BENTLEY PHARMACEUTICALS INC
Form 10-Q
November 09, 2004

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2004

OR

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

For the transition period from to

Commission File Number 1-10581

BENTLEY PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE	**No. 59-1513162**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

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

(Current Address of Principal Executive Offices)

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

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

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

The number of shares of the registrant s common stock outstanding as of November 4, 2004 was 21,307,195.

BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES

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

INDEX

BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)	September 30, 2004	December 31, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 33,763	$ 39,393
Marketable securities	476	1,252
Receivables, net	25,863	18,036
Inventories, net	9,013	7,106
Deferred taxes	210	213
Prepaid expenses and other	1,492	899
Total current assets	70,817	66,899
Non-current assets:		
Fixed assets, net	25,053	18,566
Drug licenses and related costs, net	14,109	13,818
Restricted cash	1,000	1,000
Other	166	180
Total non-current assets	40,328	33,564
	$ 111,145	$ 100,463
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 13,303	$ 10,154
Accrued expenses	7,395	7,103
Short-term borrowings	1,950	1,915
Current portion of long-term debt		70
Deferred income	3,216	1,956
Total current liabilities	25,864	21,198
Non-current liabilities:		
Deferred taxes	2,402	2,555
Long-term debt	369	369
Other	75	176
Total non-current liabilities	2,846	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, 21,304 and 20,573 shares	426	412
Stock purchase warrants (to purchase zero and 420 shares of common stock)		333
Additional paid-in capital	140,370	136,850
Accumulated deficit	(62,887)	(66,599)
Accumulated other comprehensive income	4,526	5,169
Total stockholders equity	82,435	76,165
	$ 111,145	$ 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 September 30, 2004	2003	For the Nine Months Ended September 30, 2004	2003
Revenues:				
Net product sales	$ 17,312	$ 14,540	$ 51,325	$ 45,371
Licensing and collaboration revenues	791	335	2,550	1,246
Total revenues	18,103	14,875	53,875	46,617
Cost of net product sales	8,568	5,744	25,161	18,684
Gross profit	9,535	9,131	28,714	27,933
Operating expenses:				
Selling and marketing	3,199	3,224	10,919	10,203
General and administrative	2,140	1,744	6,590	5,089
Research and development	1,230	966	3,171	2,863
Depreciation and amortization	447	356	1,260	967
Total operating expenses	7,016	6,290	21,940	19,122
Income from operations	2,519	2,841	6,774	8,811
Other income (expenses):				
Interest income	157	71	399	236
Interest expense	(49)	(60)	(160)	(174)
Other, net	130	9	1,405	5
Income before income taxes	2,757	2,861	8,418	8,878
Provision for income taxes	1,344	1,513	4,706	4,469
Net income	$ 1,413	$ 1,348	$ 3,712	$ 4,409
Net income per common share:				
Basic	$ 0.07	$ 0.08	$ 0.18	$ 0.25
Diluted	$ 0.06	$ 0.06	$ 0.16	$ 0.21
Weighted average common shares outstanding:				
Basic	21,049	17,911	20,764	17,635
Diluted	22,746	22,228	22,772	21,321
Net income	$ 1,413	$ 1,348	$ 3,712	$ 4,409
Other comprehensive income (loss):				
Foreign currency translation gains (losses)	895	495	(643)	2,688
Comprehensive income	$ 2,308	$ 1,843	$ 3,069	$ 7,097

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

BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS EQUITY

(in thousands, except per share data)	$.02 Par Value Common Stock Shares	Amount	Stock Purchase Warrants	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total
Balance at December 31, 2003	20,573	$ 412	$ 333	$ 136,850	$ (66,599)	$ 5,169	$ 76,165
Exercise of stock options and warrants	719	14	(333)	3,369			3,050
Equity based compensation	12			151			151
Foreign currency translation adjustment						(643)	(643)
Net income					3,712		3,712
Balance at September 30, 2004	21,304	$ 426	$	$ 140,370	$ (62,887)	$ 4,526	$ 82,435

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 Nine Months Ended September 30, 2004	2003
Cash flows from operating activities:		
Net income	$ 3,712	$ 4,409
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	2,748	1,708
Forgiveness of related party loans		(150)
Equity-based compensation expense	167	377
Other non-cash items	(80)	(317)
(Increase) decrease in assets and increase (decrease) in liabilities:		
Receivables	(8,272)	(1,649)
Inventories	(1,823)	(930)
Prepaid expenses and other current assets	(607)	144
Other assets	(1)	(7)
Accounts payable and accrued expenses	3,797	4,063
Deferred income	1,450	702
Other liabilities	(279)	
Net cash provided by operating activities	812	8,350
Cash flows from investing activities:		
Proceeds from sale of investments	149,100	163,400
Purchase of investments	(148,230)	(163,268)
Purchase of API manufacturing assets	(3,309)	
Additions to fixed assets	(6,217)	(6,016)
Additions to drug licenses and related costs	(849)	(2,193)
Net cash used in investing activities	(9,505)	(8,077)

(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 Nine Months Ended September 30, 2004	2003
Cash flows from financing activities:		
Proceeds from exercise of stock options/warrants	$ 3,061	$ 6,239
Repayment of borrowings	(3,728)	(2,646)
Proceeds from borrowings	3,729	2,193
Increase in restricted cash		(1,000)
Net cash provided by financing activities	3,062	4,786
Effect of exchange rate changes on cash	1	1,098
Net (decrease) increase in cash and cash equivalents	(5,630)	6,157
Cash and cash equivalents at beginning of period	39,393	26,581
Cash and cash equivalents at end of period	$ 33,763	$ 32,738
Supplemental Disclosures of Cash Flow Information		
The Company paid cash during the period for:		
Interest	$ 270	$ 154
Foreign income taxes	$ 3,711	$ 2,108
Supplemental Disclosures of Non-Cash Financing and Investing Activities		
The Company has issued Common Stock in exchange for services as follows:		
Shares	12	56
Amount	$ 151	$ 481
Included in accounts payable at period-end are fixed asset and drug license purchases totaling	$ 1,951	$ 1,369

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 that specializes in the manufacture of several active pharmaceutical ingredients (API), of which, one ingredient has been approved by the U.S. 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 entered into a multi-product collaboration agreement with Perrigo Company, the nation s largest manufacturer of over-the-counter pharmaceutical and nutritional products for the store brand market, to co-develop and market certain generic pharmaceutical products in the U.S. and potentially other markets.

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

delivery technologies, including product candidates that deliver insulin to diabetic patients intranasally and treat nail fungus infections topically.

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

BASIS OF CONDENSED CONSOLIDATED FINANCIAL STATEMENTS:

The consolidated financial statements of Bentley Pharmaceuticals as of September 30, 2004 and for the three and nine months ended September 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 condensed 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 condensed consolidated financial statements as of September 30, 2004 and for the three and nine months ended September 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 September 30, 2004 and the results of its operations and cash flows for the three and nine months ended September 30, 2004 and 2003. The results of operations for the three and nine months ended September 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 September 30, 2004 and December 31, 2003 are approximately $2,897,000 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 September 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 $476,000 as of September 30, 2004, compared to $1,252,000 as of December 31, 2003. The Company s investments are carried at amortized cost which approximates fair value due to the short-term nature of these investments.

Accordingly, no unrealized gains or losses have been recognized on these investments. Should the fair values differ significantly from the amortized costs, unrealized gains or losses would be included as a component of *other comprehensive income (loss).*

INVENTORIES:

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

		September 30, 2004		December 31, 2003
Raw materials	$	6,262	$	5,351
Finished goods		2,819		1,829
		9,081		7,180
Less allowance for slow moving inventory		(68)		(74)
	$	9,013	$	7,106

FIXED ASSETS:

Fixed assets consist of the following (in thousands):

		September 30, 2004		December 31, 2003
Land	$	2,400	$	1,900
Buildings and improvements		13,442		9,085
Equipment		14,333		10,953
Furniture and fixtures		1,570		1,497
Leasehold improvements				43
		31,745		23,478
Less accumulated depreciation		(6,692)		(4,912)
	$	25,053	$	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 $3,309,000. 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 increasing capacity at our finished pharmaceutical product manufacturing facility through a series of improvements. During the nine months ended September 30, 2004, the Company invested over $6,000,000 in machinery, equipment and improvements, including new high speed manufacturing and packaging equipment.

Depreciation expense of approximately $516,000 and $256,000 has been charged to operations as a component of *depreciation and amortization expense* in the Consolidated Income Statements for the nine months ended September 30, 2004 and 2003, respectively. We have included depreciation totaling approximately $1,488,000 and $741,000 in *cost of net product sales* during the three months ended September 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, principally the Euro. The exchange rates at September 30, 2004 and December 31, 2003 were .81 Euros and .80 Euros per U.S. Dollar, respectively. The weighted average exchange rates for the three months ended September 30, 2004 and 2003 were .82 Euros and .89 Euros per U.S. Dollar, respectively. The weighted average exchange rates for the nine months ended September 30, 2004 and 2003 were .82 Euros and .90 Euros per U.S. Dollar, respectively. The effect of foreign currency fluctuations on long lived assets for the nine months ended September 30, 2004 was a decrease of $643,000 and the cumulative historical effect was an increase of $4,526,000, 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 nine months ended September 30, 2004, we received proceeds totaling $600,000 from the issuance of 400,000 shares of Common Stock upon exercise of common stock warrants and an additional $2,461,000 from the issuance of 319,000 shares of Common Stock upon the exercise of stock options. We also issued approximately 12,000 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 542,000 shares of Common Stock during the nine months ended September 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. At that time, we expect to record a one-time increase in *licensing and collaboration revenues* related to the recognition of previously deferred revenue. For the three and nine months ended September 30, 2004, we recognized royalty revenues of approximately $800,000 and $2,000,000, respectively, compared to $335,000 and $543,000 in the three and nine months ended September 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 September 30, 2004 and December 31, 2003, deferred income from Testim royalties was approximately $1,240,000 and $634,000, respectively. We will continue to use available market information to determine the amount and timing of royalty revenue recognition until such time that returns from wholesalers and pharmacies can be reasonably estimated.

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 nine months ended September 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 (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:

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 second quarter of 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* for the three months ended June 30, 2004 and the nine months ended September 30, 2004, and approximately $193,000 for related interest and penalties, which have been recorded as components of *other income (expenses),* in the consolidated income statements for the three months ended June 30, 2004 and the nine months ended September 30, 2004.

As a result of reporting taxable income in Spain, we recorded provisions for foreign income taxes totaling $1,344,000 and $1,513,000 for the three months ended September 30, 2004 and 2003, respectively. The effective tax rate for the three months ended September 30, 2004 is 49% compared to 53% in the prior year third quarter. We have recorded provisions for foreign income taxes totaling $4,706,000 ($4,102,000 income tax expense on operations plus $604,000 recorded as a result of the tax audit of our Spanish subsidiary in the second quarter of 2004) and $4,469,000 for the nine months ended September 30, 2004 and 2003, respectively. The effective tax rate in Spain for the nine months ended September 30, 2004 is 56%; however, when the $604,000 tax audit settlement related to prior years is excluded, the effective tax rate is 49% compared to 50% in the comparable nine 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 $896,000 and $958,000 for the three months ended September 30, 2004 and 2003, respectively, and $2,378,000 and $2,423,000 for the nine months ended September 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 second quarter of 2004, we identified certain tax contingencies that we determined were probable and reasonably estimable. Consequently, we have included a charge totaling $188,000 in the *provision for income taxes* in the second quarter of 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 nine months ended September 30, 2004 and 2003.

The following is a reconciliation between basic and diluted net income per common share for the three and nine months ended September 30, 2004 and 2003. Dilutive securities issuable for the three and nine months ended September 30, 2004 include approximately 1,697,000 and 2,008,000 shares, respectively, issuable as a result of various stock options and warrants that are outstanding and exercisable. Dilutive securities issuable for the three and nine months ended September 30, 2003 include approximately 4,317,000 and 3,686,000 shares, respectively, issuable as a result of exercisable Class B Warrants, stock purchase warrants and stock options that were outstanding and exercisable at that time.

(in thousands, except per share data)

For the Three Months Ended September 30, 2004:

	Basic EPS	Effect of Dilutive Securities	Diluted EPS
Net Income	$ 1,413	$	$ 1,413
Weighted Average Common Shares Outstanding	21,049	1,697	22,746
Net Income Per Common Share	$ 0.07	$ (0.01)	$ 0.06

For the Three Months Ended September 30, 2003:

	Basic EPS	Effect of Dilutive Securities	Diluted EPS
Net Income	$ 1,348	$	$ 1,348
Weighted Average Common Shares Outstanding	17,911	4,317	22,228
Net Income Per Common Share	$ 0.08	$ (0.02)	$ 0.06

For the Nine Months Ended September 30, 2004:

	Basic EPS	Effect of Dilutive Securities	Diluted EPS
Net Income	$ 3,712	$	$ 3,712
Weighted Average Common Shares Outstanding	20,764	2,008	22,772
Net Income Per Common Share	$ 0.18	$ (0.02)	$ 0.16

For the Nine Months Ended September 30, 2003:

	Basic EPS	Effect of Dilutive Securities	Diluted EPS
Net Income	$ 4,409	$	$ 4,409
Weighted Average Common Shares Outstanding	17,635	3,686	21,321
Net Income Per Common Share	$ 0.25	$ (0.04)	$ 0.21

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 options and warrants to purchase an aggregate of approximately 740,000 and 583,000 shares of Common Stock, for the three and nine months ended September 30, 2004, respectively, and options and warrants to purchase an aggregate of 185,000 and 347,000 shares of Common Stock, for the three and nine months ended September 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 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 nine months ended September 30, 2004 include $14,000 and $61,000, respectively, of non-cash equity-based compensation. General and administrative expenses for the three and nine months ended September 30, 2003 include $75,000 and $177,000, respectively, of non-cash equity-based compensation. Research and development expenses for the three and nine months ended September 30, 2004 include $24,000 and $106,000, respectively, of non-cash equity-based compensation. Research and development expenses for the three and nine months ended September 30, 2003 include $65,000 and $200,000, respectively, of non-cash equity-based compensation.

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2004	2003	2004	2003
Net income, as reported	$ 1,413	$ 1,348	$ 3,712	$ 4,409
Add: Stock-based employee compensation expense included in reported net income	38	140	167	377
Deduct: Total stock-based employee compensation expense determined under fair value method for all awards	(467)	(850)	(2,168)	(2,367)
Pro forma net income	$ 984	$ 638	$ 1,711	$ 2,419
Net income per common share:				
Basic - as reported	$ 0.07	$ 0.08	$ 0.18	$ 0.25
Basic - pro forma	$ 0.05	$ 0.04	$ 0.08	$ 0.14
Diluted - as reported	$ 0.06	$ 0.06	$ 0.16	$ 0.21
Diluted - pro forma	$ 0.04	$ 0.03	$ 0.08	$ 0.11

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 September 30,		For the Nine Months Ended September 30,	
	2004	2003	2004	2003
Risk-free interest rate	2.59%	3,48%	2.96%	3.88%
Dividend yield	0.00%	0.00%	0.00%	0.00%
Expected life	5 years	5 years	5 years	5 years
Volatility	48.14%	53.12%	49.25%	54.25%
Fair value of options granted	$ 5.62	$ 4.79	$ 6.02	$ 4.99

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 (E1TF) 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.

RECLASSIFICAT1ONS:

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.

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 OPERATTONS:

Three Months Ended September 30, 2004 versus Three Months Ended September 30, 2003

Revenues

	For the Three Months Ended September 30,				Change	
(in thousands)	**2004**	**%**	**2003**	**%**	**$**	**%**
Revenues:						
Net product sales	*$ 17, 312*	*96%*	*$ 14,540*	*98% $*	*2,772*	*19%*
Licensing and collaboration revenues	*791*	*4%*	*335*	*2%*	*456*	*136%*
Total revenues	*$ 18,103*	*100%*	*$ 14,875*	*100% $*	*3,228*	*22%*

Total revenues for the three months ended September 30, 2004 increased 22% from the same period in the prior year. However, our total revenues increased approximately 12% 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 $1,378,000, 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 nine 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, have increased our revenues by approximately $456,000 in the three months ended September 30, 2004 over the same period in the prior year.

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

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

Product Line	Sales Within Spain: Branded Products	Sales Within Spain: Generic Products	Contract Manu-facturing	Other Revenues	Total	% of Total Revenues
Omeprazole	$ 742	$ 3,296	$	$	$ 4,038	22%
Simvastatin	374	929			1,303	7%
Enalapril	725	348			1,073	6%
Paraxetine	225	698			923	5%
Pentoxifylline		668			668	4%
All other products	2,216	1,144		809	4,169	23%
Contract manufacturing			3,077		3,077	17%
Sales outside of Spain				2.061	2,061	12%
Licensing and collaborations				791	791	4%
Total Revenues	$ 4,282	$ 7,083	$ 3,077	$ 3,661	$ 18,103	100%
% of Total Revenues	24%	39%	17%	20%	100%	

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

Product Line	Sales Within Spain: Branded Products	Sales Within Spain: Generic Products	Contract Manu-facturing	Other Revenues	Total	% of TotaI Revenues
Omeprazole	$ 1,515	$ 3,238	$	$	$ 4,753	32%
Simvastatin	618	1,109			1,727	12%
Enalapril	646	379			1,025	7%
Paroxetine		135			135	1%
Pentoxifylline		489			489	3%
All other products	1,672	941			2,613	18%
Contract manufacturing			1,856		1,856	12%
Sales outside of Spain				1,942	1,942	13%
Licensing and collaborations				335	335	2%
Total Revenues	$ 4,451	$ 6,291	$ 1,856	$ 2,277	$ 14,875	100%
% of Total Revenues	30%	42%	13%	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 third quarter 2004 product sales over the 2003 third quarter is due primarily to a 66% increase in contract manufacturing sales, sales of active pharmaceutical ingredients (API) from our new manufacturing facility (included in *All other products* above), revenues from our paroxetine product line, which was launched in May of 2003 and growth in the number of units sold and marketshare, partially offset by lower prices. Contract manufacturing sales increased by $1,221,000 when compared to the prior year quarter and accounted for approximately 38% of our revenue growth in the period. API sales added $809,000

to our revenues in the third quarter of 2004 and accounted for 25% of our revenue growth in the period. Our paroxetine product line generated net sales of $923,000, representing 5% of our total revenues during the three months ended September 30, 2004, compared to 1% in the comparable period of the prior year and accounted for 24% of our revenue growth in the period. However, revenues from our top two selling products, omeprazole and simvastatin, comprised an aggregate of 29% of our total revenues in the third quarter of 2004, compared to 44% in the same quarter of the prior year, as a result of lower selling prices 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 nine 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 of 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 April and May of 2004 were decreased from the first quarter but remained elevated; however, returns subsequent to May of 2004 have returned to levels consistent with our historical experience. Gross margins on pharmaceutical product sales excluding sales of active pharmaceutical ingredients were 53% in the second and third quarters of 2004 up from 51% in the first quarter of 2004. See additional discussion in the *Gross Profit* section.

Over the past nine 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. The ability to manufacture active pharmaceutical ingredients 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

	For the Three Months Ended September 30,				Change	
(in thousands)	**2004**	**%**	**2003**	**%**	**$**	**%**
Branded Product Sales:						
Omeprazole	$ 742	*17%*	$ 1,515	*34%*	$ (773)	*-51%*
Enalapril	725	*17%*	647	*15%*	78	*12%*
Codeisan	607	*14%*	454	*10%*	153	*34%*
All other branded products	2,208	*52%*	1,835	*41%*	373	*20%*
Total branded sales	$ 4,282	*100%*	$ 4,451	*100%*	$ (169)	*-4%*

Sales of our branded pharmaceutical products in the three months ended September 30, 2004 decreased by approximately 4% compared to the same period of the prior year, and they accounted for 24% of total revenues during the three months ended September 30, 2004 compared to 30% of total revenues during the three months ended September 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 $347,000 in the third quarter of 2004. Price reductions continued to erode the sales of our branded omeprazole and simvastatin, which decreased by approximately $773,000 and $244,000, 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 increasing market share of Belmazol with a 16% increase in units sold in the third quarter of 2004 when compared to the same period of the prior year. Generic competition has led to a 30% decrease in unit volume of Belmalip, our branded simvastatin, in the three months ended September 30, 2004 when compared to the same period of the prior year, which has been partially offset by a 22% increase in unit volume of our generic simvastatin. Sales of our branded enalapril experienced a 55% increase in unit volume when compared to the same period of the prior year and accounted for 17% of total branded 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 those of our branded products.

Generic Pharmaceutical Products

(in thousands)	For the Three Months Ended September 30. 2004	%	2003	%	Change $	%
Generic Product Sales:						
Omeprazole	$ 3,296	*47%*	$ 3,238	*51%*	$ 58	*2%*
Simvastatin	929	*13%*	1,109	*18%*	(180)	*-16%*
Paroxetine	698	*10%*	135	*2%*	563	*417%*
Pentaxifylline	668	*9%*	489	*8%*	179	*37%*
All other generic products	1,492	*21%*	1,320	*21%*	172	*13%*
Total generic sales	$ 7,083	*100%*	$ 6,291	*100%*	$ 792	*13%*

Sales of our generic pharmaceutical products in the three months ended September 30, 2004 increased by approximately 13% compared to the same period of the prior year, and they accounted for 39% of total revenues during the three months ended September 30, 2004 compared to 42% of total revenues during the three months ended September 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 $565,000 in the third quarter of 2004. Sales of our generic omeprazole in the third quarter of 2004, while 18% higher in terms of units sold, increased by only 2% in U.S. dollars when compared to the prior year and accounted for 47% of our generic pharmaceutical revenues in the third quarter of 2004, compared to 51% of generic revenues in the third 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 16% when expressed in U.S. Dollars. Sales of our generic paroxetine, which was launched in May of 2003, added approximately $563,000 to our generic sales, and continued to be a major contributor again in the third quarter of 2004 accounting for 10% of generic product sales, compared to 2% in the third quarter of the prior year. Sales of our generic pentoxifylline in the third quarter of 2004 increased by approximately $179,000, or approximately 37% 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 September 30, 2004	2003	Change $	%
Contract manufacturing	*$ 3,077*	*$ 1,856*	*$ 1,221*	*66%*

In addition to manufacturing our own products, our Spanish manufacturing facility supplies branded and generic products to several entities in Spain under approximately 30 contract manufacturing supply agreements. These customers market the products under their own names with their own labeling. Revenues generated from contract manufacturing represented 17% of total revenues in the three months ended September 30, 2004, compared to 12% of total revenues in the three months ended September 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 $246,000 in the third quarter of 2004.

Sales Outside of Spain

(in thousands)	For the Three Months Ended September 30, 2004	2003	Change $	%
Sales outside of Spain	*$ 2,061*	*$ 1,942*	*$ 119*	*6%*

21

We have more than 30 license agreements pursuant to which we are selling our products outside of Spain. However, we currently have an additional 57 signed license agreements to sell our products outside of Spain awaiting regulatory approvals. These license agreements are usually accompanied by five-year exclusive supply agreements whereby the related products can only be purchased from our subsidiaries. Sales under these supply agreements increased by $119,000 or 6% when compared to the comparable period of the prior year. The 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 saving 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 $165,000 during the three months ended September 30, 2004 compared to the third quarter of 2003.

Licensing and Collaboration Revenues

(in thousands)	For the Three Months Ended September 30, 2004	2003	Change $	Change %
Licensing and collaboration	*$ 791*	*$ 335*	*$ 456*	*136%*

Licensing and collaboration revenues accounted for 4% of total revenues in the three months ended September 30, 2004 compared to 2% of total revenues in the three months ended September 30, 2003. These revenues include royalties of approximately $800,000 (compared to $335,000 in the third 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 11-12% of all new testosterone gel replacement prescriptions in the market.

Gross Profit. Gross profit increased by approximately $404,000, or 4%, in the three months ended September 30, 2004 when compared to the three months ended September 30, 2003, while our gross margins on net product sales have decreased from 60% in the three months ended September 30, 2003 to 51% in the three months ended September 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 and related product returns in Spain; however, product returns subsequent to May 2004 have returned to levels consistent with our historical experience.

Selling and Marketing Expenses

(in thousands)	For the Three Months Ended September 30, 2004	2003	Change $	Change %
Selling and marketing	$ 3,199	$ 3,224	$ (25)	-1%

Selling and marketing expenses for the three months ended September 30, 2004 remained relatively consistent with the same period in the prior year when expressed in U.S. dollars; however, 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 $266,000 in the three months ended September 30, 2004. Selling and marketing expenses as a percentage of net product sales decreased from 22% in the three months ended September 30, 2003, to 18% in the three months ended September 30, 2004.

General and Administrative Expenses

(in thousands)	For the Three Months Ended September 30, 2004	2003	Change $	Change %
General and administrative	$ 2,140	$ 1,744	$ 396	23%

General and administrative expenses for the three months ended September 30, 2004 increased 23% over the same period in the prior year. The $396,000 increase was the result of increased general and administrative activities required to support our continued growth and prepare for our anticipated 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 including costs of regulatory filings related to products that we anticipate selling in the future under license agreements and costs associated with the implementation of the Sarbanes-Oxley Act of 2002. General and administrative expenses as a percent of total revenues in the three months ended September 30, 2004 remained at a consistent 12% when compared to the three months ended September 30, 2003. General and administrative expenses would have been approximately $80,000 lower, absent the increase in the weighted average value of the Euro, in relation to the U.S. Dollar, in the three months ended September 30, 2004. We expect that our future expenditures for general and administrative expenses will continue to increase as we grow.

Research and Development Expenses

(in thousands)	For the Three Months Ended September 30, 2004	2003	Change $	Change %
Research and development	$ 1,230	$ 966	$ 264	27%

Research and development expenses for the three months ended September 30, 2004 increased 27% over 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. Our Phase I trial demonstrated the effective delivery of insulin intranasally in healthy human subjects. We have recently completed the in-patient stage of a Phase II study of our clinical program for the intranasal delivery of insulin and are in the data analysis and reporting stages of that study. We initiated certain clinical programs to support our strategy for the eventual distribution of certain of our Spanish generic pharmaceutical products in other countries, including the U.S. In order to further our strategy, we recently entered into a multi-product collaboration agreement with Perrigo Company to

co-develop and market certain generic pharmaceutical products in the U.S. and potentially other markets. 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 as a result of our increased development activities.

Provision for Income Taxes

	For the Three Months Ended September 30, 2004		
(in thousands)	**Spain**	**U.S.**	**Consolidated**
Income (loss) before income taxes	*$ 3,653*	*$ (896)*	*$ 2,757*
Provision (benefit) for income taxes	*1,344*	*(305)*	*1,039*
Valuation allowance		*305*	*305*
Net provision for income taxes	*1,344*		*1,344*
Net income (loss)	*$ 2,309*	*$ (896)*	*$ 1,413*
Effective tax rate	*37%*	*0%*	*49%*

As a result of reporting taxable income in Spain, we recorded provisions for foreign income taxes totaling $1,344,000 and $ 1,513,000 for the three months ended September 30, 2004 and 2003, respectively. The effective tax rate in Spain for the three months ended September 30, 2004 is 37% compared to 40% in the prior year third quarter. The provision for foreign income taxes would have been approximately $102,000 lower than reported, absent the increase in the weighted average value of the Euro, in relation to the U.S. Dollar, during the twelve months ended September 30, 2004.

We generated additional U.S. federal net operating loss carry-forwards in the three months ended September 30, 2004 and 2003 as a result of U.S. pre-tax losses of $896,000 and $958,000, 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 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 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 September 30, 2004	2003	Change $	Change %
Net income	*$ 1,413*	*$ 1,348*	*$ 65*	*5%*
Net income per common share:				
Basic	*$ 0.07*	*$ 0.08*	*$ (0.01)*	*-13%*
Diluted	*$ 0.06*	*$ 0.06*	*$*	*0%*
Weighted average common shares outstanding:				
Basic	*21,049*	*17,911*	*3,138*	*18%*
Diluted	*22,746*	*22,228*	*518*	*2%*

We reported income from operations of $2,519,000 in the three months ended September 30, 2004 compared to $2,841,000 in the three months ended September 30, 2003. The combination of income from operations of $2,519,000 and the non-operating items, primarily the provision for income taxes of $1,344,000, resulted in net income of $1,413,000, or $0.07 per basic common share ($0.06 per diluted common share) on 21,049,000 weighted average basic common shares outstanding (22,746,000 weighted average diluted common shares outstanding) in the three months ended September 30, 2004, compared to net income of $1,348,000, or $0.08 per basic common share ($0.06 per diluted common share) on 17,911,000 weighted average basic common shares outstanding (22,228,000 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.

Nine Months Ended September 30, 2004 versus Nine Months Ended September 30, 2003

Revenues

(in thousands)	For the Nine Months Ended September 30, 2004	%	2003	%	Change $	%
Revenues:						
Net product sales	$ 51,325	95%	$ 45,371	97%	$ 5,954	13%
Licensing and collaboration revenues	2,550	5%	1,246	3%	1,304	105%
Total revenues	$ 53,875	100%	$ 46,617	100%	$ 7,258	16%

Total revenues for the nine months ended September 30, 2004 increased 16% from the same nine month period in the prior year. However, our total revenues increased approximately 5% 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 $4,913,000, partially offsetting the impact of price reductions in Spain. 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 $1,304,000 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 nine months ended September 30, 2004 (in thousands):

Product Line	Sales Within Spain: Branded Products	Sales Within Spain: Generic Products	Sales Within Spain: Contract Manu-facturing	Other Revenues	Total	% of Total Revenues
Omeprazole	$ 1,923	$ 9,783	$	$	$ 11,706	22%
Simvastatin	968	2,570			3,538	7%
Enalapril	2,280	883			3,163	6%
Paroxetine	703	2,282			2,985	5%
Codeisan	2,118				2,118	4%
All other products	4,852	5,149		1,076	11,077	20%
Contract manufacturing			7,915		7,915	15%
Sales outside of Spain				8,823	8,823	16%
Licensing and collaborations				2,550	2,550	5%
Total Revenues	$ 12,844	$ 20,667	$ 7,915	$ 12,449	$ 53,875	100%
% of Total Revenues	24%	38%	15%	23%	100%	

For the nine months ended September 30, 2003 (in thousands):

Product Line	Sales Within Spain: Branded Products	Sales Within Spain: Generic Products	Contract Manu-facturing	Other Revenues	Total	% of Total Revenues
Omeprazole	*$ 4,769*	*$ 9,780*	*$*	*$*	*$ 14,549*	*31%*
Simvastatin	*1,579*	*3,021*			*4,600*	*10%*
Enalapril	*1,867*	*1,334*			*3,201*	*7%*
Paroxetine		*340*			*340*	*1%*
Codeisan	*1,678*				*1,678*	*3%*
All other products	*3,676*	*4,547*			*8,223*	*18%*
Contract manufacturing			*6,949*		*6,949*	*15%*
Sales outside of Spain				*5,831*	*5,831*	*12%*
Licensing and collaborations				*1,246*	*1,246*	*3%*
Total Revenues	*$ 13,569*	*$ 19,022*	*$ 6,949*	*$ 7,077*	*$ 46,617*	*100%*
% of Total Revenues	*29%*	*41%*	*15%*	*15%*	*100%*	

Spanish Operations. The increase in product sales for the nine months ended September 30, 2004 over the same period of 2003 was primarily due to the introduction of our paroxetine product line, which was launched in May of 2003, increases in contract manufacturing and growth in licensing and collaboration revenues. Our paroxetine product line generated net sales of $2,985,000, representing 5% of our total revenues during the nine months ended September 30, 2004 and 36% of our growth. In spite of reduced selling prices, revenues from our omeprazole products in the first nine months of 2004 comprised 22% of our revenues, compared to 31% in the same period of the prior year.

Branded Pharmaceutical Products

(in thousands)	For the Nine Months Ended September 30, 2004	%	2003	%	Change $	Change %
Branded Product Sales:						
Omeprazole	$ 1,923	*15%*	$ 4,769	*35%*	$ (2,846)	*-60%*
Enalapril	2,280	*18%*	1,867	*14%*	413	*22%*
Codeisan	2,118	*16%*	1,678	*12%*	440	*26%*
All other branded products	6,523	*51%*	5,255	*39%*	1,268	*24%*
Total branded sales	$ 12,844	*100%*	$ 13,569	*100%*	$ (725)	*-5%*

Sales of our branded pharmaceutical products decreased by approximately 5% in U.S. Dollars compared to the prior year, and accounted for 24% of total revenues during the nine months ended September 30, 2004 compared to 29% of total revenues during the nine months ended September 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 $1,207,000 in the nine months ended September 30, 2004. Price reductions continued to negatively impact our branded product sales year-to-date. Most significantly, sales of our branded omeprazole and simvastatin products decreased by approximately $2,843,000 and $1,062,000, respectively, from the same period in the prior year, as a result of price reductions effected in December 2003. In the face of price cuts and strong generic competition, we were successful in increasing market share of Belmazol with a 6% increase in the number of units of sold in the nine

27

months ended September 30, 2004 when compared to the same period of the prior year. Sales of our branded enalapril, which experienced a 60% increase in unit volume compared to the same period of the prior year, increased 22% 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.

Generic Pharmaceutical Products

	For the Nine Months Ended September 30,				Change	
(in thousands)	**2004**	**%**	**2003**	**%**	**$**	**%**
Generic Product Sales:						
Omeprazole	$ 9,783	*47%*	$ 9,780	*51%*	$ 3	*0%*
Simvastatin	2,570	*12%*	3,021	*16%*	(451)	*-15%*
Paroxetine	2,282	*11%*	340	*2%*	1,942	*571%*
Pentoxifylline	1,946	*9%*	1,457	*8%*	489	*34%*
Trimetazidine	1,424	*7%*	346	*2%*	1,078	*312%*
All other generic products	2,662	*13%*	4,078	*21%*	(1,416)	*-35%*
Total generic sales	$ 20,667	*100%*	$ 19,022	*100%*	$ 1,645	*9%*

Sales of our generic pharmaceutical products increased by 9% during the nine months ended September 30, 2004 compared to the nine months ended September 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 $1,942,000 in the first nine months of 2004. Sales of our generic omeprazole, which experienced a 9% increase in unit volume, remained consistent when expressed in U.S. Dollars as a result of price reductions and accounted for 47% of our generic pharmaceutical revenues in the nine months ended September 30, 2004, compared to 51% of generic revenues in the comparable period of the prior year. 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 $1,942,000 to our generic sales when compared to the same period in the prior year, positioning it third behind our generic omeprazole and simvastatin products in the nine months ended September 30, 2004. Sales of our generic trimetazidine increased by approximately $1,078,000, or approximately 312% from the comparable period of the prior year, while sales of our generic pentoxifylline increased by $489,000 or approximately 34%. Trimetazidine became a major contributor to our generic pharmaceutical sales during the nine months ended September 30, 2004.

Contract Manufacturing

	For the Nine Months Ended September 30,		Change	
(in thousands)	**2004**	**2003**	**$**	**%**
Contract manufacturing	*$ 7,915*	*$ 6,949*	*$ 966*	*14%*

Revenues generated from contract manufacturing represented a consistent 15% of total revenues in the nine months ended September 30, 2004 when compared to the comparable period of the prior year. 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 $744,000 in the nine months ended September 30, 2004.

Sales Outside of Spain

(in thousands)	For the Nine Months Ended September 30, 2004	2003	Change $	%
Sales outside of Spain	*$ 8,823*	*$ 5,831*	*$ 2,992*	*51%*

Sales outside of Spain under our supply agreements increased 51% from the nine months ended September 30, 2003. The $2,992,000 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 $829,000 during the nine months ended September 30, 2004.

Licensing and Collaboration Revenues

(in thousands)	For the Nine Months Ended September 30, 2004	2003	Change $	%
Licensing and collaboration	*$ 2,550*	*$ 1,246*	*$ 1,304*	*105%*

Licensing and collaboration revenues accounted for 5% of total revenues in the nine months ended September 30, 2004. These revenues include royalties of approximately $2,000,000 (compared to $543,000 in the same period of the prior year) from the commercialization and continuing sales of Testim. Licensing and collaboration revenues in the comparable prior year period included a one-time milestone payment of $500,000.

Gross Profit. Gross profit increased by approximately $781,000, or 3%, in the nine months ended September 30, 2004 when compared to the nine months ended September 30, 2003, while our gross margins on net product sales decreased from 59% to 51% in those periods (52% gross margins on sales of pharmaceutical products, excluding sales of active pharmaceutical ingredients). Product returns of approximately $2,500,000 in the nine months ended September 30, 2004 served to reduce revenues by approximately $2,300,000 during the period; however, product returns subsequent to May 2004 have returned to levels consistent with our historical experience.

Selling and Marketing Expenses

(in thousands)	For the Nine Months Ended September 30, 2004	2003	Change $	%
Selling and marketing	*$ 10,919*	*$ 10,203*	*$ 716*	*7%*

Selling and marketing expenses for the nine months ended September 30, 2004 increased 7% 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

$1,028,000 in the nine month period, indicating that selling and marketing expenses actually decreased in local currency from the same period in the prior year. Selling and marketing expenses as a percentage of net product sales in the nine months ended September 30, 2004 decreased to 21% from 22% in the same period of the prior year.

General and Administrative Expenses

(in thousands)	For the Nine Months Ended September 30, 2004	2003	Change $	Change %
General and administrative	*$ 6,590*	*$ 5,089*	*$ 1,501*	*29%*

General and administrative expenses for the nine months ended September 30, 2004 increased 29% over the same period in the prior year. The $1,501,000 increase was the result of increased general and administrative activities required to support our continued growth and prepare for our anticipated growth. General and administrative expenses as a percent of total revenues increased to approximately 12% in the nine months ended September 30, 2004, from approximately 11% of total revenues in the nine months ended September 30, 2003. General and administrative expenses would have been approximately $347,000 lower, absent the increase in the weighted average value of the Euro, in relation to the U.S. Dollar, in the twelve months ended September 30, 2004. This foreign currency impact accounted for 23% of the increase in general and administrative expenses when compared to the same period of the prior year.

Research and Development Expenses

(in thousands)	For the Nine Months Ended September 30, 2004	2003	Change $	Change %
Research and development	*$ 3,171*	*$ 2,863*	*$ 308*	*11%*

Research and development expenses for the nine months ended September 30, 2004 increased 11% over the same period in the prior year consistent with our increase in research and development activities in the current year. These activities include additional studies performed on our intranasal insulin delivery technology and other clinical programs to support the eventual distribution of certain of our Spanish generic pharmaceutical products in other countries, including the U.S.

Other, net

(in thousands)	For the Nine Months Ended September 30, 2004	2003	Change $	Change %
Other, net	*$ 1,405*	*$ 5*	*$ 1,400*	*

* *Not meaningful*

Other, net for the nine months ended September 30, 2004 increased by $1,400,000 over 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*) during the second quarter of 2004. We recorded a pre-tax benefit totaling $1,467,000 ($954,000 after taxes) as a component of *other income (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 second quarter of 2004.

30

Provision for Income Taxes

(in thousands)	For the Nine Months Ended September 30, 2004 Spain	U.S.	Consolidated
Income (loss) before income taxes	$ 10,795	$ (2,377)	$ 8,418
Provision (benefit) for income taxes	4,102	(808)	3,294
Tax liability, 1998-2000 audit	604		604
Total provision (benefit) for income taxes	4,706	(808)	3,898
Valuation allowance		808	808
Net provision for income taxes	4,706		4,706
Net income (loss)	$ 6,089	$ (2,377)	$ 3,712
Effective tax rate	44%	0%	56%

A tax review of our Spanish subsidiary, Laboratories 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 nine months ended September 30, 2004.

We have recorded provisions for foreign income taxes totaling $4,706,000 ($4,102,000 income tax expense on operations plus $604,000 recorded as a result of the 1998 - 2000 tax audit of our Spanish subsidiary) and $4,469,000 for the nine months ended September 30, 2004 and 2003, respectively. The effective tax rate in Spain for the nine months ended September 30, 2004 is 44%; however, when the $604,000 tax audit settlement related to prior years is excluded, the effective tax rate is 38% compared to 40% in the comparable nine month period of the prior year. The provision for foreign income taxes would have been approximately $439,000 lower than reported, absent the increase in the weighted average value of the Euro, in relation to the U.S. Dollar, during the twelve months ended September 30, 2004.

We generated additional U.S. federal net operating loss carry-forwards in the nine months ended September 30, 2004 and 2003 as a result of U.S. pre-tax losses of $2,377,000 and $2,423,000, 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.

During the second quarter of 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* related to these contingencies.

Net Income

(in thousands, except per share data)	For the Nine Months Ended September 30, 2004	2003	Change $	Change %
Net income	*$ 3,712*	*$ 4,409*	*$ (697)*	*-16%*
Net income per common share:				
Basic	*$ 0.18*	*$ 0.25*	*$ (0.07)*	*-28%*
Diluted	*$ 0.16*	*$ 0.21*	*$ (0.05)*	*-24%*
Weighted average common shares outstanding:				
Basic	*20,764*	*17,635*	*3,129*	*18%*
Diluted	*22,772*	*21,321*	*1,451*	*7%*

We reported income from operations of $6,774,000 in the nine months ended September 30, 2004 compared to $8,811,000 (which included a non-recurring one-time milestone revenue payment of $500,000) in the nine months ended September 30, 2003. The combination of income from operations of $6,774,000 and the non-operating items, primarily the provision for income taxes of $4,706,000 and the reversal of previously accrued tax assessments totaling $1,467,000 resulted in net income of $3,712,000, or $0.18 per basic common share ($0.16 per diluted common share) on 20,764,000 weighted average basic common shares outstanding (22,772,000 weighted average diluted common shares outstanding) in the nine months ended September 30, 2004, compared to net income of $4,409,000, or $0.25 per basic common share ($0.21 per diluted common share) on 17,635,000 weighted average basic common shares outstanding (21,321,000 weighted average diluted common shares outstanding) in the nine months ended September 2003.

LIQUIDITY AND CAPITAL RESOURCES:

Total assets increased from $100,463,000 at December 31, 2003 to $111,145,000 at September 30, 2004, while stockholders equity increased from $76,165,000 at December 31, 2003 to $82,435,000 at September 30, 2004. The increase in stockholders equity during the nine months ended September 30, 2004 primarily reflects net income of $3,712,000 and net proceeds from the exercise of stock options and warrants of approximately $3,061,000, partially offset by the negative impact of the fluctuation of the Euro/U.S. dollar exchange rate, which totaled $643,000.

Cash, cash equivalents and marketable securities decreased by almost 16% or $6,406,000 from $40,645,000 at December 31, 2003 to $34,239,000 at September 30, 2004. The decrease was primarily due to the cash acquisition of an active pharmaceutical ingredients manufacturing facility for approximately $3,309,000 and other fixed asset additions of approximately $6,217,000, which decreases were partially offset by cash provided by operating activities totaling approximately $812,000 and proceeds from exercises of stock options and warrants totaling approximately $3,061,000. Cash and cash equivalents at September 30, 2004 include approximately $2,897,000 of short-term liquid investments considered to be cash equivalents.

Receivables increased by 43% from $18,036,000 at December 31, 2003 to $25,863,000 at September 30, 2004. Our receivable balances at December 31, 2003 and September 30, 2004 include approximately $884,000 and $2,012,000, respectively, of royalties due from Auxilium, evidencing the continued success of Testim sales. Fluctuation in foreign currency exchange rates during 2004 decreased receivables reported in U.S. dollars by approximately $445,000. In addition to royalties receivable from Auxilium, receivables at September 30, 2004 are comprised of trade receivables totaling $21,929,000, VAT receivables totaling $1,617,000 and other receivables totaling $305,000. Receivables from one international customer totaled $6,335,000 at September 30, 2004 and are secured by bills of exchange. We owe the same customer approximately $3,300,000 for co-marketing expenses. Subsequent to September 30, 2004 this customer has made arrangements to pay approximately $1,464,000 toward its receivable balance and we have received $958,000 from Auxilium toward its receivable balance. We have not experienced any material delinquencies on any of our receivables that have had a material effect on our financial position, results of operations or cash flows.

Inventories increased by approximately $1,907,000 from $7,106,000 at December 31, 2003 to $9,013,000 at September 30, 2004, primarily as a result of increased production during the period required to meet anticipated sales demand and purchases of raw materials to facilitate product testing, launches and manufacturing demand. Inventory increased by approximately $1,741,000 in local currency, and fluctuations in foreign currency exchange rates increased inventories reported in U.S. dollars by approximately $166,000.

The combined total of accounts payable and accrued expenses increased from $17,257,000 at December 31, 2003 to $20,698,000 at September 30, 2004. The $3,441,000 increase was primarily attributed to increases in accounts payable of $815,000 for inventory purchases and $282,000 for fixed asset purchases, an increase in income taxes payable of approximately $2,057,000 and an increase of $1,445,000 in co-marketing costs payable, partially offset by, a $1,457,000 decrease in accrued expenses as a result of the reversal of previously accrued tax assessments and a decrease of approximately $356,000 as a result of fluctuations in foreign currency exchange rates.

Short-term borrowings and current portion of long-term debt decreased from $1,985,000 at December 31, 2003 to $1,950,000 at September 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 September 30, 2004 was 4.7%.

Operating activities for the nine months ended September 30, 2004 provided net cash of $812,000 compared to $8,350,000 in the nine months ended September 30, 2003. The reduction in operating cash flows was primarily due to increased receivable balances and reduced selling prices on certain of our pharmaceutical products. 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 ingredients 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 $9,505,000 during the nine months ended September 30, 2004.

Financing activities during the nine months ended September 30, 2004 provided cash totaling $3,062,000, primarily representing the proceeds from the exercise of stock options and our remaining stock purchase warrants.

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. At that time, we expect to record a one-time increase in *licensing and collaboration revenues* related to the recognition of previously deferred revenue. For the nine months ended September 30, 2004 and 2003, we recognized royalty revenues of approximately $2,000,000 and $543,000, 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 September 30, 2004 and December 31, 2003, deferred income from Testim royalties was approximately $1,240,000 and $634,000, respectively. We will continue to use available market information to determine the amount and timing of royalty revenue recognition until such time that returns from wholesalers and pharmacies can be reasonably estimated.

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 $3,309,000, which specializes in the manufacture of several active pharmaceutical ingredients. We also plan to continue

improving and expanding both of our manufacturing facilities in Spain and purchasing new equipment to support our research and development activities in the U.S. We expect to invest an additional $1,500,000 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 $34,239,000 as of September 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 $812,000 in the nine months ended September 30, 2004), there can be no assurance that changes in our research and development plans, capital expenditures and 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. For a more detailed discussion of our critical accounting policies and estimates, we refer the reader to the complete discussion included in our Annual Report on Form 10-K for the year ended December 31, 2003.

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;

Anticipated regulatory approvals; and

The sufficiency of capital to fund our operations.

These forward-looking statements are based on our current expectations, beliefs,

assumptions, estimates, forecasts and projections for our business and the industry and markets in which we compete. These statements are not guarantees of future performance and involve certain risks, uncertainties and assumptions that are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed in such forward-looking statements. We caution investors not to place undue reliance on the forward-looking statements contained in this report. These statements speak only as of the date of this report, and we do not undertake any obligation to update or revise them, except as required by law. The following factors, among others, create risks and uncertainties that could affect our future or other performance: expanding generic and branded drug operations, efficacy and safety of our products, 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, principally the Euro. The exchange rates at September 30, 2004 and December 31, 2003 were .81 Euros and .80 Euros per U.S. Dollar, respectively. The weighted average exchange rates for the three months ended September 30, 2004 and 2003 were .82 Euros and .89 Euros per U.S. Dollar, respectively. The weighted average exchange rates for the nine months ended September 30, 2004 and 2003 were .82 Euros and .90 Euros per U.S. Dollar, respectively. The effect of foreign currency fluctuations on long lived assets for the nine months ended September 30, 2004 was a decrease of $643,000 and the cumulative historical effect was an increase of $4,526,000, 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, or vice versa, 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 September 30, 2004, the weighted average interest rate on our short-term borrowings of $1,582,000 is 4.7%. A portion of our long-term borrowings is non-interest bearing and the balance outstanding on these borrowings at September 30, 2004 is $369,000 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 5.7% 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 $19,000 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, summarized 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 September 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(c) and 15(d)-15(c)). 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 changes that have materially affected, or are reasonably likely to materially affect Bentley s internal controls over financial reporting during the quarter ended September 30, 2004.

PART II. **OTHER INFORMATION**

Item 1. Legal Proceedings

In September 2004, a legal action was filed against us in the U.S. District Court for the District of Delaware by Ethypharm S.A., a French-based drug delivery company, primarily claiming misappropriation of unspecified alleged trade secrets in connection with the manufacture of omeprazole since March 2002 by Laboratorios Belmac, one of our Spanish subsidiaries. A related claim was previously brought against Laboratorios Belmac in the Spanish courts requesting preliminary inquiries into possible patent infringement, which remains unresolved. We intend to vigorously defend against the claims in the U.S. and Laboratorios Belmac is doing the same in the Spanish proceeding.

Also, 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 6. 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.

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

November 4, 2004	By:	/s/ James R. Murphy James R. Murphy Chairman of the Board of Directors, President and Chief Executive Officer (Principal Executive Officer)
November 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

Exhibit Number	Description of Exhibit
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.