,000 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. The provision for foreign income taxes would have been approximately \$342,000 lower than reported, absent the increase in the weighted average value of the Euro, in relation to the U.S. Dollar, during the six months ended June 30, 2004.



We generated additional U.S. federal net operating loss carry-forwards in the six months ended June 30, 2004 and 2003 as a result of U.S. pre-tax losses of (\$1,481,000) and (\$1,465,000), respectively. As future domestic operating profits cannot be reasonably assured, no tax benefit has been recorded for U.S. losses. Accordingly, we have established a valuation allowance equal to the full amount of the U.S. deferred tax assets.

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 and/or reasonably estimable by Bentley 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.

### Net Income

(in thousands, except per share data)	For the Six Months Ended June 30,				Change	%
	2004	2003	\$			
<i>Net income</i>	\$ 2,298	\$ 3,061	\$ (763)			-25%
<i>Net income per common share:</i>						
<i>Basic</i>	\$ 0.11	\$ 0.17	\$ (0.06)			-35%
<i>Diluted</i>	\$ 0.10	\$ 0.15	\$ (0.05)			-33%
<i>Weighted average common shares outstanding:</i>						
<i>Basic</i>	20,620	17,495	3,125			18%
<i>Diluted</i>	22,787	20,617	2,170			11%

We reported income from operations of \$4,254,000 in the six months ended June 30, 2004 compared to \$5,970,000 (which included a non-recurring one-time milestone revenue payment of \$500,000) in the six months ended June 30, 2003. The combination of income from operations of \$4,254,000 and the non-operating items, primarily the provision for income taxes of \$3,361,000 and the reversal of previously accrued tax assessments totaling \$1,467,000 resulted in net income of \$2,298,000, or \$0.11 per basic common share (\$0.10 per diluted common share) on 20,620,000 weighted average basic common shares outstanding (22,787,000 weighted average diluted common shares outstanding) in the first half of 2004, compared to net income of \$3,061,000, or \$0.17 per basic common share (\$0.15 per diluted common share) on 17,495,000 weighted average basic common shares outstanding (20,617,000 weighted average diluted common shares outstanding) in the first half of 2003. 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 \$109,787,000 at June 30, 2004, while stockholders' equity increased from \$76,165,000 at December 31, 2003 to \$78,657,000 at June 30, 2004. The increase in stockholders' equity primarily reflects net income for the six months of \$2,298,000 and net proceeds from the exercise of stock options of approximately \$1,600,000, partially offset by the negative impact of the fluctuation of the Euro/U.S. dollar exchange rate, which totaled \$1,538,000 in the six month period ended June 30, 2004.

Cash, cash equivalents and marketable securities decreased by 11% or \$4,437,000 from \$40,645,000 at December 31, 2003 to \$36,208,000 at June 30, 2004. The decrease was primarily attributed to the cash acquisition of an active pharmaceutical ingredient manufacturing facility for approximately \$3,300,000 and additions to other fixed assets totaling \$3,476,000, which were partially offset by operating activities and proceeds from exercises of stock options totaling approximately \$3,170,000. Cash and cash equivalents at June 30, 2004 include approximately \$4,604,000 of short-term liquid investments considered to be cash equivalents.

Receivables increased by 32% from \$18,036,000 at December 31, 2003 to \$23,772,000 at June 30, 2004. Receivables increased by approximately \$4,882,000 in local currency, but fluctuations in foreign currency exchange rates increased receivables reported in U.S. dollars by approximately \$854,000. Receivables are comprised of trade receivables totaling \$21,545,000, VAT receivables totaling \$2,096,000 and other receivables totaling \$131,000. Receivables from one international customer total \$6,281,000 at June 30, 2004 and are secured by an irrevocable letter of credit to secure payment. 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 \$2,499,000 from \$7,106,000 at December 31, 2003 to \$9,605,000 at June 30, 2004, primarily as a result of increased production during the quarter required to meet anticipated sales demand and purchases of raw materials to facilitate product testing, launches and manufacturing demand. Inventory increased by approximately \$2,127,000 in local currency, and fluctuations in foreign currency exchange rates increased inventories reported in U.S. dollars by approximately \$372,000.

The combined total of accounts payable and accrued expenses increased from \$17,257,000 at December 31, 2003 to \$23,304,000 at June 30, 2004. The \$6,047,000 increase was primarily attributed to an increase in accounts payable of \$3,162,000 for inventory purchases, an increase in income taxes payable of approximately \$1,516,000 and a \$1,986,000 increase in co-marketing costs payable while fluctuations in foreign currency exchange rates increased accounts payable and accrued expenses reported in U.S. dollars by approximately \$713,000.

Short-term borrowings and current portion of long-term debt decreased from \$1,985,000 at December 31, 2003 to \$1,871,000 at June 30, 2004, primarily as a result of 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 June 30, 2004 was 3.7%.

Operating activities for the six months ended June 30, 2004 provided net cash of \$1,567,000. Our future operating cash flows could be negatively impacted as a result of government regulations that impact pharmaceutical pricing in Spain and anticipated increases in research and development spending for 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: (i) acquire an active pharmaceutical ingredient manufacturing facility in Spain; (ii) increase the capacity of our other manufacturing facility in Spain; and (iii) increase our manufacturing and packaging capabilities, along with additions to drug licenses and related costs, partially offset by proceeds from investment maturities, used net cash of \$6,453,000 during the six months ended June 30, 2004.

Financing activities during the six months ended June 30, 2004 provided cash totaling \$1,553,000, and included proceeds from the exercise of stock options totaling approximately \$1,600,000. These proceeds were partially offset by net repayments of borrowings of approximately \$50,000

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 six months ended June 30, 2004 and 2003, we recognized royalty revenues of \$1,198,000 and \$208,000, 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 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.

*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 revenues 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 a manufacturing facility located in Spain, for approximately \$3,300,000, which specializes in the manufacture of several active pharmaceutical ingredients. We estimate that capital investments of approximately \$2,500,000 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 \$3,500,000 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 \$36,208,000 as of June 30, 2004, which we believe will be sufficient to fund our operations for the foreseeable future. Even though we are generating positive cash flow from operations, (approximately \$1,567,000 in the six months ended June 30, 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. 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. 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;

Sales growth;

Anticipated sources of future revenues;

Anticipated 2004 expenses, margins and operating performance;

Expected launch of new products;

Anticipated expenses and spending;

Commencing and continuing clinical trials;

The sufficiency of capital to fund our operations.

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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 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 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.* As of June 30, 2004, the weighted average interest rate on our short-term borrowings of \$1,871,000 is 3.7%. A portion of our long-term borrowings is non-interest bearing and the balance outstanding on these borrowings at June 30, 2004 is \$360,000 including imputed interest (ranging from 4.8% to 6.0%) of \$75,000. 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 an average of 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 \$22,000 annually.

**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 June 30, 2004, Bentley carried out an evaluation, under the supervision of, and with the participation of Bentley's management, including Bentley'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 15(d)-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, and in ensuring that such information 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 Bentley'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 during the quarter ended June 30, 2004.

**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings**

See Item 1. Legal Proceedings in our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2004.

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 our financial position, results of operations or cash flows.

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

Our Annual Meeting of Stockholders was held on June 7, 2004 and adjourned until June 11, 2004, at which time it was concluded, for the purpose of electing two directors and consideration of proposals to amend and restate our Restated Certificate of Incorporation that would prohibit stockholder action by written consent, amend the classified board provisions and remove the indemnification provisions. Proxies for the meeting were solicited pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, and there was no solicitation in opposition.

The following members were elected to our Board of Directors:

Nominee	Term Expiring	Shares Voted For	Shares Voted Against
F. Ross Johnson	2007	18,285,868	527,354
Edward J. Robinson	2007	18,285,700	527,522

Additionally, three of our employee directors, Messrs. Robert M. Stote, Senior Vice President and Chief Medical Officer, Robert J. Gyurik, Vice President of Pharmaceutical Development, and Michael D. Price, Vice President and Chief Financial Officer, each submitted letters of resignation from the Board of Directors. These resignations were accepted by the Chairman of the Board effective May 12, 2004 concurrent with the listing of our common stock on the New York Stock Exchange. There were no disagreements involved with the resignations and these three officers continue to serve as Executive Officers of Bentley. They tendered their resignations to proactively strengthen our Corporate Governance, so that the Board of Directors would be comprised solely of outside directors and Bentley's Chief Executive Officer. Also, on June 7, 2004, the Board of Directors designated retiring independent director, Charles L. Bolling, a Director Emeritus of Bentley.

The following proposals to amend and restate our Certificate of Incorporation required the affirmative vote of 10,300,084 shares (the holders of a majority of the shares of our outstanding Common Stock on the Record Date of the Annual Meeting, April 13, 2004). The first matter considered was a proposal to prohibit stockholder action by written consent. This proposal was not approved by the following vote:

<b>Shares Voted For</b>	<b>Shares Voted Against</b>	<b>Shares Abstaining</b>
8,300,972	4,442,887	7,856,307

The second matter considered was a proposal to amend the classified board provisions. This proposal also required the affirmative vote of 10,300,084 shares (the holders of a majority of the shares of our outstanding Common Stock on April 13, 2004). This proposal was not approved by the following vote:

Shares Voted For	Shares Voted Against	Shares Abstaining
8,203,016	4,543,537	7,853,613

The final matter considered was a proposal to remove the indemnification provisions from our Restated Certificate of Incorporation. This proposal also required the affirmative vote of 10,300,084 shares (the holders of a majority of the shares of our outstanding Common Stock on April 13, 2004). This proposal was approved by the following vote:

Shares Voted For	Shares Voted Against	Shares Abstaining
17,223,372	1,644,375	1,732,419

**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 June 30, 2004:

(i) We furnished a Current Report on Form 8-K dated May 5, 2004, announcing earnings for the three months ended March 31, 2004 and attaching a press release related thereto. (Item 12) \*

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\* 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

August 4, 2004

By: /s/ James R. Murphy  
James R. Murphy  
Chairman of the Board of Directors, President and Chief  
Executive Officer  
(Principal Executive Officer)

August 4, 2004

By: /s/ Michael D. Price  
Michael D. Price  
Vice President, Chief Financial Officer,  
Treasurer and Secretary (Principal Financial  
and Accounting Officer)

**Exhibit Index**

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
3.1	Certificate of Amendment of Restated Certificate of Incorporation filed with the Secretary of State of the State of Delaware on July 23, 2004. 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.