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BENTLEY PHARMACEUTICALS INC  
Form 10-Q  
August 05, 2003

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2003  
-----

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number 1-10581

BENTLEY PHARMACEUTICALS, INC.  
(Exact name of registrant as specified in its charter)

DELAWARE  
(State or other jurisdiction of  
incorporation or organization)

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

Bentley Park, 2 Holland Way, Exeter, NH 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 X           NO  
-----           -----

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

The number of shares of the registrant's common stock outstanding as of July 31, 2003 was 17,763,908.

BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES  
FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2003  
INDEX

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BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)

June 30,  
2003

ASSETS

-----  
Current assets:

|                            |           |
|----------------------------|-----------|
| Cash and cash equivalents  | \$ 24,823 |
| Marketable securities      | 436       |
| Receivables, net           | 17,325    |
| Inventories, net           | 5,563     |
| Deferred foreign taxes     | 134       |
| Prepaid expenses and other | 1,174     |

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|   |           |
|---|-----------|
| Total current assets  | 49,455    |
| <hr/>   |           |
| Non-current assets:   |           |
| Fixed assets, net   | 14,096    |
| Drug licenses and related costs, net  | 13,261    |
| Restricted cash   | 1,000     |
| Other   | 180       |
| <hr/>   |           |
| Total non-current assets  | 28,537    |
| <hr/>   |           |
|   | \$ 77,992 |
| <hr/>   |           |
| <hr/>   |           |
| LIABILITIES AND STOCKHOLDERS' EQUITY  |           |
| <hr/>   |           |
| Current liabilities:  |           |
| Accounts payable  | \$ 9,676  |
| Accrued expenses  | 7,136     |
| Short-term borrowings   | 1,606     |
| Current portion of long-term debt   | 138       |
| Deferred income   | 1,168     |
| <hr/>   |           |
| Total current liabilities   | 19,724    |
| <hr/>   |           |
| Non-current liabilities:  |           |
| Deferred foreign taxes  | 2,335     |
| Long-term debt  | 322       |
| Other   | 179       |
| <hr/>   |           |
| Total non-current liabilities   | 2,836     |
| <hr/>   |           |
| Commitments and contingencies   |           |
| Stockholders' equity:   |           |
| Preferred stock, \$1.00 par value, authorized 2,000 shares,<br>issued and outstanding, none                   | -         |
| Common stock, \$.02 par value, authorized 100,000 shares,<br>issued and outstanding, 17,664 and 17,404 shares | 354       |
| Stock purchase warrants (to purchase 3,147 and 3,292<br>shares of common stock)                               | 429       |
| Additional paid-in capital  | 122,507   |
| Accumulated deficit   | (69,635)  |
| Accumulated other comprehensive income (loss)   | 1,777     |
| <hr/>   |           |
| Total stockholders' equity  | 55,432    |
| <hr/>   |           |
|   | \$ 77,992 |
| <hr/>   |           |
| <hr/>   |           |

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

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(in thousands, except per share data)

|   | For the Three Months Ended June 30, |          | Fo |
|---|-------------------------------------|----------|----|
|   | 2003                                | 2002     |    |
| Revenues:                                   |                                     |          |    |
| Net product sales                           | \$ 16,596                           | \$ 9,809 |    |
| Licensing and collaboration revenues        | 158                                 | 58       |    |
| Total revenues                              | 16,754                              | 9,867    |    |
| Cost of net product sales                   | 6,819                               | 4,249    |    |
| Gross profit                                | 9,935                               | 5,618    |    |
| Operating expenses:                         |                                     |          |    |
| Selling and marketing                       | 3,626                               | 2,608    |    |
| General and administrative                  | 1,786                               | 1,315    |    |
| Research and development                    | 879                                 | 583      |    |
| Depreciation and amortization               | 328                                 | 237      |    |
| Total operating expenses                    | 6,619                               | 4,743    |    |
| Gain on sale of drug licenses               | -                                   | 520      |    |
| Income from operations                      | 3,316                               | 1,395    |    |
| Other income (expenses):                    |                                     |          |    |
| Interest income                             | 82                                  | 85       |    |
| Interest expense                            | (60)                                | (67)     |    |
| Other                                       | (4)                                 | (8)      |    |
| Income before income taxes                  | 3,334                               | 1,405    |    |
| Provision for foreign income taxes          | 1,805                               | 886      |    |
| Net income                                  | \$ 1,529                            | \$ 519   |    |
| Net income per common share:                |                                     |          |    |
| Basic                                       | \$ 0.09                             | \$ 0.03  |    |
| Diluted                                     | \$ 0.07                             | \$ 0.03  |    |
| Weighted average common shares outstanding: |                                     |          |    |
| Basic                                       | 17,534                              | 16,823   |    |
| Diluted                                     | 20,878                              | 20,484   |    |
| Net income                                  | \$ 1,529                            | \$ 519   |    |

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|                                    |          |          |
|------------------------------------|----------|----------|
| Other comprehensive income (loss): |          |          |
| Foreign currency translation gains | 1,513    | 2,105    |
|                                    | -----    | -----    |
| Comprehensive income               | \$ 3,042 | \$ 2,624 |
|                                    | =====    | =====    |

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

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BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

| (in thousands, except per share data)   | \$.02 Par Value<br>Common Stock |        | Stock<br>Purchase<br>Warrants | Additional<br>Paid-In<br>Capital | Accum<br>Def |
|---|---------------------------------|--------|-------------------------------|----------------------------------|--------------|
|   | Shares                          | Amount |                               |                                  |              |
|   | -----                           | -----  | -----                         | -----                            | -----        |
| Balance at December 31, 2002            | 17,404                          | \$ 348 | \$ 431                        | \$121,084                        | \$ (72)      |
| Exercise of stock options and warrants  | 205                             | 4      | (2)                           | 960                              |              |
| Equity based compensation               | 55                              | 2      | -                             | 463                              |              |
| Foreign currency translation adjustment | -                               | -      | -                             | -                                |              |
| Net income                              | -                               | -      | -                             | -                                | 3            |
|   | -----                           | -----  | -----                         | -----                            | -----        |
| Balance at June 30, 2003                | 17,664                          | \$ 354 | \$ 429                        | \$122,507                        | \$ (69)      |
|   | =====                           | =====  | =====                         | =====                            | =====        |

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

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### BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

|   | For the Six Months Ended J |    |
|---|----------------------------|----|
|   | 2003                       | 20 |
| <b>Cash flows from operating activities:</b>  |                            |    |
| Net income  | \$ 3,061                   | \$ |
| Adjustments to reconcile net income to net cash provided by (used in) operating activities: |                            |    |
| Gain on sale of drug licenses   | -                          |    |
| Depreciation and amortization   | 1,078                      |    |
| Equity-based compensation expense   | 237                        |    |
| Other non-cash items  | (149)                      |    |
| (Increase) decrease in assets and increase (decrease) in liabilities:                       |                            |    |
| Receivables   | (4,709)                    |    |
| Inventories   | 33                         |    |
| Prepaid expenses and other current assets   | (134)                      |    |
| Other assets  | (9)                        |    |
| Accounts payable and accrued expenses   | 3,732                      |    |
| Deferred income   | 753                        |    |
| Other liabilities   | (7)                        |    |
|   | 3,886                      |    |
| <b>Cash flows from investing activities:</b>  |                            |    |
| Proceeds from sale of drug licenses   | -                          |    |
| Proceeds from sale of investments   | 114,600                    |    |
| Purchase of investments   | (114,509)                  |    |
| Additions to fixed assets   | (4,131)                    |    |
| Additions to drug licenses and related costs  | (2,054)                    |    |
|   | (6,094)                    |    |

(Continued on following page)

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

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BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF CASH FLOWS (concluded)

(in thousands)

|  | For the Six Months Ended J |       |
|--|----------------------------|-------|
|  | 2003                       | 20    |
| Cash flows from financing activities:                |                            |       |
| Proceeds from offering of common stock, net          | \$ -                       | \$    |
| Proceeds from exercise of stock options/warrants     | 962                        |       |
| Repayment of borrowings                              | (1,329)                    |       |
| Proceeds from borrowings                             | 1,150                      |       |
| Increase in restricted cash                          | (1,000)                    |       |
|  | -----                      | ----- |
| Net cash (used in) provided by financing activities  | (217)                      |       |
|  | -----                      | ----- |
| Effect of exchange rate changes on cash              | 667                        |       |
|  | -----                      | ----- |
| Net (decrease) increase in cash and cash equivalents | (1,758)                    |       |
| Cash and cash equivalents at beginning of period     | 26,581                     |       |
|  | -----                      | ----- |
| Cash and cash equivalents at end of period           | \$ 24,823                  | \$    |
|  | =====                      | ===== |

SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION

The Company paid cash during the period for:

|                      |        |       |
|----------------------|--------|-------|
| Interest             | \$ 97  | \$    |
|                      | =====  | ===== |
| Foreign income taxes | \$ 847 | \$    |
|                      | =====  | ===== |

SUPPLEMENTAL DISCLOSURES OF NON-CASH FINANCING  
AND INVESTING ACTIVITIES

The Company has issued shares of common stock to employees in lieu of cash compensation as follows:

|        |        |       |
|--------|--------|-------|
| Shares | 55     |       |
|        | =====  | ===== |
| Amount | \$ 465 | \$    |

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Included in accounts payable are fixed  
asset and drug license purchases totaling

=====  
\$ 1,222  
=====

=====  
\$  
=====

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

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BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

HISTORY AND OPERATIONS:

Bentley Pharmaceuticals, Inc. and Subsidiaries (which may be referred to as Bentley Pharmaceuticals, Bentley, the Company, we, us or our) is a U.S.-based international specialty pharmaceutical company focused on advanced drug delivery technologies and pharmaceutical products. We own U.S. and international patent and other proprietary rights to technologies that enhance or facilitate the absorption of drugs across biological membranes. We are developing products incorporating these technologies and seek to form strategic alliances with other pharmaceutical and biotechnology companies to facilitate the development and commercialization of our products. We currently have strategic alliances with Pfizer Inc. and Auxilium Pharmaceuticals, Inc. and are in preliminary discussions with a number of pharmaceutical companies to form additional alliances. Bentley Pharmaceuticals is incorporated in the State of Delaware.

We also have a commercial presence in Spain, where we manufacture, market and sell branded and generic pharmaceutical products primarily within four therapeutic areas: cardiovascular, gastrointestinal, neurological and infectious diseases.

We anticipated the opportunities that the emerging generic drug market in Spain presented and began taking measures over four years ago to enter the Spanish generic drug market. We created Laboratorios Davur, a wholly-owned subsidiary of our Spanish entity, Laboratorios Belmac, to register, market and distribute generic pharmaceutical products in Spain and began aligning our business model to be competitive, including hiring and training a new generic sales force, submission of generic-equivalent products to the Spanish Ministry of Health for approval and a marketing campaign designed to position our Spanish generic subsidiary as a leader in the Spanish generic drug market. In July 2000, we entered into a strategic alliance with Teva Pharmaceutical Industries, Ltd. (Teva), whereby we have received the right to register and market in Spain more than 75 of Teva's products. Teva also entered into a supply agreement with us pursuant to which Teva will manufacture the products and supply them to us for marketing and sale in Spain. Teva was also granted a right of first refusal to



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acquire Laboratorios Davur in the event that we decide to sell that subsidiary or its direct parent, Laboratorios Belmac. We also granted Teva the right to bid for Laboratorios Belmac in the event we decide to sell that subsidiary.

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### BASIS OF CONSOLIDATED FINANCIAL STATEMENTS:

The consolidated financial statements of Bentley Pharmaceuticals at June 30, 2003 and 2002, included herein, have been prepared by us, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted in so far as such information was disclosed in our consolidated financial statements for the year ended December 31, 2002. These consolidated financial statements should be read in conjunction with the summary of significant accounting policies and the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2002.

In the opinion of management, the accompanying unaudited consolidated financial statements for the period ended June 30, 2003 and 2002 are presented on a basis consistent with the audited consolidated financial statements for the year ended December 31, 2002 and contain all adjustments, consisting only of normal recurring adjustments, necessary to present fairly Bentley's financial position as of June 30, 2003 and the results of our operations and our cash flows for the six months ended June 30, 2003 and 2002. The results of operations for the six months ended June 30, 2003 should not necessarily be considered indicative of the results to be expected for the year.

### CASH AND CASH EQUIVALENTS AND RESTRICTED CASH:

Included in cash and cash equivalents at June 30, 2003 and December 31, 2002 are approximately \$22,015,000 and \$23,360,000, respectively, of short-term investments considered to be cash equivalents, as the remaining maturity dates of such investments were three months or less when purchased.

We acquired intellectual property during the quarter ended June 30, 2003 for \$1,000,000 plus future royalties on sales and licensing income. We have obtained a renewable, irrevocable letter of credit in the amount of \$1,000,000 in favor of the assignor to guarantee future royalty payments. We have classified the \$1,000,000 used to secure the letter of credit as restricted cash in the Consolidated Balance Sheets as of June 30, 2003.

### MARKETABLE SECURITIES:

We have investments in securities, with remaining maturities of greater than three months when purchased, totaling \$436,000 and \$396,000, which are classified as marketable securities as of June 30, 2003 and December 31, 2002, respectively. These investments are considered available-for-sale and are carried at fair value. Unrealized gains or losses, if any, are recorded as a component of other comprehensive income in the Consolidated Balance Sheets.

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INVENTORIES:

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

|  | JUNE 30, 2003<br>----- | DECEMBER 31, 2002<br>----- |
|--|------------------------|----------------------------|
| Raw materials                            | \$3,534                | \$3,518                    |
| Finished goods                           | 2,097                  | 1,677                      |
|  | -----                  | -----                      |
|  | 5,631                  | 5,195                      |
| Less allowance for slow moving inventory | (68)                   | (62)                       |
|  | -----                  | -----                      |
|  | \$5,563                | \$5,133                    |
|  | =====                  | =====                      |

FIXED ASSETS:

Fixed assets consist of the following (in thousands):

|                               | JUNE 30, 2003<br>----- | DECEMBER 31, 2002<br>----- |
|-------------------------------|------------------------|----------------------------|
| Land                          | \$ 1,789               | \$ 930                     |
| Buildings                     | 7,220                  | 5,576                      |
| Equipment                     | 7,641                  | 5,197                      |
| Furniture and fixtures        | 1,451                  | 1,006                      |
| Leasehold improvements        | 43                     | 52                         |
|                               | -----                  | -----                      |
|                               | 18,144                 | 12,761                     |
| Less accumulated depreciation | (4,048)                | (3,196)                    |
|                               | -----                  | -----                      |
|                               | \$14,096               | \$9,565                    |
|                               | =====                  | =====                      |

We purchased a 15,700 square foot commercial building located on approximately 14 acres of land in Exeter, NH for \$1,776,600 in January 2003. The purchase included furniture and fixtures in the building and the purchase price was allocated to the following components in accordance with their relative fair market values: land - \$775,100, buildings - \$898,400, and furniture and fixtures - \$103,100. We moved our corporate headquarters into the new building in April 2003. We have expensed \$42,000 for the remaining lease costs and abandonment of leasehold improvements related to the former office space, all of which has been recorded in general and administrative expenses in the Consolidated Income Statements for the quarter ended June 30, 2003. The lease agreement ends in February 2004.

Depreciation expense of approximately \$147,000 and \$114,000 has been charged to operations as a component of depreciation and amortization expense on

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the Consolidated Income Statements for the six months ended June 30, 2003 and 2002, respectively. We have included depreciation totaling approximately \$467,000 and \$251,000 in cost of net product sales during the six months ended June 30, 2003 and 2002, respectively.

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### STOCKHOLDERS' EQUITY:

A substantial amount of our business is conducted in Europe and is therefore influenced to the extent to which there are fluctuations in the U.S. Dollar's value against other currencies, specifically the Euro. The exchange rate at June 30, 2003 and December 31, 2002 was .88 Euros and .95 Euros per U.S. Dollar, respectively. The weighted average exchange rate for the three months ended June 30, 2003 and 2002 was .88 Euros and 1.09 Euros per U.S. Dollar, respectively. The weighted average exchange rate for the six months ended June 30, 2003 and 2002 was .91 Euros and 1.11 Euros per U.S. Dollar, respectively. The effect of foreign currency fluctuations on long lived assets for the six months ended June 30, 2003 was an increase of \$2,193,000 and the cumulative historical effect on equity was an increase of \$1,777,000, as reflected in our Consolidated Balance Sheets as accumulated other comprehensive income.

At our Annual Meeting of Stockholders on May 21, 2003, the stockholders of the Company approved an increase in the number of the Company's authorized Common Shares from 35,000,000 to 100,000,000.

### LICENSING AND COLLABORATION REVENUES:

Auxilium Pharmaceuticals, Inc. launched its new testosterone replacement gel, Testim TM, which utilizes Bentley's patented CPE-215TM drug delivery technology, during the first quarter of 2003. Auxilium paid a milestone payment to us during the first quarter of 2003, which we recorded as licensing and collaboration revenues in the Consolidated Income Statement for the three months ended March 31, 2003. In connection with the Testim product launch, Bentley began earning royalty revenues on a percentage of Testim sales as defined in the licensing agreement with Auxilium. Royalty revenues on Testim product sales are recognized based on an estimate of Auxilium's sell-through of the Testim product based on prescriptions written, until such time that returns from wholesalers and pharmacies can be reasonably estimated. For the three and six months ended June 30, 2003, we recognized royalty revenues of \$158,000 and \$208,000, respectively, based on an estimate of prescriptions written. The difference between the total amount due from Auxilium under the royalty arrangement and the amount recognized as net product sales has been recorded as deferred income in the Consolidated Balance Sheet as of June 30, 2003. We will continue to use available market information to determine the amount and timing of royalty revenue recognition.

### PROVISION FOR INCOME TAXES:

As a result of reporting taxable income for tax purposes in Spain, we recorded provisions for foreign income taxes totaling \$1,805,000 and \$886,000 for the three months ended June 30, 2003 and 2002, respectively. These amounts represent 42% and 43% of the pre-tax income reported in Spain for the three months ended June 30, 2003 and 2002, respectively. We have recorded provisions for foreign income taxes totaling \$2,956,000 and \$1,483,000 for the six months ended June 30, 2003 and 2002, respectively. These amounts represent 40% and 41% of the pre-tax income reported in Spain for the six

months ended June 30, 2003 and 2002, respectively. No tax benefit has been recorded for U.S. losses, which totaled (\$976,000) and (\$651,000) for the three months ended June 30, 2003 and 2002, respectively, and (\$1,465,000) and (\$1,453,000) for the six months ended June 30, 2003 and 2002, respectively, as future domestic operating profits cannot be assured. Accordingly, we have established a valuation allowance equal to the full amount of the U.S. deferred tax assets. The provisions for income taxes differ from the amounts computed by applying the U.S. federal income tax rate of 34% to pretax income, primarily as a result of the increase in the valuation allowance to offset U.S. deferred tax assets, certain nondeductible expenses in Spain and the higher statutory income tax rate of 35% in Spain.

Certain tax contingencies exist and when probable and reasonably estimable, are provided for in the Consolidated Financial Statements. Accordingly, as of June 30, 2003, no amounts have been provided for related to these contingencies.

BASIC AND DILUTED NET INCOME PER COMMON SHARE:

Basic and diluted net income per common share is based on the weighted average number of shares of common stock outstanding during each period. The dilutive effect of our outstanding stock options and stock purchase warrants were considered in the income per share calculations for the three and six months ended June 30, 2003 and 2002.

The following is a reconciliation between basic and diluted net income per common share for the three and six months ended June 30, 2003 and 2002. Dilutive securities issuable for the three and six months ended June 30, 2003 include approximately 1,334,000 and 1,260,000 shares, respectively, issuable as a result of exercisable Class B Warrants and approximately 2,010,000 and 1,862,000 shares, respectively, issuable as a result of various stock options and other warrants that are outstanding and exercisable. Dilutive securities issuable for the three and six months ended June 30, 2002 include approximately 1,499,000 and 2,048,000 shares, respectively, issuable as a result of exercisable Class B Warrants and approximately 2,162,000 and 1,421,000 shares issuable as a result of various stock options and other warrants that are outstanding and exercisable.

(in thousands, except per share data)

For the Three Months Ended June 30, 2003:

|                             | Basic EPS | Effect of Dilutive<br>Securities | D     |
|-----------------------------|-----------|----------------------------------|-------|
|                             | -----     | -----                            | ----- |
| Net Income                  | \$ 1,529  | \$ -                             |       |
| Number of Common Shares     | 17,534    | 3,344                            |       |
| Net Income Per Common Share | \$ .09    | (\$ .02)                         |       |

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For the Six Months Ended June 30, 2003:

|                             | Basic EPS | Effect of Dilutive<br>Securities |
|-----------------------------|-----------|----------------------------------|
|                             | -----     | -----                            |
| Net Income                  | \$ 3,061  | \$ -                             |
| Number of Common Shares     | 17,495    | 3,122                            |
| Net Income Per Common Share | \$ .17    | (\$ .02)                         |

For the Three Months Ended June 30, 2002:

|                             | Basic EPS | Effect of Dilutive<br>Securities |
|-----------------------------|-----------|----------------------------------|
|                             | -----     | -----                            |
| Net Income                  | \$ 519    | \$ -                             |
| Number of Common Shares     | 16,823    | 3,661                            |
| Net Income Per Common Share | \$ .03    | (\$ .00)                         |

For the Six Months Ended June 30, 2002:

|                             | Basic EPS | Effect of Dilutive<br>Securities |
|-----------------------------|-----------|----------------------------------|
|                             | -----     | -----                            |
| Net Income                  | \$ 654    | \$ -                             |
| Number of Common Shares     | 15,735    | 3,469                            |
| Net Income Per Common Share | \$ .04    | (\$ .01)                         |

Excluded from the diluted EPS presentation, because their exercise prices were greater than the average fair value of the Common Stock in the respective periods, were warrants and options to purchase an aggregate of 518,000 and 1,328,000 shares of Common Stock, for the three and six months ended June 30, 2003, respectively, and warrants and options to purchase an aggregate of 212,000 and 327,000 shares of Common Stock for the three and six months ended June 30, 2002, respectively.

#### STOCK BASED COMPENSATION:

We have stock-based employee compensation plans that are described more fully in Note 11 of the Notes to Consolidated Financial Statements included in the Annual Report on Form 10-K for the year ended December 31, 2002. We account for these plans under the recognition and measurement principles of APB Opinion No. 25, Accounting for Stock Issued to Employees, and related Interpretations. Options granted under these plans have exercise prices equal to or greater than the market value of the underlying common stock on the dates of grant, which is the date on which compensation is measured. In addition to these plans, we also sponsor a 401(k) plan for eligible employees and match eligible contributions with shares of our Common Stock. From time to time, at the discretion of the

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Compensation Committee, we grant shares of our Common Stock to employees in lieu of cash compensation. Related stock-based employee compensation costs are reflected in the Consolidated Income Statements and Statements of Cash Flows.

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

|   | FOR THE THREE MONTHS ENDED<br>JUNE 30, |                    | FOR THE S         |
|---|--|--------------------|-------------------|
|   | 2003                                   | 2002               | 2003              |
| Net income, as reported   | \$ 1,529                               | \$ 519             | \$ 3,061          |
| Add: Stock-based employee compensation expense included in reported net income                            | 109                                    | 37                 | 237               |
| Deduct: Total stock-based employee compensation expense determined under fair value method for all awards | (775)                                  | (980)              | (1,512)           |
| Pro forma net income (loss)   | \$ 863<br>=====                        | \$ (424)<br>=====  | \$ 1,786<br>===== |
| Net income (loss) per share:  |  |                    |                   |
| Basic - as reported   | \$ 0.09<br>=====                       | \$ 0.03<br>=====   | \$ 0.17<br>=====  |
| Basic - pro forma   | \$ 0.05<br>=====                       | \$ (0.03)<br>===== | \$ 0.10<br>=====  |
| Diluted - as reported   | \$ 0.07<br>=====                       | \$ 0.03<br>=====   | \$ 0.15<br>=====  |
| Diluted - pro forma   | \$ 0.04<br>=====                       | \$ (0.03)<br>===== | \$ 0.09<br>=====  |

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<br>JUNE 30, |      | FOR THE S |
|--|--|------|-----------|
|  | 2003                                   | 2002 | 2003      |

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|                               |         |         |        |
|-------------------------------|---------|---------|--------|
| Risk-free interest rate       | 3.62%   | 5.13%   | 3.89   |
| Dividend yield                | 0.00%   | 0.00%   | 0.00   |
| Expected life                 | 5 years | 5 years | 5 year |
| Volatility                    | 53.06%  | 93.23%  | 54.30  |
| Fair value of options granted | \$4.87  | \$5.74  | \$4.98 |

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

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Conjunction with Selling, Goods or Services and other related interpretations. Under this method, the equity based instrument is valued at either the fair value of the consideration received or the equity instrument issued on the measurement date, which is typically the date of grant. The resulting compensation cost is recognized and charged to operations over the service period, which is usually the vesting period.

At our Annual Meeting of Stockholders on May 21, 2003, the Company's stockholders approved an increase in the number of shares authorized for issuance under the Company's 2001 Employee Stock Option Plan by 1,500,000 shares and an increase in the number of shares authorized for issuance under the Company's 2001 Directors' Stock Option Plan by 500,000 shares.

#### RECLASSIFICATIONS:

Certain prior period amounts have been reclassified to conform with the current period's presentation. Such reclassifications are not material to the consolidated financial statements.

#### NEW ACCOUNTING PRONOUNCEMENTS:

In December 2002, the Financial Accounting Standards Board issued Interpretation No. 45, Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others ("FIN 45"). FIN 45 elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under certain guarantees that it has issued. It also clarifies that a guarantor is required to recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. We have adopted the disclosure requirements of FIN 45 as of December 31, 2002 and determined that no additional disclosures were required. In addition, we are required to adopt the initial recognition and measurement of the fair value of the obligation undertaken in issuing the guarantee on a prospective basis to guarantees issued or modified after December 31, 2002. The adoption of FIN 45 has not had, nor do we expect it to have, a material effect on our financial position, results of operations or cash flows.

In November 2002, the Emerging Issues Task Force ("EITF") issued EITF Issue No. 00-21, Accounting for Revenue Arrangements with Multiple Deliverables. EITF Issue No. 00-21 addresses certain aspects of the accounting by a vendor for arrangements under which it will perform multiple revenue-generating activities.

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EITF Issue No. 00-21 establishes three principles: revenue arrangements with multiple deliverables should be divided into separate units of accounting, arrangement consideration should be allocated among the separate units of accounting based on their relative fair values, and revenue recognition criteria should be considered individually for each separate unit of accounting. EITF Issue No. 00-21 is effective for all revenue arrangements entered into in fiscal periods beginning after June 15, 2003, with early adoption permitted. We do not believe EITF Issue No. 00-21 will have a material effect on our financial position, results of operations or cash flows.

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### ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

#### CRITICAL ACCOUNTING POLICIES

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Our significant accounting policies are more fully described in Note 2 to our consolidated financial statements in our Annual Report of Form 10-K for the year ended December 31, 2002. However, certain of our accounting policies are particularly important to the portrayal of our financial position and results of operations and require the application of significant judgment by our management; as a result they are subject to an inherent degree of uncertainty. In applying those policies, our management uses its judgment to determine the appropriate assumptions to be used in the determination of certain estimates. Those estimates are based on our historical experience, terms of existing contracts, our observance of trends in the industry, information provided by our customers and information available from other outside sources, as appropriate. Our significant accounting policies include:

- o Inventories. Inventories are stated at the lower of cost or market, cost being determined on the first-in, first-out method. Reserves for slow moving and obsolete inventories are provided based on historical experience and current product demand. We evaluate the adequacy of these reserves quarterly.
- o Revenue recognition and accounts receivable. 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. We generally obtain purchase authorizations from our customers for a specified amount of product at a specified price and consider delivery to have occurred when the customer takes possession of the products. We provide our customers with a right of return. Revenue is recognized upon delivery of products and a reserve for sales returns is recorded. We have demonstrated the ability to make reasonable and reliable estimates of product returns in accordance with SFAS No. 48 and of allowances for doubtful accounts based on significant historical experience. Revenue from service sales is recognized when the service procedures have been completed or applicable milestones have been achieved. Revenue from research and development contracts is recognized over applicable contractual periods or as defined milestones are attained, as specified by each contract and as costs related to the contracts are incurred. Royalty revenue is recognized based on an estimate of sell-through of product based on prescriptions written, until such time that returns from wholesalers and pharmacies can be reasonably estimated.
- o Foreign currency translation. The financial position and results of operations of our foreign subsidiaries are measured using local currency as the functional currency. Assets and liabilities of each foreign subsidiary are translated at the rate of exchange in effect at the end of the period.



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Revenues and expenses are translated at the average exchange rate for the period. Foreign currency translation gains and losses are credited to or charged against other comprehensive income (loss). Foreign currency translation gains and losses arising from cash transactions are credited to or charged against current earnings.

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- o Drug licenses and related costs. Drug licenses and related costs incurred in connection with acquiring licenses, patents and other proprietary rights related to our commercially developed products are capitalized. Capitalized drug licenses and related costs are being amortized on a straight-line basis for periods not exceeding 15 years from the dates of acquisition. Carrying values of such assets are reviewed quarterly by comparing the carrying amounts to their estimated undiscounted cash flows and adjustments are made for any diminution in value.

### RESULTS OF OPERATIONS:

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THREE MONTHS ENDED JUNE 30, 2003 VERSUS THREE MONTHS ENDED JUNE 30, 2002  
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Net Product Sales. Net product sales increased by 69% from \$9,809,000 in the three months ended June 30, 2002 to \$16,596,000 in the three months ended June 30, 2003. The \$6,787,000 increase was primarily the result of our increased sales in the generic drug market in Spain. We anticipated the opportunities in the emerging generic drug market in Spain and began taking measures over four years ago to enter the Spanish generic drug market. We began to register, manufacture and market generic pharmaceutical products in Spain and began aligning our business model to be competitive in this arena, including hiring and training a new generic products sales force, submission of generic-equivalent products to the Spanish Ministry of Health for approval and a marketing campaign designed to position ourselves as a leader in the Spanish generic drug market. We experienced an increase in net sales of 37% in local currency in Spain in the three months ended June 30, 2003 compared to the same period of the prior year. An increase in the weighted average value of the Euro, in relation to the U.S. Dollar, had the effect of increasing revenues by approximately \$3,178,000 during the three months ended June 30, 2003.

Prices for prescription pharmaceuticals in Spain must be approved by the Ministry of Health. In order to control rising healthcare costs, substitution of generically equivalent products is often encouraged. In certain circumstances, local governments in Spain require that prescriptions for generic medications be filled using one of the three least expensive products on the market unless the prescription specifies a particular manufacturer's product. There can be no assurance that other local government agencies or the Ministry of Health will not adopt similar practices. These policies may have the effect of eroding gross margins, as sales of higher priced branded products may be replaced with sales of lower priced generic products. We are striving to maintain product sales and gross margins by concentrating our efforts on increasing sales volume, being competitive in the generic drug market, developing new products and increasing exports outside Spain.

Licensing and Collaboration Revenues. Licensing and collaboration revenues totaled \$158,000 in the three months ended June 30, 2003 and represent royalties from sales of Testim, the first product containing our CPE-215 technology to be marketed in the U.S.

**Gross Profit.** Gross profit increased by 77% from \$5,618,000 in the three months ended June 30, 2002 to \$9,935,000 in the three months ended June 30, 2003. The \$4,317,000 increase was the direct result of the growth in our net product sales, combined with U.S. royalty revenues. Our gross margins on net product sales in the three months ended June 30, 2003 totaled 59% compared to 57% for the same period in the prior year. We experienced an increase in gross profit of 45% in local currency in the three months ended June 30, 2003 compared to the same period of the prior year. An increase in the weighted average value of the Euro, in relation to the U.S. Dollar, had the effect of increasing gross profit by approximately \$1,796,000 during the three months ended June 30, 2003. Sales of generic products accounted for approximately 43% of our net product sales for the three months ended June 30, 2003. Although we expect to continue to benefit from economies of scale in the future as we grow, gross margins may decrease as sales of generic products, with lower margins, become more significant in the future. Additionally, the Ministry of Health in Spain levies a tax on pharmaceutical companies for the purpose of funding rising healthcare costs in Spain. In the three months ended June 30, 2003, this tax had the effect of reducing gross profit by approximately \$210,000 and gross margins by approximately 1 percentage point.

**Selling and Marketing Expenses.** Selling and marketing expenses increased by 39% from \$2,608,000 in the three months ended June 30, 2002 to \$3,626,000 in the three months ended June 30, 2003. The \$1,018,000 increase was instrumental in achieving a 69% increase in net product sales during the period, as a result of our successful sales and marketing programs. The increase in the weighted average value of the Euro, in relation to the U.S. Dollar, had the effect of increasing selling and marketing expenses by \$691,000 in the three months ended June 30, 2003. Selling and marketing expenses as a percentage of net product sales decreased to 22% in the three months ended June 30, 2003 compared to 27% of sales in the same period of the prior year.

**General and Administrative Expenses.** General and administrative expenses increased by 36% from \$1,315,000 in the three months ended June 30, 2002 to \$1,786,000 in the three months ended June 30, 2003. The \$471,000 increase was the result of increased general and administrative activities required to support our revenue growth in the current quarter. General and administrative expenses as a percent of total revenues decreased to less than 11% for the three months ended June 30, 2003, compared to more than 13% of total revenues for the same period of the prior year. General and administrative expenses would have been approximately \$202,000 lower in the three months ended June 30, 2003, absent the increase in the weighted average value of the Euro, in relation to the U.S. Dollar. We expect that our future expenditures for general and administrative expenses will continue to increase as we grow. Although we cannot reasonably estimate the total costs associated with implementation of the internal control provisions of the Sarbanes-Oxley Act of 2002, we are presently incurring costs and expect to incur additional costs not previously experienced; however, we do not believe that these costs will be material to our financial position, results of operations or cash flows.

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increased by 51% from \$583,000 in the three months ended June 30, 2002 to \$879,000 in the three months ended June 30, 2003. The \$296,000 increase was the result of pre-clinical programs underway in collaboration with universities and with product formulation and testing efforts being performed in the laboratory in our U.S. headquarters and at our facility in Zaragoza, Spain. We are using our U.S. laboratory to develop potential product applications using our drug delivery technologies. The expenditures in research and development reflect our focus on projects that are necessary for expansion of our portfolio of marketed products and clinical trials involving our drug delivery technologies. We expect that our future expenditures for research and development activities will continue to increase as a result of programs that are necessary to advance new applications of our technologies.

**Depreciation and Amortization Expenses.** Depreciation and amortization expenses increased by 38% from \$237,000 in the three months ended June 30, 2002 to \$328,000 in the three months ended June 30, 2003. The \$91,000 increase was primarily the result of higher depreciation charges with respect to recent asset additions and the effect of fluctuations in foreign currency exchange rates.

**Provision for Income Taxes.** We generated additional U.S. federal net operating loss carry-forwards in the three months ended June 30, 2003 and 2002 as a result of U.S. pretax losses of (\$976,000) and (\$651,000), respectively. However, since we are not assured of future profitable domestic operations, we have recorded a valuation allowance for any future tax benefit of such losses in the U.S. Therefore, no tax benefit has been recognized with respect to U.S. losses reported in the three months ended June 30, 2003 or 2002. We recorded a provision for foreign income taxes totaling \$1,805,000 (approximately 42% of the Spanish pretax income of \$4,310,000) for the three months ended June 30, 2003 compared to a provision for foreign income taxes of \$886,000 (approximately 43% of the Spanish pretax income of \$2,056,000) in the same period of the prior year. The provision for foreign income taxes for the current quarter would have been approximately \$371,000 lower than reported, absent the increase in the weighted average value of the Euro, in relation to the U.S. Dollar.

**Net Income.** We reported income from operations of \$3,316,000 for the three months ended June 30, 2003 compared to income from operations of \$1,395,000 (including \$520,000 of pre-tax gain on sale of drug licenses) in the same period of the prior year. The combination of income from operations of \$3,316,000 and the non-operating items, primarily the provision for foreign income taxes of \$1,805,000, resulted in net income of \$1,529,000, or \$.09 per basic common share (\$.07 per diluted common share) on 17,534,000 weighted average basic common shares outstanding (20,878,000 weighted average diluted common shares outstanding) for the three months ended June 30, 2003, compared to net income for the three months ended June 30, 2002 of \$519,000, or \$.03 per basic and diluted common share (on 16,823,000 weighted average basic common shares outstanding and 20,484,000 weighted average diluted common shares outstanding).

### SIX MONTHS ENDED JUNE 30, 2003 VERSUS SIX MONTHS ENDED JUNE 30, 2002

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**Net Product Sales.** Net product sales increased by 63% from \$18,866,000 in the six months ended June 30, 2002 to \$30,831,000 in the six months ended June 30, 2003. The \$11,965,000 increase was primarily the result of our increased sales in the generic drug market in Spain. We anticipated the opportunities in the emerging generic drug market in Spain and began taking measures over four years ago to enter the Spanish generic drug market. We began to register,

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manufacture and market generic pharmaceutical products in Spain and began aligning our business model to be competitive in this arena, including hiring and training a new generic products sales force, submission of generic-equivalent products to the Spanish Ministry of Health for approval and a marketing campaign designed to position ourselves as a leader in the Spanish generic drug market. We experienced an increase in net sales of 37% in local currency in Spain in the six months ended June 30, 2003 compared to the same period of the prior year. An increase in the weighted average value of the Euro, in relation to the U.S. Dollar, had the effect of increasing revenues by approximately \$5,032,000 during the six months ended June 30, 2003.

Prices for prescription pharmaceuticals in Spain must be approved by the Ministry of Health. In order to control rising healthcare costs, substitution of generically equivalent products is often encouraged. In certain circumstances, local governments in Spain require that prescriptions for generic medications be filled using one of the three least expensive products on the market unless the prescription specifies a particular manufacturer's product. There can be no assurance that other local government agencies or the Ministry of Health will not adopt similar practices. These policies may have the effect of eroding gross margins, as sales of higher priced branded products may be replaced with sales of lower priced generic products. We are striving to maintain product sales and gross margins by concentrating our efforts on increasing sales volume, being competitive in the generic drug market, developing new products and increasing exports outside Spain.

Licensing and Collaboration Revenues. Licensing and collaboration revenues totaled \$911,000 in the six months ended June 30, 2003. These revenues include royalties from sales of Testim, the first product containing our CPE-215 technology to be marketed in the U.S., milestone payments from collaboration agreements, and revenues generated from licensing agreements for certain of our existing products to market such products in other foreign markets.

Gross Profit. Gross profit increased by 71% from \$11,016,000 in the six months ended June 30, 2002 to \$18,802,000 in the six months ended June 30, 2003. The \$7,786,000 increase was the direct result of the growth in our net product sales, combined with our first significant U.S. royalty revenues. Our gross margins on net product sales in the six months ended June 30, 2003 totaled 58% compared to 57% for the same period of the prior year. We experienced an increase in gross profit of 45% in local currency in the six months ended June 30, 2003 compared to the same period of the prior year. An increase in the weighted average value of the Euro, in relation to the U.S. Dollar, had the effect of increasing gross profit by approximately \$2,832,000 during the six months ended June 30, 2003. Sales of generic products accounted for approximately 42% of our net product sales for the six months ended June 30, 2003. Although we expect to continue to benefit from economies of scale in the future as we grow, gross margins may decrease as sales of generic products, with lower margins, become more significant in the future. Additionally, the Ministry of Health in Spain levies a tax on pharmaceutical companies for the purpose of funding rising healthcare costs in Spain. In the six months ended June 30, 2003,

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this tax had the effect of reducing gross profit by approximately \$397,000 and gross margins by approximately 1 percentage point.

**Selling and Marketing Expenses.** Selling and marketing expenses increased by 34% from \$5,218,000 in the six months ended June 30, 2002 to \$6,979,000 in the six months ended June 30, 2003. The \$1,761,000 increase was instrumental in achieving a 63% increase in net product sales during the period, as a result of our successful sales and marketing programs. The increase in the weighted average value of the Euro, in relation to the U.S. Dollar, had the effect of increasing selling and marketing expenses by \$1,131,000 in the six months ended June 30, 2003. Selling and marketing expenses as a percentage of net product sales decreased to 23% in the six months ended June 30, 2003 compared to 28% of net product sales in the same period of the prior year.

**General and Administrative Expenses.** General and administrative expenses increased by 39% from \$2,409,000 in the six months ended June 30, 2002 to \$3,345,000 in the six months ended June 30, 2003. The \$936,000 increase was the result of increased general and administrative activities required to support our revenue growth in the six months ended June 30, 2003. General and administrative expenses as a percent of total revenues decreased to less than 11% in the six months ended June 30, 2003, compared to almost 13% of total revenues in the same period of the prior year. General and administrative expenses would have been approximately \$292,000 lower in the six months ended June 30, 2003, absent the increase in the weighted average value of the Euro, in relation to the U.S. Dollar. We expect that our future expenditures for general and administrative expenses will continue to increase as we grow. Although we cannot reasonably estimate the costs associated with implementation of the internal control provisions of the Sarbanes-Oxley Act of 2002, we are presently incurring costs and expect to incur additional costs not previously experienced; however, we do not believe that these costs will be material to our financial position, results of operations or cash flows.

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**Research and Development Expenses.** Research and development expenses increased by 41% from \$1,347,000 for the six months ended June 30, 2002 to \$1,897,000 for the six months ended June 30, 2003. The \$550,000 increase was the result of pre-clinical programs underway in collaboration with universities and with product formulation and testing efforts being performed in the laboratory in our U.S. headquarters and at our facility in Zaragoza, Spain. We are using our U.S. laboratory to develop potential product applications using our drug delivery technologies. The expenditures in research and development reflect our focus on projects that are necessary for expansion of our portfolio of marketed products and clinical trials involving our drug delivery technologies. We expect that our future expenditures for research and development activities will continue to increase as a result of programs that are necessary to advance new applications of our technologies.

**Depreciation and Amortization Expenses.** Depreciation and amortization expenses increased by 26% from \$484,000 for the six months ended June 30, 2002 to \$611,000 for the six months ended June 30, 2003. The \$127,000 increase was primarily the result of higher depreciation charges with respect to recent asset additions and the effect of fluctuations in foreign currency exchange rates.

**Provision for Income Taxes.** We generated additional U.S. federal net operating loss carry-forwards in the six months ended June 30, 2003 and 2002 as

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a result of U.S. pretax losses of (\$1,465,000) and (\$1,476,000), respectively. However, since we are not assured of future profitable domestic operations, we have recorded a valuation allowance for any future tax benefit of such losses in the U.S. Therefore, no tax benefit has been recognized with respect to U.S. losses reported in the six months ended June 30, 2003 or 2002. We recorded a provision for foreign income taxes totaling \$2,956,000 (approximately 40% of the Spanish pretax income of \$7,482,000) for the six months ended June 30, 2003 compared to a provision for foreign income taxes of \$1,483,000 (approximately 41% of the Spanish pretax income of \$3,613,000) in the same period of the prior year. The provision for foreign income taxes for the six months ended June 30, 2003 would have been approximately \$506,000 lower than reported, absent the increase in the weighted average value of the Euro, in relation to the U.S. Dollar.

**Net Income.** We reported income from operations of \$5,970,000 for the first half of 2003 compared to income from operations of \$2,150,000 (including \$592,000 of pre-tax gain on sale of drug licenses) in the first half of the prior year. The combination of income from operations of \$5,970,000 and the non-operating items, primarily the provision for foreign income taxes of \$2,956,000, resulted in net income of \$3,061,000, or \$.17 per basic common share (\$.15 per diluted common share) on 17,495,000 weighted average basic common shares outstanding (20,617,000 weighted average diluted common shares outstanding) for the six months ended June 30, 2003, compared to net income for the six months ended June 30, 2002 of \$654,000, or \$.04 per basic common share (\$.03 per diluted common share) on 15,735,000 weighted average basic common shares outstanding (19,204,000 weighted average diluted common shares outstanding).

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### LIQUIDITY AND CAPITAL RESOURCES:

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Total assets increased from \$64,692,000 at December 31, 2002 to \$77,992,000 at June 30, 2003, while stockholders' equity increased from \$48,751,000 at December 31, 2002 to \$55,432,000 at June 30, 2003. The increase in stockholders' equity reflects primarily net income of \$3,061,000 and the positive impact of the fluctuation of the Euro/U.S. dollar exchange rate, which totaled \$2,193,000.

Working capital decreased by \$972,000 or 3% from \$30,703,000 at December 31, 2002 to \$29,731,000 at June 30, 2003, primarily as a result of investing activities such as additions to fixed assets and purchase of intellectual property.

Cash, cash equivalents and marketable securities decreased by 6% or \$1,718,000 from \$26,977,000 at December 31, 2002 to \$25,259,000 at June 30, 2003, primarily as a result of additions to fixed assets totaling \$4,131,000, expenditures for drug licenses and related costs totaling \$2,054,000, increase in restricted cash of \$1,000,000 and net repayment of borrowings totaling \$179,000, partially offset by cash provided by operating activities of \$3,886,000 and proceeds from option and warrant exercises totaling \$962,000. Included in cash and cash equivalents at June 30, 2003 are approximately \$22,015,000 of short-term liquid investments considered to be cash equivalents.

Receivables increased by 59% from \$10,874,000 at December 31, 2002 to \$17,325,000 at June 30, 2003 as a direct result of the increase in net product sales. Receivables increased by approximately \$4,275,000 in local currency, but

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fluctuations in foreign currency exchange rates increased receivables reported in U.S. dollars by approximately \$1,377,000. We have not experienced any material delinquencies on our receivables that have had a material effect on our financial position, results of operations or cash flows. Inventories increased from \$5,133,000 at December 31, 2002 to \$5,563,000 at June 30, 2003, primarily as a result of fluctuations in foreign currency exchange rates, which increased inventories reported in U.S. dollars by approximately \$462,000. In local currency, inventories decreased by approximately \$34,000.

The combined total of accounts payable and accrued expenses increased from \$11,265,000 at December 31, 2002 to \$16,812,000 at June 30, 2003, primarily due to accruals for income taxes, taxes levied by the Ministry of Health in Spain to fund the rising healthcare costs and VAT taxes payable (approximately \$2,694,000), the net effect of fluctuations in foreign currency exchange rates (approximately \$1,449,000) and additions to fixed assets (approximately \$275,000).

Short-term borrowings and current portion of long-term debt increased from \$1,725,000 at December 31, 2002 to \$1,744,000 at June 30, 2003, as a result of the effect of fluctuations in foreign currency exchange rates, partially offset by net repayment of short-term borrowings. The weighted average interest rate on our short-term borrowings and current portion of long-term debt at June 30, 2003 was 4.1%.

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Long-term debt, which totaled \$345,000 at December 31, 2002, was reduced to \$322,000 during the six months ended June 30, 2003. The weighted average interest rate (including imputed interest) on our long-term debt was 5.6%.

In addition to our short-term borrowings and long-term debt, we have fixed contractual obligations under various lease agreements. Our contractual obligations were comprised of the following as of June 30, 2003:

| CONTRACTUAL OBLIGATIONS                                  | TOTAL    | PAYMENTS DUE BY PERIOD |                |
|--|----------|------------------------|----------------|
|  |          | LESS THAN 1 YEAR       | 1-3 YEARS      |
|  |          |                        |                |
|  |          |                        | (in thousands) |
| Short-term borrowings.....                               | \$ 1,606 | \$ 1,606               | \$ -           |
| Long-term debt, including imputed interest of \$105..... | 550      | 138                    | 98             |
| Operating leases.....                                    | 2,259    | 873                    | 1,386          |
|  | -----    | -----                  | -----          |
| Total contractual cash obligations.....                  | \$ 4,415 | \$ 2,617               | \$ 1,484       |
|  | =====    | =====                  | =====          |

Operating activities for the six months ended June 30, 2003 provided net cash of \$3,886,000. Investing activities, primarily the purchase of our corporate office/research and development facility in the U.S. and pharmaceutical manufacturing equipment in Spain and additions to drug licenses

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and related costs used net cash of \$6,094,000 during the six months ended June 30, 2003. Financing activities, consisting of proceeds received from the exercise of stock options and warrants (approximately \$962,000), were offset by cash deposited in a restricted cash account (\$1,000,000) and net repayments of borrowings (approximately \$179,000) during the six months ended June 30, 2003.

Auxilium Pharmaceuticals, Inc. launched its new testosterone replacement gel, Testim, which contains our patented CPE-215 drug delivery technology, during the first quarter of 2003. Auxilium paid a milestone payment to us during the first quarter of 2003, which we recorded as licensing and collaboration revenues in the three months ended March 31, 2003. In connection with the Testim product launch, Bentley began earning royalty revenues on a percentage of Testim sales as defined in the licensing agreement with Auxilium. Royalty revenue on Testim product sales is recognized based on an estimate of Auxilium's sell-through of the Testim product based on prescriptions written, until such time that returns from wholesalers and pharmacies can be reasonably estimated. For the six months ended June 30, 2003, we recognized royalty revenue of \$208,000 based on an estimate of prescriptions written. The \$586,000 difference between the total amount due from Auxilium under the royalty arrangement and the amount recognized as royalty revenue has been recorded as deferred income in the Consolidated Balance Sheet as of June 30, 2003. We will continue to use available market information to determine the amount and timing of royalty revenue recognition.

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

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

**Liquidity.** We plan to continue making improvements to our manufacturing facility in 2003 including the acquisition of additional manufacturing equipment, in order to accommodate our continuing growth. We expect these improvements to total approximately \$4,337,000 during the balance of 2003. Additionally, we purchased a 15,700 square foot commercial building situated on approximately 14 acres of land in Exeter, New Hampshire in January 2003. We moved our corporate headquarters and research and development laboratory into this facility in April 2003. We paid approximately \$1,776,600 cash for the property and spent approximately \$175,000 in order to expand our research and development facility and add necessary research equipment. Given our current liquidity and cash balances, and considering our future strategic plans (including our planned capital improvements and equipment purchases), we should have sufficient liquidity to fund operations for at least the next twenty-four months. As mentioned above, we have cash, cash equivalents and short-term liquid investments totaling approximately \$25,259,000 as of June 30, 2003. We also have outstanding at June 30, 2003 warrants, including our publicly traded Class B Warrants, to purchase approximately 3,147,000 shares of Common Stock. There can be no assurance that any of the warrants will be exercised prior to expiration; however, if all warrants that are currently outstanding are exercised, we would receive aggregate cash proceeds of approximately \$14,633,000. On October 14, 2002, our Board of Directors extended the expiration date of our Class B warrants from December 31, 2002 to December 31, 2003. Two Class B Redeemable Warrants, together, entitle a holder, until December 31, 2003, to purchase one



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share of Common Stock at a price of \$5.00 per share. There can be no assurance, however, that changes in our research and development plans, capital expenditures or other events affecting our net product sales or operating expenses will not result in the earlier depletion of our funds. We continue to explore alternative sources for financing our business activities. In appropriate situations, that 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.

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### NEW ACCOUNTING PRONOUNCEMENTS

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In December 2002, the Financial Accounting Standards Board issued Interpretation No. 45, Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others ("FIN 45"). FIN 45 elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under certain guarantees that it has issued. It also clarifies that a guarantor is required to recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. We have adopted the disclosure requirements of FIN 45 as of December 31, 2002 and determined that no additional disclosures were required. In addition, we are required to adopt the initial recognition and measurement of the fair value of the obligation undertaken in issuing the guarantee on a prospective basis to guarantees issued or modified after December 31, 2002. The adoption of FIN 45 has not had, nor do we expect it to have, a material effect on our financial position, results of operations or cash flows.

In November 2002, the Emerging Issues Task Force ("EITF") issued EITF Issue No. 00-21, Accounting for Revenue Arrangements with Multiple Deliverables. EITF Issue No. 00-21 addresses certain aspects of the accounting by a vendor for arrangements under which it will perform multiple revenue-generating activities. EITF Issue No. 00-21 establishes three principles: revenue arrangements with multiple deliverables should be divided into separate units of accounting, arrangement consideration should be allocated among the separate units of accounting based on their relative fair values, and revenue recognition criteria should be considered individually for each separate unit of accounting. EITF Issue No. 00-21 is effective for all revenue arrangements entered into in fiscal periods beginning after June 15, 2003, with early adoption permitted. We do not believe EITF Issue No. 00-21 will have a material effect on our financial position, results of operations or cash flows.

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### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Foreign Currency. A substantial amount of our business is conducted in Europe and is therefore influenced to the extent to which there are fluctuations in the U.S. Dollar's value against other currencies, specifically the Euro. The

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exchange rate at June 30, 2003 and December 31, 2002 was .88 Euros and .95 Euros per U.S. Dollar, respectively. The weighted average exchange rate for the three months ended June 30, 2003 and 2002 was .88 Euros and 1.09 Euros per U.S. Dollar, respectively. The weighted average exchange rate for the six months ended June 30, 2003 and 2002 was .91 Euros and 1.11 Euros per U.S. Dollar, respectively. The effect of foreign currency fluctuations on long lived assets for the six months ended June 30, 2003 was an increase of \$2,193,000 and the cumulative historical effect on equity was an increase of \$1,777,000, as reflected in our Consolidated Balance Sheets as accumulated other comprehensive income. Although exchange rates fluctuated significantly in recent years, we do not believe that the effect of foreign currency fluctuation is material to our results of operations as the expenses related to much of our foreign currency revenues are in the same currency as such revenues. However, the carrying value of assets and reported values can be materially impacted by foreign currency translation, as can the translated amounts of revenues and expenses. Nonetheless, we do not plan to modify our business practices.

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 Spain, currency rate fluctuations in the future could have a significant impact on us. However, at the present time, we do not anticipate altering our business plans and practices to compensate for future currency fluctuations.

**Interest Rates.** The weighted average interest rate on our short-term borrowings and current portion of long-term debt is 4.1% and the balance outstanding is \$1,744,000 as of June 30, 2003. A portion of our long-term borrowings is non-interest bearing and the balance outstanding on these borrowings at June 30, 2003 is \$412,000 including imputed interest (ranging from 4.8% to 6.0%) of \$105,000. The weighted average interest rate on our long-term borrowings is 5.6%. The effect of an increase in the interest rate of one percentage point (one hundred basis points) to 5.1% on short-term borrowings and to 6.6% on long-term borrowings would have the effect of increasing interest expense by approximately \$22,000 annually.

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### ITEM 4. CONTROLS AND PROCEDURES

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

As of June 30, 2003, Bentley carried out an evaluation, under the supervision and with the participation of Bentley's management, including the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of Bentley's disclosure controls and procedures pursuant to Exchange Act Rule 13a-14. Based on that evaluation, Bentley's Chief Executive Officer and Chief Financial Officer concluded that Bentley's disclosure controls and procedures are effective in timely alerting them to material information relating to Bentley (including its consolidated subsidiaries) which is required to be included in its publicly filed reports or

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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. There have been no significant changes in Bentley's internal controls or in other factors which could significantly affect internal controls since that evaluation.

CAUTIONARY STATEMENTS FOR PURPOSES OF THE "SAFE HARBOR" PROVISIONS OF THE  
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PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995  
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The statements contained in this Quarterly Report on Form 10-Q, which are not historical facts contain forward looking information with respect to plans, projections or future performance of Bentley Pharmaceuticals, the occurrence of which involve certain risks and uncertainties that could cause our actual results to differ materially from those expected by Bentley, including but not limited to risks associated with identifying suitable drugs for combination with our drug delivery technologies, expanding generic and branded drug operations, development and commercialization of our products, relationships with our strategic partners, uncertainty of clinical trials results, regulatory approval process, product sales concentration, unpredictability of patent protection, technological changes, the effect of economic conditions, and other uncertainties detailed in Bentley's Annual Report on Form 10-K (SEC File No. 1-10581) for the year ended December 31, 2002.

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PART II. OTHER INFORMATION  
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ITEM 1. LEGAL PROCEEDINGS

See Item 1. Legal Proceedings in our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2003.

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

ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

As noted in Item 4. below, at our Annual Meeting of Stockholders on May 21, 2003, the Company's stockholders approved an increase in the number of authorized shares of the Company's Common Stock from 35,000,000 to 100,000,000. This increase does not affect the rights of the holders of currently outstanding Common Stock, except for the effects incidental to increasing the number of share of Common Stock outstanding should additional shares be issued, such as dilution of the earnings per share and voting rights of the holders of currently outstanding Common Stock. The Company has no immediate plans, arrangements, commitments or understandings with respect to the issuance of any additional shares of Common Stock authorized by this increase.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

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Our Annual Meeting of Stockholders was held on May 21, 2003 for the purpose of electing three directors, approving an increase in the number of authorized shares of the Company's Common Stock, and approving increases in the number of shares authorized for issuance under the Company's 2001 Employee Stock Option Plan and 2001 Directors' Stock Option Plan. Proxies for the meeting were solicited pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, and there was no solicitation in opposition.

The following members were elected to our Board of Directors.

| NOMINEE          | TERM EXPIRING | SHARES VOTED FOR | SHARES VOTED AGAINST |
|------------------|---------------|------------------|----------------------|
| Michael McGovern | 2006          | 15,731,798       | 576,226              |
| Michael D. Price | 2006          | 15,731,796       | 576,228              |
| John W. Spiegel  | 2006          | 15,731,698       | 576,326              |

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Directors whose terms of office continued after the meeting are as follows:

| NAME               | TERM EXPIRING |
|--------------------|---------------|
| Miguel Fernandez   | 2005          |
| James R. Murphy    | 2005          |
| Robert M. Stote    | 2005          |
| Charles L. Bolling | 2004          |
| Robert J. Gyurik   | 2004          |
| William A. Packer  | 2004          |

The proposal to increase the number of authorized shares of the Company's Common Stock to 100,000,000 was approved by the following vote:

| SHARES VOTED FOR | SHARES VOTED AGAINST | SHARES ABSTAINING |
|------------------|----------------------|-------------------|
| 13,265,822       | 3,020,019            | 20,983            |

The proposal to increase the number of shares authorized for issuance under the Company's 2001 Employee Stock Option Plan by 1,500,000 was approved by the following vote:

| SHARES VOTED FOR | SHARES VOTED AGAINST | SHARES ABSTAINING |
|------------------|----------------------|-------------------|
| 8,883,519        | 3,268,876            | 71,294            |

The proposal to increase the number of shares authorized for issuance under the Company's 2001 Directors' Stock Option Plan by 500,000 was approved by the following vote:

| SHARES VOTED FOR | SHARES VOTED AGAINST | SHARES ABSTAINING |
|------------------|----------------------|-------------------|
| 8,677,467        | 3,503,861            | 42,353            |

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits:

- 3.1 Certificate of Amendment of Restated Certificate of Incorporation.
- 31.1 Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certification of the Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification of the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(b) Reports on Form 8-K filed during the quarter ended June 30, 2003:

The Company furnished a Current Report on Form 8-K dated April 29, 2003, announcing earnings for the quarter ended March 31, 2003 and attaching a press release related thereto.

All other items required in Part II have been previously filed or are not applicable for the quarter ended June 30, 2003.

SIGNATURES

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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.

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Registrant

July 31, 2003

By: /s/ James R. Murphy

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James R. Murphy

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Chairman, President and Chief Executive Officer  
(Principal Executive Officer)

July 31, 2003

By: /s/ Michael D. Price

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