

BENTLEY PHARMACEUTICALS INC
Form 10-Q
November 09, 2005

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended **September 30, 2005**

or

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

For the transition period from _____ to _____

Commission File Number **1-10581**

BENTLEY PHARMACEUTICALS, INC.

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(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction of
incorporation or organization)

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

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

(Current Address of Principal Executive Offices)

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

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

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

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

The number of shares of the registrant's common stock outstanding as of November 8, 2005 was 21,841,564.

Bentley Pharmaceuticals, Inc. and Subsidiaries

Form 10-Q for the Quarter Ended September 30, 2005

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Bentley Pharmaceuticals, Inc. and Subsidiaries

Consolidated Balance Sheets

| (in thousands, except per share data) | September 30, 2005 | December 31, 2004 |
|--|-----------------------|----------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 35,813 | \$ 34,230 |
| Marketable securities | 469 | 528 |
| Receivables, net | 26,856 | 27,860 |
| Inventories, net | 12,758 | 10,258 |
| Deferred taxes | 613 | 479 |
| Prepaid expenses and other | 1,568 | 1,355 |
| Total current assets | 78,077 | 74,710 |
| Non-current assets: | | |
| Fixed assets, net | 30,820 | 30,849 |
| Drug licenses and related costs, net | 13,944 | 14,863 |
| Restricted cash | 1,000 | 1,000 |
| Other | 976 | 508 |
| Total non-current assets | 46,740 | 47,220 |
| | \$ 124,817 | \$ 121,930 |
| Liabilities and Stockholders' Equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 15,608 | \$ 17,048 |
| Accrued expenses | 9,686 | 6,169 |
| Related party payable | 736 | |
| Short-term borrowings | 2,129 | 2,754 |
| Current portion of long-term debt | 27 | 31 |
| Deferred income | 2,674 | 1,594 |
| Total current liabilities | 30,860 | 27,596 |
| Non-current liabilities: | | |
| Deferred taxes | 2,047 | 2,319 |
| Long-term debt | 319 | 349 |
| Deferred income | 2,360 | 1,944 |
| Other | 47 | 65 |
| Total non-current liabilities | 4,773 | 4,677 |
| 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, 21,840 and 21,312 shares | 437 | 426 |
| Additional paid-in capital | 139,677 | 140,418 |
| Accumulated deficit | (53,646) | (60,909) |
| Accumulated other comprehensive income | 2,716 | 9,722 |
| Total stockholders' equity | 89,184 | 89,657 |
| | \$ 124,817 | \$ 121,930 |

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

Bentley Pharmaceuticals, Inc. and Subsidiaries

Consolidated Income Statements

| (in thousands, except per share data) | For the Three Months Ended September 30, | | For the Nine Months Ended September 30, | |
|--|---|-----------|--|-----------|
| | 2005 | 2004 | 2005 | 2004 |
| Revenues: | | | | |
| Net product sales | \$ 22,057 | \$ 17,312 | \$ 68,769 | \$ 51,325 |
| Licensing and collaboration revenues | 1,455 | 791 | 3,751 | 2,550 |
| Total revenues | 23,512 | 18,103 | 72,520 | 53,875 |
| Cost of net product sales | 11,104 | 8,662 | 33,923 | 25,383 |
| Gross profit | 12,408 | 9,441 | 38,597 | 28,492 |
| Operating expenses: | | | | |
| Selling and marketing | 3,503 | 3,199 | 12,118 | 10,919 |
| General and administrative | 3,036 | 2,140 | 9,072 | 6,590 |
| Research and development | 1,775 | 1,230 | 4,734 | 3,171 |
| Depreciation and amortization | 416 | 353 | 1,359 | 1,038 |
| Total operating expenses | 8,730 | 6,922 | 27,283 | 21,718 |
| Income from operations | 3,678 | 2,519 | 11,314 | 6,774 |
| Other income (expenses): | | | | |
| Interest income | 238 | 157 | 610 | 399 |
| Interest expense | (53) | (49) | (163) | (160) |
| Other, net | (1) | 130 | 23 | 1,405 |
| Income before income taxes | 3,862 | 2,757 | 11,784 | 8,418 |
| Provision for income taxes | 1,377 | 1,344 | 4,521 | 4,706 |
| Net income | \$ 2,485 | \$ 1,413 | \$ 7,263 | \$ 3,712 |
| Net income per common share: | | | | |
| Basic | \$ 0.11 | \$ 0.07 | \$ 0.34 | \$ 0.18 |
| Diluted | \$ 0.11 | \$ 0.06 | \$ 0.32 | \$ 0.16 |
| Weighted average common shares outstanding: | | | | |
| Basic | 21,652 | 21,049 | 21,455 | 20,764 |
| Diluted | 22,970 | 22,746 | 22,700 | 22,772 |

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) | Shares | \$.02 Par Value Common Stock Amount | Additional Paid-In Capital | Accumulated Deficit | Accumulated Other Comprehensive Income (Loss) | Total |
|--|--------|---|----------------------------------|------------------------|--|-----------|
| Balance at December 31, 2004 | 21,312 | \$ 426 | \$ 140,418 | \$ (60,909) | \$ 9,722 | \$ 89,657 |
| Comprehensive income (loss): | | | | | | |
| Net income | | | | 7,263 | | 7,263 |
| Other comprehensive loss: | | | | | | |
| Foreign currency translation adjustment | | | | | (7,006) | (7,006) |
| Comprehensive income | | | | | \$ | 257 |
| Exercise of stock options | 876 | 18 | 3,182 | | | 3,200 |
| Purchase of treasury shares | (364) | (7) | (4,102) | | | (4,109) |
| Equity-based compensation | 16 | | 179 | | | 179 |
| Balance at September 30, 2005 | 21,840 | \$ 437 | \$ 139,677 | \$ (53,646) | \$ 2,716 | \$ 89,184 |

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, | |
|---|--|-----------|
| | 2005 | 2004 |
| Cash flows from operating activities: | | |
| Net income | \$ 7,263 | \$ 3,712 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | |
| Depreciation and amortization | 3,872 | 2,748 |
| Equity-based compensation expense | 179 | 167 |
| Loss on disposal of assets | 190 | |
| Other non-cash items | 32 | (80) |
| (Increase) decrease in assets and increase (decrease) in liabilities: | | |
| Receivables | (2,175) | (8,272) |
| Inventories | (4,193) | (1,823) |
| Deferred income taxes | (192) | |
| Prepaid expenses and other current assets | (357) | (607) |
| Other assets | (564) | (1) |
| Accounts payable and accrued expenses | 4,423 | 3,797 |
| Deferred income | 1,880 | 1,450 |
| Other liabilities | (14) | (279) |
| Net cash provided by operating activities | 10,344 | 812 |
| Cash flows from investing activities: | | |
| Additions to fixed assets | (6,673) | (6,217) |
| Additions to drug licenses and related costs | (1,477) | (849) |
| Proceeds from maturity of investments | 158 | 149,100 |
| Purchase of investments | (158) | (148,230) |
| Purchase of API manufacturing assets | | (3,309) |
| Net cash used in investing activities | (8,150) | (9,505) |

(Continued on following page)

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

| (in thousands) | For the Nine Months Ended September 30, | |
|--|--|-----------|
| | 2005 | 2004 |
| Cash flows from financing activities: | | |
| Proceeds from the exercise of stock options/warrants | \$ 1,800 | \$ 3,061 |
| Remittance of employee tax liabilities in exchange for common stock tendered to the Company | (1,082) | |
| Purchases of treasury stock | (305) | |
| Proceeds from borrowings | 1,338 | 3,729 |
| Repayment of borrowings | (1,684) | (3,728) |
| Net cash provided by financing activities | 67 | 3,062 |
| Effect of exchange rate changes on cash | (678) | 1 |
| Net increase (decrease) in cash and cash equivalents | 1,583 | (5,630) |
| Cash and cash equivalents at beginning of period | 34,230 | 39,393 |
| Cash and cash equivalents at end of period | \$ 35,813 | \$ 33,763 |
| Supplemental Disclosures of Cash Flow Information | | |
| The Company paid cash during the period for: | | |
| Interest | \$ 153 | \$ 270 |
| Foreign income taxes | \$ 3,209 | \$ 3,711 |
| Supplemental Disclosures of Non-Cash Financing and Investing Activities | | |
| The Company has issued Common Stock as equity-based compensation in lieu of cash during the period as follows: | | |
| Shares | 16 | 12 |
| Amount | \$ 161 | \$ 151 |
| Amounts included in accounts payable at end of period for fixed asset and drug license purchases | \$ 1,836 | \$ 1,951 |

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 individually and collectively as Bentley Pharmaceuticals, Bentley, or the Company), headquartered in the U.S., is an international specialty pharmaceutical company, incorporated in the State of Delaware, focused on:

development, licensing and sales of generic and branded pharmaceutical products and active pharmaceutical ingredients (API) and the manufacturing of pharmaceuticals for others; and

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

Bentley's pharmaceutical product sales and licensing activities are based primarily in Spain, where it has a significant commercial presence and manufactures and markets approximately 35 products through three wholly-owned Spanish subsidiaries; Laboratorios Belmac, Laboratorios Davur and Laboratorios Rimafar. Bentley's products include approximately 135 product formulations of various dosages and strengths in four primary therapeutic areas: cardiovascular, gastrointestinal, neurological and infectious diseases. The Company continually adds to its product portfolio in response to increasing market demand for generic and branded therapeutic agents and, when appropriate, divests portfolio products considered to be redundant or that have become non-strategic. Although most of the Company's sales of these products are currently in the Spanish market, it has recently focused on increasing sales in other European countries and other geographic regions through strategic alliances with companies in these territories. In April 2004, the Company purchased a manufacturing facility located in Zaragoza, Spain that specializes in the manufacture of active pharmaceutical ingredients. The facility has been approved by the U.S. Food and Drug Administration for the manufacture of one ingredient for marketing and sale in the U.S. The Company manufactures and markets active pharmaceutical ingredients through its subsidiary, Bentley API.

The Company has U.S. and international patents and other proprietary rights to technologies that facilitate the absorption of drugs. Bentley is developing products that incorporate its drug delivery technologies and has licensed applications of its proprietary CPE-215® drug delivery technology to Auxilium Pharmaceuticals, Inc., which launched Testim® in the U.S. market, in February 2003. Testim, which incorporates Bentley's CPE-215 drug delivery technology, is a gel indicated for low testosterone levels. Bentley continues to seek other pharmaceutical and biotechnology companies to form additional strategic alliances to facilitate the development and commercialization of other products using its drug delivery technologies, including product formulations that deliver insulin to diabetic patients intranasally and that treat nail fungus infections topically.

Basis of Condensed Consolidated Financial Statements

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The condensed consolidated financial statements of Bentley Pharmaceuticals as of September 30, 2005 and for the three and nine months ended September 30, 2005 and 2004, included herein, have been prepared by the Company, 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 the Company's consolidated financial statements for the year ended December 31, 2004. These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto, including the summary of significant accounting policies, included in Bentley's Annual Report on Form 10-K for the year ended December 31, 2004.

In the opinion of management, the accompanying unaudited condensed consolidated financial statements as of September 30, 2005 and for the three and nine months ended September 30, 2005 and 2004 are presented on a basis consistent with the audited consolidated financial statements for the year ended December 31, 2004 and contain all adjustments, consisting only of normal recurring adjustments, necessary to present fairly Bentley's financial position as of September 30, 2005 and the results of its operations for the three and nine months ended September 30, 2005 and 2004 and cash flows for the nine months ended September 30, 2005 and 2004. The results of operations for the three and nine months ended September 30, 2005 should not necessarily be considered indicative of the results to be expected for the full year ending December 31, 2005 or any other interim period.

Cash and cash equivalents

The Company considers all highly liquid investments with remaining maturities of three months or less when purchased to be cash equivalents for purposes of classification in the Consolidated Balance Sheets and the Consolidated Statements of Cash Flows. Investments in securities that do not meet the definition of cash equivalents are classified as *marketable securities* in the Consolidated Balance Sheets.

Included in *cash and cash equivalents* at September 30, 2005 and December 31, 2004 are approximately \$11,062,000 and \$3,684,000, respectively, of short-term investments considered to be cash equivalents, as the original maturity dates of such investments were three months or less when purchased.

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 \$469,000 as of September 30, 2005, compared to \$528,000 as of December 31, 2004. 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)*.

Receivables

Receivables consist of the following (in thousands):

| | September 30, 2005 | December 31, 2004 |
|---|--------------------|-------------------|
| Trade receivables (of which \$2,129 and \$2,754, respectively, collateralize short-term borrowings with Spanish financial institutions) | \$ 22,675 | \$ 23,586 |
| VAT receivable | 1,457 | 2,428 |
| Royalties receivable | 2,944 | 1,882 |
| Other | 230 | 339 |
| | 27,306 | 28,235 |
| Less allowance for doubtful accounts | (450) | (375) |
| | \$ 26,856 | \$ 27,860 |

Inventories

Inventories are stated at the lower of cost or market, cost being determined on the first in, first out (FIFO) method. Reserves for slow moving and obsolete inventories are provided based on historical experience and current product demand.

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Inventory balances are comprised of the following (in thousands):

| | September 30, 2005 | | December 31, 2004 |
|--|--------------------|----|-------------------|
| Raw materials | \$ 8,162 | \$ | 5,953 |
| Finished goods | 4,662 | | 4,380 |
| | 12,824 | | 10,333 |
| Less allowance for slow moving inventory | (66) | | (75) |
| | \$ 12,758 | \$ | 10,258 |

Fixed assets

Fixed assets consist of the following (in thousands):

| | September 30, 2005 | | December 31, 2004 |
|-------------------------------|--------------------|----|-------------------|
| Land | \$ 2,701 | \$ | 2,573 |
| Buildings and improvements | 16,068 | | 16,076 |
| Equipment | 19,283 | | 18,448 |
| Furniture and fixtures | 1,978 | | 1,850 |
| Other | 146 | | 102 |
| | 40,176 | | 39,049 |
| Less accumulated depreciation | (9,356) | | (8,200) |
| | \$ 30,820 | \$ | 30,849 |

In order to support the Company's growth in Europe, management is expanding the capacity of its manufacturing facilities through a series of capital investments. The Company invested approximately \$6,673,000 in capital additions, including \$367,000 for the purchase of land, during the nine months ended September 30, 2005. A decrease in the value of the Euro compared to the U.S. Dollar from December 31, 2004 to September 30, 2005 has reduced the value of net fixed assets by approximately \$3,807,000.

Depreciation expense of approximately \$235,000 and \$220,000 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, 2005 and 2004, respectively. Depreciation totaling approximately \$2,513,000 and \$1,710,000 has been included in *cost of net product sales* during the nine months ended September 30, 2005 and 2004, respectively.

Stockholders' equity

A substantial amount of the Company's business is conducted in Europe and is therefore influenced by fluctuations in the U.S. Dollar's value in relation to other currencies, specifically the Euro. The exchange rates at September 30, 2005 and December 31, 2004 were .83 Euros and .73 Euros per U.S. Dollar, respectively. The weighted average exchange rate for the three months ended September 30, 2005 and 2004 was .82 Euros per U.S. Dollar. The weighted average exchange rates for the nine months ended September 30, 2005 and 2004 were .79 Euros and .82 Euros per U.S. Dollar, respectively. The net effect of foreign currency translation on the Company's Condensed Consolidated Financial Statements for the nine months ended September 30, 2005 was a net decrease of \$7,006,000 and the cumulative historical effect as of September 30, 2005 was an increase of \$2,716,000, as reflected in the Consolidated Balance Sheets as *accumulated other comprehensive*

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income. The carrying value of assets and liabilities can be materially affected by foreign currency translation, as can the translated amounts of revenues and expenses. Nonetheless, management does not plan to modify its business practices.

During the nine months ended September 30, 2005, the Company issued approximately 16,000 shares of Common Stock as equity-based compensation to the Company-sponsored 401(k) retirement savings plan. Certain employees and an independent consultant were granted stock options to purchase an aggregate of 819,500 shares of Common Stock in the nine months ended September 30, 2005 at exercise prices ranging from \$7.39 to \$12.01 per share, which resulted in a weighted average exercise price of \$8.93 per share.

Supplemental disclosures related to Consolidated Statements of Cash Flows

During the nine months ended September 30, 2005, the Chief Executive Officer (CEO), the Chief Financial Officer (CFO) and the Chief Medical Officer (CMO) of the Company exercised stock options to purchase an aggregate of 801,300 shares of the Company's Common Stock. In satisfaction of the option exercise prices, the Company received approximately \$1,218,000 in cash proceeds and an aggregate of approximately 127,000 shares of previously acquired Bentley Common Stock, with a fair market value of approximately \$1,400,000. The Company also received a total of approximately 147,800 shares of Common Stock, with a fair market value of approximately \$1,668,000, from the three employees in order to satisfy minimum federal and statutory tax withholding requirements. Approximately \$1,082,000 of the withholding taxes on these option exercises were remitted by the Company during the nine months ended September 30, 2005 and the remaining \$586,000 were remitted subsequent to September 30, 2005. Additionally, the Company repurchased approximately 90,600 shares of Common Stock with a fair market value of approximately \$1,041,000 from the CEO and CMO, of which approximately \$736,000, representing the repurchase of approximately 62,800 shares, was recorded as a related party payable to the CEO at September 30, 2005 and subsequently paid. The shares of Common Stock acquired by the Company in connection with these stock option exercises were recorded at fair market value and are held by the Company as treasury shares.

Revenue recognition

Revenue on product sales is recognized when persuasive evidence of an arrangement exists, the price is fixed and final, delivery has occurred and there is a reasonable assurance of collection of the sales proceeds. The Company generally obtains purchase authorizations from its customers for a specified amount of product at a specified price and considers delivery to have occurred when the customer takes possession of the product. The Company provides its customers with a limited right of return. Revenue is recognized upon delivery and a reserve for sales returns is recorded when considered appropriate. The Company has demonstrated the ability to make reasonable and reliable estimates of product returns in accordance with Statement of Financial Accounting Standards (SFAS) No. 48, *Revenue Recognition When Right of Return Exists*, and of allowances for doubtful accounts based on significant historical experience.

Revenue from service, research and development, and licensing agreements is recognized when the service procedures have been completed or as revenue recognition criteria have been met for each separate unit of accounting as defined in Emerging Issues Task Force (EITF) Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*. The Company has deferred the recognition of approximately \$2,707,000 and \$2,147,000 of licensing revenues as of September 30, 2005 and December 31, 2004, respectively, for which the earnings process has not been completed.

Royalty revenues on Testim product sales are currently recognized based on an estimate of Auxilium's sell-through of the Testim product based on prescriptions dispensed. For the three and nine months ended September 30, 2005, the Company recognized royalty revenues of \$1,391,000 and \$3,512,000, respectively, compared to approximately \$800,000 and \$2,000,000 in the three and nine months ended September 30, 2004, respectively. Under SFAS No. 48, the Company cannot recognize all of the royalty revenues earned on product shipments of Testim until product returns related to those shipments can be reasonably estimated. 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 current *deferred income* in the Consolidated Balance Sheets. Once returns can be reasonably estimated, the Company expects to record a one-time increase in *licensing and collaboration revenues* related to the recognition of previously deferred royalty revenues. As of September 30, 2005 and December 31, 2004, deferred income from Testim royalties totaled \$1,635,000 and \$1,233,000, respectively.

Provision for income taxes

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Spanish tax authorities completed a tax review of the Company's Spanish subsidiary, Laboratorios Belmac S.A., during the second quarter of 2004 for the tax years 1998, 1999 and 2000. As a result of this audit, the subsidiary was assessed an additional tax liability of approximately \$604,000, which was recorded as a component of *provision for income taxes* for the nine months ended September 30, 2004, and approximately \$193,000 for related interest and penalties, which were recorded as components of *other income (expenses)*, in the consolidated income statements for the nine months ended September 30, 2004.

As a result of reporting taxable income in Spain, the Company recorded a provision for foreign income taxes totaling \$1,377,000 and \$1,344,000 for the three months ended September 30, 2005 and 2004, respectively. The Company recorded provisions for foreign income taxes totaling \$4,521,000 and \$4,706,000 (which amount includes the \$604,000 tax audit settlement) for the nine months ended September 30, 2005 and 2004, respectively. The effective tax rate in Spain for the nine months ended September 30, 2005 and 2004 is 33% and 44% (38% when excluding the \$604,000 tax audit settlement), respectively.

As future domestic operating profits cannot be reasonably assured, no tax benefit has been recorded for U.S. losses, which totaled \$251,000 and \$896,000 for the three months ended September 30, 2005 and 2004, respectively, and \$1,819,000 and \$2,377,000 for the nine months ended September 30, 2005 and 2004, respectively. Accordingly, the Company has established a valuation allowance equal to the full amount of the U.S. net deferred tax asset. The 2004 provision for income taxes differs 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 the Company determine that it is more likely than not that it will realize certain of its deferred tax assets for which it had previously provided a valuation allowance, an adjustment would be required to reduce the existing valuation allowance.

Basic and diluted net income per common share

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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 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, 2005 and 2004.

The following is a reconciliation between basic and diluted net income per common share for the three and nine months ended September 30, 2005 and 2004. Dilutive securities issuable for the three and nine months ended September 30, 2005 include approximately 1,318,000 and 1,245,000 dilutive incremental shares, respectively, issuable as a result of various stock options that are outstanding. Dilutive securities issuable for the three and nine months ended September 30, 2004 included approximately 1,697,000 and 2,008,000 dilutive incremental shares, respectively, issuable as a result of various stock options and warrants that were outstanding.

For the Three Months Ended September 30, 2005 (in thousands, except per share data):

| | Basic EPS | Effect of Dilutive Securities | Diluted EPS |
|--|-----------|-------------------------------|-------------|
| Net Income | \$ 2,485 | \$ | \$ 2,485 |
| Weighted Average Common Shares Outstanding | 21,652 | 1,318 | 22,970 |
| Net Income Per Common Share | \$ 0.11 | \$ | \$ 0.11 |

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For the Three Months Ended September 30, 2004 (in thousands, except per share data):

| | 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 Nine Months Ended September 30, 2005 (in thousands, except per share data):

| | Basic EPS | Effect of Dilutive Securities | Diluted EPS |
|--|-----------|----------------------------------|-------------|
| Net Income | \$ 7,263 | \$ | \$ 7,263 |
| Weighted Average Common Shares Outstanding | 21,455 | 1,245 | 22,700 |
| Net Income Per Common Share | \$ 0.34 | \$ (0.02) | \$ 0.32 |

For the Nine Months Ended September 30, 2004 (in thousands, except per share data):

| | 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 |

Excluded from the diluted earnings per share presentation, because their exercise prices were greater than the average fair market value of the Common Stock in the respective periods, were options to purchase an aggregate of approximately 702,000 and 1,135,000 shares of Common Stock, for the three and nine months ended September 30, 2005, respectively, and options 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.

Equity-based compensation

The Company has equity-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, 2004. The Company currently accounts 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. However, the Company is required to adopt SFAS No. 123 (Revised), *Share-Based Payment* as of January 1, 2006, which will change the method the Company uses to account for its equity-based compensation. Stock 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, the Company also sponsors a 401(k) Plan for eligible employees and matches eligible contributions with shares of the Company's Common Stock.

As previously disclosed, the Company acquired shares of Common Stock from certain employees in connection with stock option exercises during the nine months ended September 30, 2005. In accordance with APB Opinion No. 25 and FASB Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation*, no compensation expense has been recorded as a result of the stock option exercises or shares acquired by the Company. Although the ultimate disposition of the treasury shares has not yet been determined, the Company has elected to follow the accounting treatment prescribed for the retirement of stock, which has resulted in a \$4,109,000 reduction of *stockholders' equity* in the Consolidated Balance Sheet as of September 30, 2005, representing the fair market value of the 364,000 shares of Common Stock acquired.

General and administrative expenses for the three and nine months ended September 30, 2005 include approximately \$30,000 and \$74,000, respectively, of non-cash equity-based compensation. General and administrative expenses for the three and nine months ended September 30, 2004 include approximately \$14,000 and \$61,000, respectively, of non-cash equity-based compensation. Research and development expenses for the three and nine months ended September 30, 2005 include approximately \$35,000 and \$105,000, respectively, of non-cash equity-based compensation. Research and development expenses for the three and nine months ended September 30, 2004 include approximately \$24,000 and \$106,000, respectively, of non-cash equity-based compensation. Included in equity based compensation of \$179,000 in the nine months ended September 30, 2005 is approximately \$161,000, representing approximately 16,000 shares of Common Stock issued to the Company-sponsored 401(k) retirement savings plan.

The following table illustrates the effect on net income per share if the Company had applied the fair value recognition provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, to equity-based employee compensation (in thousands, except per share data):

| | For the Three Months Ended September 30, | | For the Nine Months Ended September 30, | |
|--|---|----------|--|----------|
| | 2005 | 2004 | 2005 | 2004 |
| Net income, as reported | \$ 2,485 | \$ 1,413 | \$ 7,263 | \$ 3,712 |
| Add: Equity-based employee compensation expense included in reported net income | 65 | 38 | 179 | 167 |
| Deduct: Total equity-based employee compensation expense determined under fair value method for all awards | (1,232) | (467) | (2,565) | (2,168) |
| Pro forma net income | \$ 1,318 | \$ 984 | \$ 4,877 | \$ 1,711 |
| Net income per common share: | | | | |
| Basic - as reported | \$ 0.11 | \$ 0.07 | \$ 0.34 | \$ 0.18 |
| Basic - pro forma | \$ 0.06 | \$ 0.05 | \$ 0.23 | \$ 0.08 |
| Diluted - as reported | \$ 0.11 | \$ 0.06 | \$ 0.32 | \$ 0.16 |
| Diluted - pro forma | \$ 0.06 | \$ 0.04 | \$ 0.22 | \$ 0.08 |

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, | |
|-------------------------------|---|---------|--|---------|
| | 2005 | 2004 | 2005 | 2004 |
| Risk-free interest rate | 4.09% | 2.59% | 3.97% | 2.96% |
| Dividend yield | 0.00% | 0.00% | 0.00% | 0.00% |
| Expected life | 5 years | 5 years | 5 years | 5 years |
| Volatility | 46.28% | 48.14% | 45.44% | 49.25% |
| Fair value of options granted | \$5.02 | \$5.62 | \$3.87 | \$6.02 |

Reclassifications

Certain prior period depreciation amounts have been reclassified from *operating expenses* to *cost of net product sales* to conform with the current period's presentation. Such reclassifications are not material to the Condensed Consolidated Financial Statements.

New Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 123 (Revised), *Share-Based Payment*. This Statement is a revision of SFAS No. 123, *Accounting for Stock-Based Compensation*, and will supersede APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and its related implementation guidance. SFAS No. 123 (Revised) focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions. The Statement will require entities to recognize stock compensation expense for awards of equity instruments to employees based on the grant-date fair value of those awards (with limited exceptions). On April 14, 2005, the Securities and Exchange Commission delayed the effective date of SFAS No. 123 (Revised) to the beginning of the first fiscal year after September 15, 2005. As a result, the Company anticipates adopting SFAS No. 123 (Revised) on January 1, 2006. Management is evaluating the two methods of adoption allowed by SFAS No. 123 (Revised), the modified-prospective transition method and the modified-retrospective transition method, and the related impact on its Consolidated Financial Statements. Adoption of this Statement will have a significant impact on the Company's results of operations, the impact of which cannot be estimated at this time, although it is not expected to have any material impact on the Company's overall financial position or cash flows.

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

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You should read the following discussion and analysis together with all financial and non-financial information appearing elsewhere in this report and with our consolidated financial statements and related notes included in our Annual Report on Form 10-K for the year ended December 31, 2004, which has been previously filed with the SEC. In addition to historical information, the following discussion and other parts of this report contain forward-looking information that involves risks and uncertainties. Our actual results could differ materially from those anticipated by such forward-looking information due to competitive factors and other risks discussed below under the caption **Important Factors That May Affect Future Results**.

Overview

We are a specialty pharmaceutical company focused on:

development, licensing and sales of generic and branded pharmaceutical products and active pharmaceutical ingredients and the manufacturing of pharmaceuticals for ourselves and others in Spain, other parts of Europe and international markets, including the U.S. market; and

research, development and licensing/commercialization of advanced proprietary drug delivery technologies for new and existing pharmaceutical products.

Branded and Generic Pharmaceuticals

Our pharmaceutical product sales activities are based in Spain, where we have a significant commercial presence and we manufacture and market approximately 35 products. Our products include approximately 135 product formulations of various dosages and strengths in four primary therapeutic areas: cardiovascular, gastrointestinal, neurological and infectious diseases. In 2004 approximately 30% of our product revenues were derived from two of our product lines. We market our branded and generic products to physicians and pharmacists through our three separate sales and marketing organizations based in Spain: Laboratorios Belmac, Laboratorios Davur and Laboratorios Rimafar. As prices for prescription pharmaceuticals have been lowered in Spain by action of the Ministry of Health, which has authority to approve pharmaceutical prices, we are working to improve the efficiency of our manufacturing operations to reduce our costs, while also increasing sales. We have recently focused on increasing our sales in other European countries and other geographic regions through strategic alliances with other generic companies and distributors in these territories. We also target markets that offer compatible regulatory approval regimes and attractive product margins.

We also expect to grow our business by acquiring or licensing additional products to sell through our organization and our strategic alliances. We continually acquire rights to new products in response to increasing market demand for generic and branded therapeutic products and, when appropriate, we divest products that we consider to be redundant or that have become non-strategic. For example, in November 2004, we entered into a collaboration agreement with Perrigo Company, the largest U.S. manufacturer of over-the-counter pharmaceutical and nutritional products for the store brand market, to co-develop and market a generic pharmaceutical product in the U.S. and potentially other markets.

We also manufacture pharmaceuticals for other drug companies. In April 2004, we purchased a manufacturing facility located in Spain that specializes in the manufacture of active pharmaceutical ingredients. The facility has been approved by the FDA for the manufacture of one ingredient for marketing and sale in the U.S. We are manufacturing and marketing active pharmaceutical ingredients through our subsidiary, Bentley API. In addition, our Spanish pharmaceutical product manufacturing facility produces pharmaceutical products that are marketed by

other pharmaceutical companies both in Spain and in other international markets.

Proprietary Drug Delivery Technologies and Products

We develop products that incorporate our drug delivery technologies that we have developed in the United States. We have licensed applications of our proprietary CPE-215 drug delivery technology to Auxilium Pharmaceuticals, Inc., which launched Testim, the first product incorporating our CPE-215 drug delivery technology, in the United States in February 2003. Testim is a gel indicated for low testosterone levels. Testim was launched in Germany in January 2005 and in the United Kingdom in April 2005. On April 25, 2005, we announced that we had entered into a license agreement with Dong Sung Pharm. Co. Ltd. for the development of an intranasal spray formulation of insulin for the South Korean market and possibly additional territories. On May 2, 2005 we announced the discovery and synthesis of a thermodynamically stable, biodegradable Nanocaplet™ technology for the delivery of macromolecule therapeutics as a result of a four-year sponsored research collaboration with the University of New Hampshire. We are also 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 formulations to treat nail fungus infections topically.

Effect of Foreign Currency Fluctuations

A substantial amount of our business is conducted in Europe and is therefore influenced by fluctuations in the U.S. Dollar's value in relation to other currencies, specifically the Euro. Foreign currency fluctuations had no material impact on our third quarter results. However an increase in the weighted average value of the Euro over the past year, in relation to the U.S. Dollar had the following impact on our operations for the nine months ended September 30, 2005: (1) total revenues were increased by approximately \$1,975,000, (2) gross profit was increased by approximately \$1,015,000, (3) operating expenses were increased by approximately \$585,000, (4) provision for income taxes was increased by approximately \$130,000, and (5) net income was increased by approximately \$300,000. At the present time, we do not anticipate altering our business plans and practices to compensate for future currency fluctuations.

RESULTS OF OPERATIONS:

Three Months Ended September 30, 2005 versus Three Months Ended September 30, 2004

Revenues

| (in thousands) | For the Three Months Ended September 30, | | | | Change | |
|---|--|------|-----------|------|----------|-----|
| | 2005 | % | 2004 | % | \$ | % |
| <i>Net product sales</i> | \$ 22,057 | 94% | \$ 17,312 | 96% | \$ 4,745 | 27% |
| <i>Licensing and collaboration revenues</i> | 1,455 | 6% | 791 | 4% | 664 | 84% |
| <i>Total revenues</i> | \$ 23,512 | 100% | \$ 18,103 | 100% | \$ 5,409 | 30% |

Total revenues for the three months ended September 30, 2005 increased 30% from the same period in the prior year. Our current period growth was driven primarily by increased sales outside of Spain, strong sales of our top three products (omeprazole, simvastatin and enalapril) and increased royalty revenues from sales of Testim, the first marketed product incorporating our CPE-215 drug delivery technology. Our growing royalty stream from Testim sales contributed approximately \$1,391,000 to our licensing and collaboration revenues in the three months ended September 30, 2005, compared to approximately \$800,000 in the third quarter of the prior year.

Our revenues are generated through our primary sales channels of branded pharmaceuticals, generic pharmaceuticals, sales to licensees and others and licensing and collaboration revenues. The following is a summary of our revenues by sales channel and top-selling product lines:

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For the three months ended September 30, 2005:

(in thousands)

| Product Line | Revenues Within Spain | | | Revenues Outside of Spain | | Total | % of Total Revenues |
|-------------------------------|-----------------------|------------------|-----------------|---------------------------|-----------|---------------|---------------------|
| | Branded Products | Generic Products | Other | | | | |
| Omeprazole | \$ 657 | \$ 3,694 | \$ | \$ | \$ | 4,351 | 19% |
| Simvastatin | 402 | 1,277 | | | | 1,679 | 7% |
| Enalapril | 933 | 407 | | | | 1,340 | 6% |
| Paroxetine | 294 | 765 | | | | 1,059 | 5% |
| Pentoxifylline | | 607 | | | | 607 | 2% |
| All other products | 2,651 | 1,765 | 86 | 424 | | 4,926 | 21% |
| Sales to licensees and others | | | 2,479 | 5,616 | | 8,095 | 34% |
| Licensing and collaborations | | | 58 | 1,397 | | 1,455 | 6% |
| Total Revenues | \$ 4,937 | \$ 8,515 | \$ 2,623 | \$ 7,437 | \$ | 23,512 | 100% |
| % of Q-3 2005 Revenues | 21% | 36% | 11% | 32% | | 100% | |

For the three months ended September 30, 2004:

(in thousands)

| Product Line | Revenues Within Spain | | | Revenues Outside of Spain | | Total | % of Total Revenues |
|-------------------------------|-----------------------|------------------|-----------------|---------------------------|-----------|---------------|---------------------|
| | Branded Products | Generic Products | Other | | | | |
| Omeprazole | \$ 742 | \$ 3,296 | \$ | \$ | \$ | 4,038 | 22% |
| Simvastatin | 374 | 929 | | | | 1,303 | 7% |
| Enalapril | 725 | 348 | | | | 1,073 | 6% |
| Paroxetine | 225 | 698 | | | | 923 | 5% |
| Pentoxifylline | | 668 | | | | 668 | 4% |
| All other products | 2,216 | 1,144 | 430 | 379 | | 4,169 | 23% |
| Sales to licensees and others | | | 3,077 | 2,061 | | 5,138 | 29% |
| Licensing and collaborations | | | | 791 | | 791 | 4% |
| Total Revenues | \$ 4,282 | \$ 7,083 | \$ 3,507 | \$ 3,231 | \$ | 18,103 | 100% |
| % of Q-3 2004 Revenues | 24% | 39% | 19% | 18% | | 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 several years has created an opportunity for our Spanish operations to expand beyond the borders of Spain into other European countries and countries outside of Europe. The increase in third quarter 2005 product sales is due primarily to an increase in sales to licensees and others totaling \$2,957,000 and an increase in sales of our three top selling product lines (omeprazole, simvastatin and enalapril) totaling \$956,000.

Branded Pharmaceutical Products

(in thousands)

| 2005 | For the Three Months Ended September 30, | | 2004 | % | \$ | Change | % |
|------|--|--|------|---|----|--------|---|
| | | | | | | | |

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| <i>Branded Product Sales:</i> | | | | | | | |
|-----------------------------------|----|-------|------|----|-------|------|------------|
| <i>Enalapril</i> | \$ | 933 | 19% | \$ | 725 | 17% | \$ 208 29% |
| <i>Omeprazole</i> | | 657 | 13% | | 742 | 17% | (85) -11% |
| <i>Codeisan</i> | | 534 | 11% | | 607 | 14% | (73) -12% |
| <i>Lansoprazole</i> | | 427 | 9% | | | 0% | 427 * |
| <i>Simvastatin</i> | | 402 | 8% | | 374 | 9% | 28 7% |
| <i>All other branded products</i> | | 1,984 | 40% | | 1,834 | 43% | 150 8% |
| <i>Total branded sales</i> | \$ | 4,937 | 100% | \$ | 4,282 | 100% | \$ 655 15% |

* Not meaningful

Sales of our branded pharmaceutical products increased by 15% during the three months ended September 30, 2005 compared to the three months ended September 30, 2004. Sales of lansoprazole, which was launched in December 2004, accounted for 9% of our branded pharmaceutical revenues during the three months ended September 30, 2005 and 65% of the increase in our branded sales. We experienced decreased sales of our branded omeprazole in favor of our generic formulations and decreased sales of Codeisan due to seasonality; however, our branded enalapril and omeprazole together accounted for 32% of our branded product sales in the three months ended September 30, 2005. While we expect to continue to develop, acquire, launch and support new and existing branded products, our focus on generics and sales outside of Spain are expected to increase those revenues at a significantly higher pace than that of our branded products.

Generic Pharmaceutical Products

| (in thousands) | For the Three Months Ended September 30, | | | | Change | |
|-----------------------------------|--|------|----------|------|----------|-----|
| | 2005 | % | 2004 | % | \$ | % |
| <i>Generic Product Sales:</i> | | | | | | |
| <i>Omeprazole</i> | \$ 3,694 | 43% | \$ 3,296 | 47% | \$ 398 | 12% |
| <i>Simvastatin</i> | 1,277 | 15% | 929 | 13% | 348 | 38% |
| <i>Paroxetine</i> | 765 | 9% | 698 | 10% | 67 | 10% |
| <i>Pentoxifylline</i> | 607 | 7% | 668 | 9% | (61) | -9% |
| <i>Trimetazidine</i> | 487 | 6% | 498 | 7% | (11) | -2% |
| <i>All other generic products</i> | 1,685 | 20% | 994 | 14% | 691 | 70% |
| <i>Total generic sales</i> | \$ 8,515 | 100% | \$ 7,083 | 100% | \$ 1,432 | 20% |

Sales of our generic pharmaceutical products increased by 20% during the three months ended September 30, 2005, compared to the three months ended September 30, 2004. Strong sales of our generic omeprazole and simvastatin accounted for approximately 52% of our increase in generic pharmaceutical sales in the third quarter of 2005 over the 2004 third quarter. Also contributing to the increase in generic pharmaceuticals sales were strong sales of our generic formulations of enalapril, lansoprazole, and ibuprofen (included in *All other generic products* above) which accounted for 24% of the increase. 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.

The Spanish Ministry of Health is evaluating a plan for nationwide expansion of a regional practice of filling prescriptions with one of the lowest-priced generics then available if a prescription does not specify a brand name or laboratory name. This proposal, if enacted, will not require government-mandated price reductions as in the past. We constantly monitor the market, prices and our competitors' activities, and occasionally adjust prices for competitive purposes. We do not anticipate that this proposal will have a material impact on our 2005 revenues and profits.

Sales to Licensees and Others

| (in thousands) | For the Three Months Ended September 30, | | Change | |
|--------------------------------------|--|----------|----------|-----|
| | 2005 | 2004 | \$ | % |
| <i>Sales to licensees and others</i> | \$ 8,095 | \$ 5,138 | \$ 2,957 | 58% |

In addition to manufacturing and selling our own branded and generic products, we license the right to market products to others within and outside of Spain. These license agreements are usually accompanied by long-term exclusive supply agreements, whereby our licensees purchase

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the licensed products from our manufacturing facility (which are recorded as *net product sales* in the Consolidated Income Statements). Our Spanish subsidiaries have executed a total of 141 license agreements. While 60 of these agreements

are pending regulatory approvals (two within Spain and 58 outside of Spain), 81 of these agreements (17 within Spain and 64 outside of Spain) cover actively marketed products that are generating revenues. Additionally, we have 16 contract manufacturing agreements in effect in Spain and 6 contract manufacturing agreements in effect for international customers. Our licensees market these products under their own names and with their own labeling. Many of the products we manufacture for others use the same active ingredients that are used in our own marketed products. Sales to licensees and others in the three months ended September 30, 2005 increased 58% when compared to the same period of the prior year.

Licensing and Collaboration Revenues. Licensing and collaboration revenues increased by 84% and accounted for 6% of total revenues for the three month period ended September 30, 2005 compared to 4% for the three month period ended September 30, 2004. These revenues include royalties of approximately \$1,391,000 in the three months ended September 30, 2005 (compared to approximately \$800,000 in the third quarter of the prior year) from the commercialization and continuing sales of Testim.

Gross Profit. Gross profit increased by approximately \$2,967,000, or 31%, in the three months ended September 30, 2005, when compared to the three months ended September 30, 2004. Gross margins on net product sales were approximately 50% in the three months ended September 30, 2005 and 2004, respectively. Increased margins resulting from economies of scale have been partially offset by the following in the three months ended September 30, 2005: (1) increased sales of lower margin products including our generic omeprazole and simvastatin, (2) losses generated by our API manufacturing facility, which is being expanded to support vertical integration, and (3) increased depreciation charges as a result of our aggressive capital investment campaign to expand our manufacturing capacity. Additionally, a charge of approximately \$290,000 has been accrued as a result of a pharmaceutical tax that was enacted in the first quarter of 2005 and included in cost of sales in the three months ended September 30, 2005.

Selling and Marketing Expenses

| (in thousands) | For the Three Months Ended September 30, | | Change | |
|-----------------------|--|----------|--------|-----|
| | 2005 | 2004 | \$ | % |
| Selling and marketing | \$ 3,503 | \$ 3,199 | \$ 304 | 10% |

Selling and marketing expenses for the three months ended September 30, 2005 increased by \$304,000 or 10% from the same period in the prior year. Increased sales force costs, primarily sales commissions resulting from our growing product sales, account for the increase in selling and marketing expenses. As a percentage of net product sales, selling and marketing expenses decreased from 18% in the three months ended September 30, 2004, to 16% in the three months ended September 30, 2005.

General and Administrative Expenses

| (in thousands) | For the Three Months Ended September 30, | | Change | |
|----------------|--|------|--------|---|
| | 2005 | 2004 | \$ | % |

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| | | | | | | | |
|-----------------------------------|----|-------|----|-------|----|-----|-----|
| <i>General and administrative</i> | \$ | 3,036 | \$ | 2,140 | \$ | 896 | 42% |
|-----------------------------------|----|-------|----|-------|----|-----|-----|

General and administrative expenses for the three months ended September 30, 2005 increased 42% over the same period in the prior year. The \$896,000 increase was the result of increased general and administrative activities required to support our continued growth. These expenditures include increased costs for: (1) Directors and Officers insurance and medical insurance, (2) additional employees, and (3) other expenses required to support the Company's growth. General and administrative expenses as a percent of total revenues increased to almost 13% for the three months ended September 30, 2005, compared to approximately 12% of total revenues in the three months ended September 30, 2004. We expect that our general and administrative expenses will continue to increase as we grow our business.

Research and Development Expenses

| (in thousands) | For the Three Months Ended September 30, | | Change | |
|--------------------------|--|----------|--------|-----|
| | 2005 | 2004 | \$ | % |
| Research and development | \$ 1,775 | \$ 1,230 | \$ 545 | 44% |

Research and development expenses have increased 44% in the three months ended September 30, 2005, to \$1,775,000, when compared to the third quarter of 2004. The increase is directly attributable to the advancement of our research and development programs. 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. In April 2005 we announced that we completed the data analysis stage of our Phase II study for the intranasal delivery of insulin, which we had concluded in December 2004. We reported the results of that trial in an abstract titled *Intranasal Insulin Administration in Type I Diabetic Patients Utilizing CPE-215 Technology* at the American Diabetes Association 65th Scientific Sessions, June 10-14, 2005, in San Diego, California. Additionally, we are continuing our 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 entered into a collaboration agreement with Perrigo Company to co-develop and market a generic pharmaceutical product 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 expect to incur increased costs for product formulation and testing efforts. We also expect to incur costs associated with the acquisition and/or development of new or improved drug delivery technologies as evidenced by our May 2, 2005 announcement of the discovery and synthesis of a thermodynamically stable, biodegradable Nanocaplet™ technology for the delivery of macromolecule therapeutics. The expenditures in research and development reflect our focus on projects that are necessary for expansion of our portfolio of marketed products and clinical trials involving our drug delivery technologies. Although some of our cost estimates are preliminary, and the specific timing is subject to change, we project that our research and development expenses in 2005 could be approximately \$2,500,000 higher than in 2004.

Provision for Income Taxes

| (in thousands) | For the Three Months Ended September 30, 2005 | | |
|--------------------------------------|---|----------|--------------|
| | Spain | U.S. | Consolidated |
| Income (loss) before income taxes | \$ 4,113 | \$ (251) | \$ 3,862 |
| Provision (benefit) for income taxes | 1,377 | (101) | 1,276 |
| Valuation allowance | | 101 | 101 |
| Net provision for income taxes | 1,377 | | 1,377 |
| Net income (loss) | \$ 2,736 | \$ (251) | \$ 2,485 |
| Effective tax rate | 33% | 0% | 36% |

As a result of reporting taxable income for our subsidiaries in Spain, we recorded a provision for foreign income taxes totaling \$1,377,000 and \$1,344,000 for the three months ended September 30, 2005 and 2004, respectively. The effective tax rate in Spain for the three months ended September 30, 2005 is 33% compared to 37% in the prior year third quarter.

We generated additional U.S. federal net operating loss carry-forwards in the three months ended September 30, 2005 and 2004 as a result of U.S. pretax losses of \$251,000 and \$896,000, respectively. Although we expect to achieve profitable U.S. operations in the future, any future domestic operating profits cannot be reasonably assured; consequently, 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.

Net Income

| (in thousands, except per share data) | For the Three Months Ended September 30, | | Change | |
|--|---|----------|----------|-----|
| | 2005 | 2004 | \$ | % |
| <i>Net income</i> | \$ 2,485 | \$ 1,413 | \$ 1,072 | 76% |
| <i>Net income per common share:</i> | | | | |
| <i>Basic</i> | \$ 0.11 | \$ 0.07 | \$ 0.04 | 57% |
| <i>Diluted</i> | \$ 0.11 | \$ 0.06 | \$ 0.05 | 83% |
| <i>Weighted average common shares outstanding:</i> | | | | |
| <i>Basic</i> | 21,652 | 21,049 | 603 | 3% |
| <i>Diluted</i> | 22,970 | 22,746 | 224 | 1% |

We reported income from operations of \$3,678,000 in the three months ended September 30, 2005 compared to \$2,519,000 in the three months ended September 30, 2004, which is an increase of 46%. The combination of income from operations of \$3,678,000 and the non-operating items, primarily the provision for income taxes of \$1,377,000, resulted in net income of \$2,485,000, or \$0.11 per basic common share (\$0.11 per diluted common share) on 21,652,000 weighted average basic common shares outstanding (22,970,000 weighted average diluted common shares outstanding) in the three months ended September 30, 2005, compared to 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 same period of the prior year.

Nine Months Ended September 30, 2005 versus Nine Months Ended September 30, 2004Revenues

| (in thousands) | For the Nine Months Ended September 30, | | | | Change | |
|--------------------------------------|---|------|-----------|------|-----------|-----|
| | 2005 | % | 2004 | % | \$ | % |
| Net product sales | \$ 68,769 | 95% | \$ 51,325 | 95% | \$ 17,444 | 34% |
| Licensing and collaboration revenues | 3,751 | 5% | 2,550 | 5% | 1,201 | 47% |
| Total revenues | \$ 72,520 | 100% | \$ 53,875 | 100% | \$ 18,645 | 35% |

Total revenues for the nine months ended September 30, 2005 increased 35% from the same period in the prior year, or 31% when expressed in constant currency. Our current period growth was driven primarily by increased product sales to licensees and others, strong sales of our top three products (omeprazole, simvastatin and enalapril) and increased royalty revenues from sales of Testim. An increase in the weighted average value of the Euro over the past year, in relation to the U.S. Dollar, had the effect of increasing year-to-date 2005 revenues by approximately \$1,975,000 compared to the same nine month period of 2004. Our growing royalty stream from sales of Testim contributed approximately \$3,512,000 to our revenues in the nine months ended September 30, 2005, compared to approximately \$2,000,000 in the first nine months of the prior year. Sales of active pharmaceutical ingredients from our new manufacturing facility (included in *All other products* in the table below) contributed approximately \$1,710,000 to our consolidated revenues for the nine months ended September 30, 2005 compared to \$1,076,000 in the nine months ended September 30, 2004.

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

For the nine months ended September 30, 2005:

| (in thousands) | Revenues Within Spain | | | Revenues Outside of Spain | Total | % of Total Revenues |
|-------------------------------|-----------------------|------------------|-----------|---------------------------|-----------|---------------------|
| | Branded Products | Generic Products | Other | | | |
| Product Line | | | | | | |
| Omeprazole | \$ 2,107 | \$ 11,948 | \$ | \$ | \$ 14,055 | 19% |
| Simvastatin | 1,275 | 3,862 | | | 5,137 | 7% |
| Enalapril | 3,084 | 1,319 | | | 4,403 | 6% |
| Paroxetine | 1,011 | 2,413 | | | 3,424 | 5% |
| Codeisan | 2,531 | | | | 2,531 | 4% |
| All other products | 7,003 | 7,429 | 271 | 1,439 | 16,142 | 22% |
| Sales to licensees and others | | | 9,722 | 13,355 | 23,077 | 32% |
| Licensing and collaborations | | | 228 | 3,523 | 3,751 | 5% |
| Total Revenues | \$ 17,011 | \$ 26,971 | \$ 10,221 | \$ 18,317 | \$ 72,520 | 100% |
| % of YTD 2005 Revenues | 23% | 37% | 14% | 26% | 100% | |

For the nine months ended September 30, 2004:

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(in thousands)

| Product Line | Revenues Within Spain | | | | Revenues Outside of Spain | Total | % of Total Revenues |
|--------------------------------------|-----------------------|------------------|----------|-----------|---------------------------|-----------|---------------------|
| | Branded Products | Generic Products | Other | | | | |
| <i>Omeprazole</i> | \$ 1,923 | \$ 9,783 | \$ | | \$ | \$ 11,706 | 22% |
| <i>Simvastatin</i> | 968 | 2,570 | | | | 3,538 | 7% |
| <i>Enalapril</i> | 2,280 | 883 | | | | 3,163 | 6% |
| <i>Paroxetine</i> | 703 | 2,282 | | | | 2,985 | 5% |
| <i>Codeisan</i> | 2,118 | | | | | 2,118 | 4% |
| <i>All other products</i> | 4,852 | 5,149 | | 466 | 610 | 11,077 | 20% |
| <i>Sales to licensees and others</i> | | | | 7,915 | 8,823 | 16,738 | 31% |
| <i>Licensing and collaborations</i> | | | | 541 | 2,009 | 2,550 | 5% |
| Total Revenues | \$ 12,844 | \$ 20,667 | \$ 8,922 | \$ 11,442 | \$ | \$ 53,875 | 100% |
| <i>% of YTD 2004 Revenues</i> | 24% | 38% | 17% | 21% | | 100% | |

Spanish Operations. The increase in the net product sales for the nine months ended September 30, 2005 compared to the nine months ended September 30, 2004 is due primarily to: (1) an increase in sales to licensees and others totaling \$6,339,000; and (2) an aggregate increase totaling \$5,188,000 in sales of our three top selling product lines (omeprazole, simvastatin and enalapril); and (3) an increase in the weighted average value of the Euro, in relation to the U.S. Dollar totaling \$1,965,000.

Branded Pharmaceutical Products

| (in thousands) | For the Nine Months Ended September 30, | | | | Change | |
|-----------------------------------|---|------|-----------|------|----------|-----|
| | 2005 | % | 2004 | % | \$ | % |
| <i>Branded Product Sales:</i> | | | | | | |
| <i>Enalapril</i> | \$ 3,084 | 18% | \$ 2,280 | 18% | \$ 804 | 35% |
| <i>Codeisan</i> | 2,531 | 15% | 2,118 | 16% | 413 | 19% |
| <i>Omeprazole</i> | 2,107 | 12% | 1,923 | 15% | 184 | 10% |
| <i>Lansoprazole</i> | 1,374 | 8% | | 0% | 1,374 | * |
| <i>Simvastatin</i> | 1,275 | 8% | 968 | 8% | 307 | 32% |
| <i>All other branded products</i> | 6,640 | 39% | 5,555 | 43% | 1,085 | 20% |
| <i>Total branded sales</i> | \$ 17,011 | 100% | \$ 12,844 | 100% | \$ 4,167 | 32% |

* Not meaningful

Sales of our branded pharmaceutical products increased by 32% during the nine months ended September 30, 2005 compared to the nine months ended September 30, 2004. Sales of branded enalapril and simvastatin, which grew by 35% and 32%, respectively, accounted for 18% and 8% of our branded pharmaceutical revenues in the nine months ended September 30, 2005, respectively. Sales of lansoprazole, which was launched in December 2004, contributed approximately \$1,374,000 to our branded product sales in the nine months ended September 30, 2005 and accounted for 33% of our growth in branded product sales during the nine months ended September 30, 2005. Strong sales of our branded ibuprofen (included in *All other branded products* above) increased 89% over the same period of the prior year and accounted for approximately 11% of the increase in branded pharmaceutical product sales. An increase in the weighted average value of the Euro over the past year, in relation to the U.S. Dollar, had the effect of increasing branded product sales by approximately \$525,000 in the first nine months of 2005.

Generic Pharmaceutical Products

| (in thousands) | For the Nine Months Ended September 30, | | | | Change | |
|-----------------------------------|---|------|-----------|------|----------|-----|
| | 2005 | % | 2004 | % | \$ | % |
| <i>Generic Product Sales:</i> | | | | | | |
| <i>Omeprazole</i> | \$ 11,948 | 45% | \$ 9,783 | 48% | \$ 2,165 | 22% |
| <i>Simvastatin</i> | 3,862 | 14% | 2,570 | 12% | 1,292 | 50% |
| <i>Paroxetine</i> | 2,413 | 9% | 2,282 | 11% | 131 | 6% |
| <i>Pentoxifylline</i> | 1,947 | 7% | 1,946 | 9% | 1 | 0% |
| <i>Trimetazidine</i> | 1,693 | 6% | 1,424 | 7% | 269 | 19% |
| <i>All other generic products</i> | 5,108 | 19% | 2,662 | 13% | 2,446 | 92% |
| <i>Total generic sales</i> | \$ 26,971 | 100% | \$ 20,667 | 100% | \$ 6,304 | 31% |

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Sales of our generic pharmaceutical products increased by 31% during the nine months ended September 30, 2005 compared to the nine months ended September 30, 2004. Increased demand for our generic omeprazole and simvastatin products accounted for 55% of our generic pharmaceutical revenue growth in the nine months ended September 30, 2005. Additionally, sales of our generic formulations of ibuprofen, enalapril, lansoprazole, and mirtazapine (included in *All other generic products* above) accounted for approximately 25% of the growth in generic pharmaceutical product sales. Paroxetine, pentoxifylline and trimetazidine continue to be major contributors to our generic pharmaceutical sales. 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 \$794,000 in the first nine months of 2005.

Sales to Licensees and Others

| (in thousands) | For the Nine Months Ended September 30, | | Change | |
|-------------------------------|---|-----------|----------|-----|
| | 2005 | 2004 | \$ | % |
| Sales to licensees and others | \$ 23,077 | \$ 16,738 | \$ 6,339 | 38% |

Sales to licensees and others in the nine months ended September 30, 2005 increased 38% when compared to the same nine month period of the prior year, or 34% in constant currency. Of these sales, 58% were to customers outside of Spain compared to 53% in the same period of the prior year. An increase in the weighted average value of the Euro over the past year, in relation to the U.S. Dollar, had the effect of increasing our revenues from sales to licensees and others by approximately \$593,000 in the first nine months of 2005.

Licensing and Collaboration Revenues. Licensing and collaboration revenues accounted for 5% of total revenues in the nine months ended September 30, 2005 and totaled \$3,751,000. These revenues include royalties of approximately \$3,512,000 in the nine months ended September 30, 2005 (compared to approximately \$2,000,000 in the nine months ended September 30, 2004) from the commercialization and continuing sales of Testim. Testim is currently reported to capture approximately 15% of all testosterone gel replacement prescriptions in the U.S. market.

Gross Profit. Gross profit increased by approximately \$10,105,000, or 35%, in the nine months ended September 30, 2005, when compared to the nine months ended September 30, 2004. Gross margins on net product sales were approximately 51% in the nine months ended September 30, 2005 and 2004. Cost of sales in the nine months ended September 30, 2005 included a charge of approximately \$1,157,000 as a result of a pharmaceutical tax that was enacted in the first quarter of 2005.

Selling and Marketing Expenses

| (in thousands) | For the Nine Months Ended September 30, | | Change | |
|-----------------------|---|-----------|----------|-----|
| | 2005 | 2004 | \$ | % |
| Selling and marketing | \$ 12,118 | \$ 10,919 | \$ 1,199 | 11% |

Selling and marketing expenses for the nine months ended September 30, 2005 increased 11% compared to 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 \$377,000 in the nine months ended September 30, 2005, accounting for 31% of the increase. See the explanation under *Selling and Marketing Expenses* for the three months ended September 30, 2005. Selling and marketing expenses as a percentage of net product sales decreased from 21% in the nine months ended September 30, 2004 to 18% in the nine months ended September 30, 2005.

General and Administrative Expenses

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| (in thousands) | For the Nine Months Ended September 30, | | Change | |
|-----------------------------------|---|----------|----------|-----|
| | 2005 | 2004 | \$ | % |
| <i>General and administrative</i> | \$ 9,072 | \$ 6,590 | \$ 2,482 | 38% |

General and administrative expenses for the nine months ended September 30, 2005 increased 38% compared to the same period in the prior year. The \$2,482,000 increase was the result of increased general and administrative activities required to support our continued growth and prepare for our anticipated future growth. See the explanation under *General and Administrative Expenses* for the three months ended September 30, 2005. General and administrative expenses as a percent of total revenues remained relatively constant for the nine months ended September 30, 2005 compared to the nine months ended September 30, 2004. General and administrative expenses would have been approximately \$137,000 lower, absent the increase in the weighted average value of the Euro, in relation to the U.S. Dollar, over the past year.

Research and Development Expenses

| (in thousands) | For the Nine Months Ended September 30, | | Change | |
|---------------------------------|---|----------|----------|-----|
| | 2005 | 2004 | \$ | % |
| <i>Research and development</i> | \$ 4,734 | \$ 3,171 | \$ 1,563 | 49% |

Research and development expenses for the nine months ended September 30, 2005 increased 49% compared to the same period in the prior year. The increase is directly attributed to the advancement of our research and development programs. See the explanation under *Research and Development Expenses* for the three months ended September 30, 2005. We expect to continue to incur increased costs to support our clinical programs in the remainder of the year.

Other Income (Expenses)

| (in thousands) | For the Nine Months Ended September 30, | | Change | |
|--------------------------------|---|----------|------------|------|
| | 2005 | 2004 | \$ | % |
| <i>Other income (expenses)</i> | \$ 470 | \$ 1,644 | \$ (1,174) | -71% |

Other income (expenses) for the nine months ended September 30, 2005 decreased by \$1,174,000 from the same period in the prior year. The reduction is primarily due to the prior year 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 in the prior year. Other income (expenses) for the nine months ended September 30, 2005 included interest income of approximately \$610,000 compared to approximately \$399,000 in the nine months ended September 30, 2004.

Provision for Income Taxes

| (in thousands) | For the Nine Months Ended September 30, 2005 | | |
|---|--|------------|--------------|
| | Spain | U.S. | Consolidated |
| <i>Income (loss) before income taxes</i> | \$ 13,603 | \$ (1,819) | \$ 11,784 |
| <i>Provision (benefit) for income taxes</i> | 4,521 | (728) | 3,793 |
| <i>Valuation allowance</i> | | 728 | 728 |
| <i>Net provision for income taxes</i> | 4,521 | | 4,521 |
| <i>Net income (loss)</i> | \$ 9,082 | \$ (1,819) | \$ 7,263 |
| <i>Effective tax rate</i> | 33% | 0% | 38% |

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We have recorded provisions for foreign income taxes totaling \$4,521,000 and \$4,706,000 (\$4,102,000 net of the \$604,000 tax audit settlement) for the nine months ended September 30, 2005 and 2004, respectively. The effective tax rate in Spain for the nine months ended September 30, 2005 is 33% compared to 44% (38% excluding the \$604,000 tax audit settlement in 2004) in the nine months ended September 30, 2004. The provision for foreign income taxes would have been approximately \$127,000 lower than reported, absent the increase in the weighted average value of the Euro in relation to the U.S. Dollar, over the past year.

We generated additional U.S. federal net operating loss carry-forwards in the nine months ended September 30, 2005 and 2004 as a result of U.S. pre-tax losses of \$1,819,000 and \$2,377,000, 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.

Net Income

| (in thousands, except per share data) | For the Nine Months Ended September 30, | | Change | |
|--|--|----------|----------|------|
| | 2005 | 2004 | \$ | % |
| <i>Net income</i> | \$ 7,263 | \$ 3,712 | \$ 3,551 | 96% |
| <i>Net income per common share:</i> | | | | |
| <i>Basic</i> | \$ 0.34 | \$ 0.18 | \$ 0.16 | 89% |
| <i>Diluted</i> | \$ 0.32 | \$ 0.16 | \$ 0.16 | 100% |
| <i>Weighted average common shares outstanding:</i> | | | | |
| <i>Basic</i> | 21,455 | 20,764 | 691 | 3% |
| <i>Diluted</i> | 22,700 | 22,772 | (72) | 0% |

We reported net income of \$7,263,000 in the nine months ended September 30, 2005 compared to \$3,712,000 in the nine months ended September 30, 2004. The combination of income from operations of \$11,314,000 and the non-operating items, primarily the provision for income taxes of \$4,521,000 resulted in net income of \$7,263,000, or \$0.34 per basic common share (\$0.32 per diluted common share) on 21,455,000 weighted average basic common shares outstanding (22,700,000 weighted average diluted common shares outstanding) for the nine months ended September 30, 2005, compared to 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) for the nine months ended September 30, 2004.

LIQUIDITY AND CAPITAL RESOURCES:

Total assets increased from \$121,930,000 at December 31, 2004 to \$124,817,000 at September 30, 2005, while stockholders' equity decreased from \$89,657,000 at December 31, 2004 to \$89,184,000 at September 30, 2005. The decrease in stockholders' equity during the nine months ended September 30, 2005 primarily reflects the effect of fluctuations in the Euro/U.S. Dollar exchange rate, which resulted in a net reduction of \$7,006,000 in our balance sheet, that was offset by net income of \$7,263,000 in the nine months ended September 30, 2005. Also contributing to the decrease in stockholders' equity, was the acquisition of approximately 364,000 shares of Common Stock, with a fair market value of approximately \$4,109,000, which were tendered to the Company by certain employees as consideration for the exercise of stock options and to satisfy minimum federal and statutory tax withholding requirements, partially offset by stock option exercises totaling \$3,200,000.

Cash and cash equivalents increased by approximately 5% or \$1,583,000 from \$34,230,000 at December 31, 2004 to \$35,813,000 at September 30, 2005, primarily as a result of increased cash flows from operations that included net income of \$7,263,000, an increase in deferred income of \$1,880,000 and the net effect of financing activities as discussed below partially offset by additions to fixed assets totaling \$6,673,000, additions to drug licenses totaling \$1,477,000 and the effect of foreign currency exchange rates that decreased cash by approximately \$678,000. Cash and cash equivalents at September 30, 2005 include approximately \$11,062,000 of short-term liquid investments considered to be cash equivalents.

Receivables decreased by approximately 4% during the nine months ended September 30, 2005 from \$27,860,000 at December 31, 2004 to \$26,856,000 at September 30, 2005. Total receivables increased by approximately \$2,175,000 in constant currency, but fluctuations in foreign currency exchange rates decreased receivables reported in U.S. Dollars by approximately \$3,179,000. Trade receivables increased by approximately \$2,194,000 in constant currency, but fluctuations in foreign currency exchange rates decreased trade receivables reported in U.S. Dollars by approximately \$3,105,000; however, the average number of days of sales outstanding in uncollected trade and royalties receivable decreased from 125 days at December 31, 2004 to 96 days at September 30, 2005. Receivables from one international customer totaled \$3,539,000 at September 30, 2005; however, we owe the same customer approximately \$2,107,000 for co-marketing expenses at September 30, 2005. Revenues from this customer are recorded net of the related co-marketing costs in the Consolidated Income Statements. 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 \$2,500,000 from \$10,258,000 at December 31, 2004 to \$12,758,000 at September 30, 2005, primarily as a result of increases in raw material and finished goods inventories totaling \$4,193,000 in constant currency required to meet anticipated fourth quarter demand, partially offset by fluctuations in foreign currency exchange rates approximating \$1,693,000.

The combined total of accounts payable and accrued expenses increased from \$23,217,000 at December 31, 2004 to \$25,294,000 at September 30, 2005. The \$2,077,000 increase was primarily attributed to increases in payables related to inventory purchases (approximately \$1,326,000), and increases in taxes payable of approximately \$2,592,000, including \$1,157,000 attributable to a new pharmaceutical tax, partially offset by fluctuations in foreign currency exchange rates that decreased accounts payable and accrued expenses reported in U.S. Dollars by approximately \$2,933,000.

Short-term borrowings and current portion of long-term debt decreased from \$2,785,000 at December 31, 2004 to \$2,156,000 at September 30, 2005, primarily as a result of the effect of fluctuations in foreign currency exchange rates totaling \$291,000 and by net repayments totaling \$346,000. The weighted average interest rate on our short-term borrowings at September 30, 2005 was 3.2%.

Operating activities for the nine months ended September 30, 2005 provided net cash of \$10,344,000 compared to \$812,000 during the nine months ended September 30, 2004. Net income, which increased to \$7,263,000 during the nine months ended September 30, 2005, and changes in working capital accounted for the majority of the increase in cash flows from operations.

Investing activities, primarily capital expenditures in Spain for land, improvements and equipment to upgrade the capacity of our manufacturing facility in Spain and to increase our manufacturing and packaging capabilities with new high speed equipment, along with additions to drug licenses and related costs, used net cash of \$8,150,000 during the nine months ended September 30, 2005.

Financing activities during the nine months ended September 30, 2005 provided cash totaling \$67,000, and primarily represented the cash proceeds of approximately \$1,800,000 received from the exercise of stock options, partially offset by the following: (1) the remittance of employee tax withholding liabilities of approximately \$1,082,000 resulting from stock option exercises, (2) the repurchase of approximately 27,000 shares of the Company's Common Stock, with a fair market value of approximately \$305,000, which were repurchased by the Company in conjunction with the exercise of employee stock options, and (3) net repayments of debt totaling \$346,000.

Our royalty revenues on Testim product sales by Auxilium Pharmaceuticals, Inc., our licensee, are recognized based on an estimate of Auxilium's sell-through of the Testim product based on prescriptions dispensed. For the nine months ended September 30, 2005 and 2004, we recognized royalty revenues of approximately \$3,512,000 and \$2,000,000, respectively, based on an estimate of prescriptions dispensed. 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 current *deferred income* in the Consolidated Balance Sheets. As of September 30, 2005 and December 31, 2004, deferred income from Testim royalties was approximately \$1,635,000 and \$1,233,000, 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 effected our net product sales or income from operations for the periods presented.

Liquidity. We expect to invest approximately \$11.6 million over the balance of 2005 and early 2006 for capital expenditures related to expansion of our manufacturing facilities to accommodate future anticipated growth. These capital expenditures will be funded from a combination of cash flows from operations and borrowings. As mentioned above, we have cash and cash equivalents totaling approximately \$35,813,000 as of September 30, 2005, which we believe is sufficient to fund our operations and cash requirements for the foreseeable future. Although the Company is generating positive cash flow from operations, (approximately \$10,344,000 in the nine months ended September 30, 2005), there can be no assurance that changes in our research and development plans, capital expenditures and/or acquisitions, or other events affecting our net product sales or operating expenses will not result in the earlier depletion of our funds. However, we continue to explore alternative sources for financing our business activities. In appropriate situations, which will be strategically determined, we may seek financial assistance from other sources,

including contribution by others to joint ventures and other collaborative or licensing arrangements for the development, testing, manufacturing and marketing of products under development.

Critical Accounting Policies and Estimates

Our significant accounting policies are more fully described in Note 2 to our consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2004. 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 observation 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, 2004.

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 2005 and 2006 expenses, margins and operating performance;

Expected launch of new products;

Anticipated expenses and spending;

Commencing and continuing clinical trials;

Anticipated regulatory changes and approvals; and

The sufficiency of capital resources 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: the timing and nature of regulatory approvals, expanding generic and branded drug operations, changes in third-party reimbursement and government mandates which impact pharmaceutical pricing, development and commercialization of our proprietary products and formulations, competition from other manufacturers of generic and proprietary pharmaceuticals, intellectual property litigation, our relationships with our strategic partners, the efficacy and safety of our products, the unpredictability of patent protection, the uncertainty of clinical trial results,

technological changes, the effects of economic conditions, risks associated with international operations, 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, 2004. 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 in relation to other currencies, specifically the Euro. The exchange rates at September 30, 2005 and December 31, 2004 were .83

Euros and .73 Euros per U.S. Dollar, respectively. The weighted average exchange rate for the three months ended September 30, 2005 and 2004 was .82 Euros per U.S. Dollar. The weighted average exchange rates for the nine months ended September 30, 2005 and 2004 were .79 Euros and .82 Euros per U.S. Dollar, respectively. The net effect of foreign currency translation on our Condensed Consolidated Financial Statements for the nine months ended September 30, 2005 was a net decrease of \$7,006,000 and the cumulative historical effect as of September 30, 2005 was an increase of \$2,716,000, as reflected in our Consolidated Balance Sheets as *accumulated other comprehensive income*. The carrying value of assets and liabilities can be materially impacted by foreign currency translation, as can the translated amounts of revenues and expenses.

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 cash requirements in Europe with U.S. funds, 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 rate fluctuations.

Interest Rates. The weighted average interest rate on our short-term borrowings is 3.2% and the amount of borrowings outstanding is \$2,156,000 as of September 30, 2005. Our long-term borrowings are non-interest bearing and the balance outstanding on these borrowings at September 30, 2005 is \$366,000 including imputed interest (ranging from 5.2% to 6.0%) of \$47,000. The weighted average interest rate on our long-term borrowings is 5.7%. The effect of an increase in interest rates of one percentage point (one hundred basis points) to an average of 4.2% on short-term borrowings and to an average of 6.7% on long-term borrowings would have the effect of increasing interest expense by approximately \$25,000 annually.

Item 4. Controls and Procedures

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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, 2005, Bentley's management carried out an evaluation, with the participation of Bentley's Chief Executive Officer and Chief Financial Officer, of the effectiveness of Bentley's disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15(d)-15(e)). Based on that evaluation, Bentley's Chief Executive Officer and Chief Financial Officer concluded that Bentley's disclosure controls and procedures are effective and designed to ensure that the information relating to Bentley (including its consolidated subsidiaries), which is required to be included in its publicly filed reports or submitted under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Although Bentley's management continually evaluates the internal control structure and strengthens Bentley's control procedures, particularly in connection with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 (including, for example, the hiring of an internal auditor in September 2005), there have been no changes in Bentley's internal control over financial reporting during the quarter ended September 30, 2005 that have materially affected, or are reasonably likely to materially affect, Bentley's internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

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On September 27, 2004, the Company was served with a complaint in an action captioned Ethypharm S.A. France & Ethypharm S.A. Spain v. Bentley Pharmaceuticals, Inc., U.S. District Court for the District of Delaware, Civil Action No. 04-1300 (SLR). In this action, Ethypharm S.A., a French-based drug delivery company, and its Spanish affiliate (collectively, Ethypharm), allege that since March 2002 the Company and its Spanish subsidiary Laboratorios Belmac, S.A. (Belmac) misappropriated unspecified Ethypharm trade secrets and confidential information and used that information in the manufacture of omeprazole, one of Belmac's pharmaceutical products. Based on Ethypharm's primary allegation of misappropriation of trade secrets, the complaint also asserted counts of fraud, unjust enrichment, and intentional interference with actual and prospective business relationships. Ethypharm's complaint seeks injunctive relief as well as damages. On September 26, 2005, the Court granted the Company's motion to dismiss two counts, Count 1 (Fraud) and Count 3 (Unjust Enrichment), of Ethypharm's complaint but denied the Company's motion to dismiss the complaint in its entirety without prejudice to its being renewed after the completion of discovery on the issue of agency. The Company intends to contest the case vigorously.

On April 11, 2005, Ethypharm's Spanish affiliate, Ethypharm S.A., filed suit against Belmac S.A. in the Commercial Court No. 5 of Madrid, Spain. The complaint alleges that Belmac refused to renew its contract with Ethypharm for the manufacture of omeprazole which expired on March 22, 2002, and that after that date Belmac's continued manufacture of omeprazole pursuant to its own patented technology has infringed Ethypharm's Spanish Patent No. ES9301319. In its complaint, Ethypharm seeks an order from the court declaring Belmac to be in violation of Ethypharm's patent, preventing further sales of omeprazole by Belmac, and awarding monetary damages. On July 5, 2005, Belmac filed an answer and counterclaim which denies Ethypharm's material allegations and seeks a declaration that Ethypharm's patent is invalid. No trial date has been set. Belmac intends to defend the case vigorously.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Issuer Repurchases

| | (a) Total Number of Shares (or Units) Purchased (1) | (b) Average Price Paid per Share(2) | (c) Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs | (d) Maximum Number (or approximate dollar value) of Shares (or Units) that may yet be Purchased under the Plans or Programs |
|--|---|---|---|--|
| July 1, 2005 through July 31, 2005 | | \$ | | |
| August 1, 2005 through August 31, 2005 | 32,056 | | 11.494 | |
| September 1, 2005 through September 30, 2005 | 112,792 | | 11.725 | |
| Total | 144,848 | \$ | 11.674 | |

(1) Represents shares tendered or repurchased by the Company for cash at fair market value from option holders using mature stock in connection with the exercise of their vested stock options and shares tendered or repurchased by the Company for cash at fair market value from option holders to satisfy minimum tax withholding liabilities.

(2) Average of the high and low prices on the NYSE on the dates of exercise.

Item 6. Exhibits

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The Exhibits filed as part of this report are listed on the Exhibit Index immediately following the signature page, 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 8, 2005

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

November 8, 2005

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

Exhibit Index

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**Exhibit
umber**

Description of Exhibit

- | | | |
|------|---|---|
| 10.1 | * | Employment Agreement dated as of August 27, 2005 between the Registrant and John A. Sedor. Filed herewith. |
| 31.1 | | Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. Filed herewith. |
| 31.2 | | Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. Filed herewith. |
| 32.1 | | Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Filed herewith. |
| 32.2 | | Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Filed herewith. |

* Indicates a management contract or compensatory plan or arrangement.
