BENTLEY PHARMACEUTICALS INC
Form 10-Q
November 05, 2001

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 September 30, 2001

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

65 Lafayette Road, 3rd Floor, North Hampton, NH 03862
(Current Address of Principal Executive Offices)

Registrant's telephone number, including area code: (603) 964-8006

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 ----

The number of shares of the registrant's common stock outstanding as of November 1, 2001 was 14,584,360.

BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES

FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2001

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BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

(IN THOUSANDS)	(UNAUDITED) SEPTEMBER 30 2001
ASSETS	
Current assets:	
Cash and cash equivalents	$4,689
Receivables, net	5,882
Inventories, net	2,504
Deferred taxes	-

Prepaid expenses and other	685
Total current assets	13,760
Non-current assets:	
Fixed assets, net	4,969
Drug licenses and related costs, net	10,526
Receivables from related parties	484
Other non-current assets, net	145
Total non-current assets	16,124
	$29,884

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:	
Accounts payable	$3,105
Accrued expenses	1,471
Short-term borrowings	2,047
Current portion of long-term debt	-
Deferred income	50
Total current liabilities	6,673
Non-current liabilities:	
Taxes payable	1,821
Long-term debt	-
Other non-current liabilities	98
Total non-current liabilities	1,919
Commitments and contingencies	
Stockholders' equity:	
Preferred stock, $1.00 par value, authorized 2,000 shares, issued and outstanding, zero shares	-
Common stock, $.02 par value, authorized 35,000 shares, issued and outstanding, 14,584 and 13,914 shares	292
Stock purchase warrants (to purchase 3,424 and 4,038 shares of common stock)	433
Additional paid-in capital	97,465
Accumulated deficit	(73,769)
Accumulated other comprehensive loss	(3,129)
Total stockholders' equity	21,292
	$29,884

The accompanying unaudited Notes to Consolidated Financial Statements are an integral part

BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS AND OF COMPREHENSIVE INCOME (
(unaudited)

(in thousands, except per share data)	For the Three Months Ended September 30,		F E
	2001	2000	2
Net sales	$6,316	$3,626	$18,
Cost of sales	2,708	1,483	7,
Gross profit	3,608	2,143	10,
Operating expenses:			
Selling, general and administrative	2,910	2,243	9,
Research and development	468	233	1,
Depreciation and amortization	223	143	
Total operating expenses	3,601	2,619	11,
Gain on sale of drug licenses	113	-	5,
Income (loss) from operations	120	(476)	4,
Other income (expenses):			
Interest income	30	85	
Interest expense	(61)	(46)	(
Other income (expense), net	7	-	
Income (loss) before income taxes	96	(437)	4,
Provision (benefit) for foreign income taxes	245	(18)	2,
Net income (loss)	($149)	($419)	$1,
Net income (loss) per common share:			
Basic	($0.01)	($0.03)	$0
Diluted	($0.01)	($0.03)	$0
Weighted average common shares outstanding:			
Basic	14,308	13,662	14,
Diluted	14,308	13,662	15,
Net income (loss)	($149)	($419)	$1,
Other comprehensive income (loss):			
Foreign currency translation gains (losses)	978	(599)	(
Comprehensive income (loss)	$829	($1,018)	$1,

The accompanying unaudited Notes to Consolidated Financial Statements are an integral part o

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

(in thousands)

	$.02 Par Value Common Stock		Additional Paid-In	Accumu- lated	A Ot
	Shares	Amount	Capital	Deficit	he
Balance at December 31, 2000	13,914	$278	$95,227	($75,693)	
Exercise of stock options/warrants	171	4	443	-	
Exercise of underwriter's warrants	460	9	1,570	-	
Common Stock issued as compensation	39	1	225	-	
Foreign currency translation adjustments, net	-	-	-	-	
Net income	-	-	-	1,924	
Balance at September 30, 2001	14,584	$292	$97,465	($73,769)	

The accompanying unaudited Notes to Consolidated Financial Statements are an integral part

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

(in thousands)

Cash flows from operating activities:
 Net income (loss)
 Adjustments to reconcile net income (loss) to
    net cash provided by (used in) operating activities:
    Depreciation and amortization
    Equity-based compensation expense
    Other non-cash items
    Deferred income and taxes
      (Increase) decrease in assets and increase (decrease) in liabilities:
        Receivables
        Inventories

Prepaid expenses and other current assets
Other assets
Accounts payable and accrued expenses
Other liabilities

Net cash provided by (used in) operating activities

Cash flows from investing activities:
Additions to fixed assets
Additions to drug licenses and related costs
Deferred income
Proceeds from sale of investments
Purchase of investments
VAT receivable
Receivables from related parties

Net cash used in investing activities

(Continued on following page)

The accompanying unaudited Notes to Consolidated Financial Statements are an integral part

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

(in thousands)

Cash flows from financing activities:
Proceeds from exercise of stock options/warrants
Proceeds from borrowings
Repayments of borrowings
Payments on capital leases

Net cash provided by financing activities

Effect of exchange rate changes on cash

Net decrease in cash and cash equivalents

Cash and cash equivalents at beginning of period

Cash and cash equivalents at end of period

SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION
The Company paid cash during the period for (in thousands):

Interest

Income taxes

SUPPLEMENTAL DISCLOSURES OF NON-CASH FINANCING ACTIVITIES

The Company has issued or is obligated to issue Common Stock in exchange for services as follows (in thousands):

Number of shares

Amount

During the nine months ended September 30, 2000, 7,254 debentures with principal amount of $7,254,000, net of discount of $1,585,000 (and applicable unamortized debt issuance costs totaling $929,000) were converted into approximately 2,901,000 shares of Common Stock.

The accompanying unaudited Notes to Consolidated Financial Statements are an integral part o

BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

HISTORY AND OPERATIONS:

Bentley Pharmaceuticals, Inc. and its Subsidiaries (the "Company") is a U.S.-based international pharmaceutical and drug delivery company specializing in the development of products based upon innovative and proprietary drug delivery systems. The Company also has a commercial presence in Europe, where it manufactures, markets and distributes branded and generic pharmaceutical products. The Company owns rights to certain U.S. and international patents and related technology covering methods to enhance the absorption of drugs delivered through biological tissues. The Company is developing this technology and is targeting U.S., European and other international markets for the new product applications. The Company is in negotiations with larger pharmaceutical companies with the objective of entering into collaborations for the development and marketing of various product applications, including: for the treatment of onychomycosis, delivery of insulin, hormone replacement therapies, vaccines and peptides. In Spain, the Company develops and registers late stage products, and manufactures, packages and distributes both its own and other companies' pharmaceutical products.

The strategic focus of the Company has shifted in response to the evolution of the global health care environment. The Company emphasizes product distribution

in Spain, strategic alliances and product acquisitions. Its overall strategy has been expanded due to the 1999 acquisition of permeation enhancement technology, with the objective of entering into strategic partnerships and/or alliances that are anticipated to lead to milestone payments and royalty arrangements, with the strategic partners bearing the majority of development costs. Since this technology is based on a series of GRAS (Generally Recognized As Safe) compounds, products may be developed in a quicker and less costly fashion. The technology facilitates the permeation of drugs administered through skin, across mucosa or through the cornea in a variety of independent pharmaceutical formats. The excipient most advanced in facilitating absorption is referred to by the Company as CPE-215(R), although there are a number of other related compounds under the same patents that also have enhancing characteristics.

The Company began taking measures over three years ago to enter the Spanish generic drug market. The Company created a wholly-owned subsidiary to register, market and distribute generic pharmaceutical products in Spain and began aligning its business model to be competitive in this arena. In July 2000, the Company also entered into a strategic alliance with Teva Pharmaceutical Industries, Ltd., whereby the Company will initially receive licenses to more than 75 of Teva's products for registration and marketing in Spain. Teva will supply the pharmaceutical products to the Company and the Company's Spanish subsidiaries, Laboratorios Belmac and Laboratorios Davur, will market the products in Spain. Teva was also granted a right of first refusal to acquire Laboratorios Davur in the event that the Company decides to divest that subsidiary.

BASIS OF CONSOLIDATED FINANCIAL STATEMENTS:

The consolidated financial statements of the Company, at September 30, 2001 and 2000 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 in so far as such information was disclosed in the Company's consolidated financial statements for the year ended December 31, 2000. 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 the Company's Annual Report on Form 10-K for the year ended December 31, 2000.

In the opinion of management, the accompanying unaudited consolidated financial statements for the period ended September 30, 2001 and 2000 are presented on a basis consistent with the audited consolidated financial statements for the year ended December 31, 2000 and contain all adjustments, consisting only of normal recurring adjustments, necessary to present fairly the Company's financial position as of September 30, 2001 and the results of its operations and its cash flows for the nine months ended September 30, 2001 and 2000. The results of operations for the nine months ended September 30, 2001 should not necessarily be considered indicative of the results to be expected for the year.

CASH AND CASH EQUIVALENTS:

Included in cash and cash equivalents at September 30, 2001 and December 31, 2000 are approximately $3,610,000 and $4,126,000, 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.

INVENTORIES:

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

	September 30, 2001	December 31, 2000
Raw materials	$1,382	$692
Finished goods	1,178	1,196
	2,560	1,888
Less allowance for slow moving inventory	(56)	(61)
	$2,504	$1,827

SALE OF CONTROLVAS(R):

Laboratorios Belmac, S.A., a subsidiary of the Company, sold the trademark, registration rights and dossier for its branded pharmaceutical product, Controlvas(R), for approximately $5,148,000 during the nine months ended September 30, 2001. The Company entered into an agreement to sell Controlvas(R) and received a 50% deposit from the purchaser in November 2000, which was reflected as Deferred income in the Consolidated Balance Sheet as of December 31, 2000. The resulting gain of approximately $4,977,000 has been recognized in the Consolidated Statement of Operations for the nine months ended September 30, 2001.

SALE OF AMANTADINE(R):

In June 2001, Laboratorios Belmac, S.A., a subsidiary of the Company, agreed to sell the trademark, registration rights and dossier for its pharmaceutical product, Amantadine(R), to a third party for 30 million Spanish pesetas (approximately $153,000). The Company received a deposit of 11 million Spanish pesetas (approximately $56,000) from the purchaser in June 2001, which was reflected as Deferred income in the Consolidated Balance Sheet as of June 30, 2001. The Company received a second payment of 11 million Spanish pesetas upon approval of the transfer of the rights to the purchaser by the Spanish Ministry of Health, which occurred during the quarter ended September 30, 2001, resulting in a recognized gain of approximately $113,000. The remaining 8 million Spanish pesetas (approximately $41,000) is payable over the next five years, in the form of a royalty arrangement.

LICENSING ACTIVITIES:

During the second quarter of 2001, the Company entered into agreements with Auxilium A2, Inc. regarding a new non-oral delivery formulation of a narcotic for pain management and a new topical product for hormone replacement therapy, both in combination with the Company's CPE-215(R) technology. The Company received $50,000 upon entering into such agreements, which has been reflected as Deferred income in the Consolidated Balance Sheets as of September 30, 2001. The Company expects to receive additional payments based upon completion of specific milestones and scaled royalties on net sales.

STOCKHOLDERS' EQUITY:

As a result of the continuing uncertainties in the stock markets and unfavorable

capital market conditions, on March 30, 2001 the Company's board of directors extended the expiration date of all of the Company's outstanding Class B Warrants from August 14, 2001 to December 31, 2002. Two Class B Warrants, together, entitle the holder to purchase one share of the Company's Common Stock at a price of $5.00 per share. The Class B Warrants are redeemable by the Company for $.05 each upon 30 day's written notice, after the closing price of the Company's Common Stock equals or exceeds $6.50 for the preceding twenty consecutive trading days. These Class B Warrants were included as a component of a Unit offering in February 1996. This extension was considered to be a modification of the terms of the 1996 offering; however, because such warrants are investor warrants and could only be settled in cash, there was no impact on the Company's consolidated financial statements as a result of the modification.

PROVISION FOR INCOME TAXES:

The Company recorded a provision for foreign income taxes totaling $245,000 and $2,298,000 for the three and nine months ended September 30, 2001, respectively, as a result of reporting taxable income for tax purposes in Spain, including the capital gains tax arising from the sale of Controlvas(R) and Amantadine(R). This amount differs from the amount computed by applying the U.S. federal income tax rate of 34% to pretax income primarily as a result of the change in the valuation allowance to offset domestic deferred tax assets and certain nondeductible expenses in Spain.

BASIC AND DILUTED INCOME (LOSS) PER COMMON SHARE:

Basic and diluted net income (loss) per common share is presented in accordance with SFAS No. 128, "Earnings per Share".

Basic and diluted net income (loss) per common share is based on the weighted average number of shares of common stock outstanding during each period. The effect of the Company's outstanding stock options and stock purchase warrants were considered in the diluted income per share calculation for the nine months ended September 30, 2001. The effect of outstanding stock options and stock purchase warrants were not considered for the three months ended September 30, 2001 and 2000, and the nine months ended September 30, 2000 because the results would have been anti-dilutive.

The following is a reconciliation between basic and diluted net income per common share for the nine months ended September 30, 2001. Dilutive securities issuable for the nine months ended September 30, 2001 include approximately 439,000 shares issuable as a result of Class B Warrants and approximately 1,091,000 shares issuable as a result of various stock options and warrants outstanding.

(in thousands, except per share data)

For the Nine Months Ended September 30, 2001:

	Basic EPS	Effect of Dilutive Securities	Diluted EPS .
Net Income	$1,924	---	$1,924
Number of Common Shares	14,064	1,530	15,594
Net Income Per Common Share	$ .14	($ .02)	$ .12

COMMITMENTS AND CONTINGENCIES:

On January 22, 2001, the Company settled a legal dispute, by paying $140,000 to Creative Technologies, Inc. and Creative Technologies, Inc. agreed to the dismissal of the related suit with prejudice. Creative Technologies had asserted that it was due a brokerage or finder's fee with respect to the Company's 1999 acquisition of permeation enhancement technology. The Company included the accrual for the $140,000 charge in the Consolidated Balance Sheet as of December 31, 2000 and included the $140,000 charge and related legal costs of approximately $55,000 in operating expenses in the Consolidated Statements of Operations for the year ended December 31, 2000.

The Company was awarded a judgment of approximately $2,130,000 during the year ended December 31, 1998, relating to the Company's claims of civil theft and breach of employment agreement filed against its former President and Chief Executive Officer, Michael M. Harshbarger, in 1993. The judgment included treble damages totaling $418,000 related to its civil theft claim and $1,712,000 related to its breach of employment agreement claim. In addition to establishing a receivable on its books, the Company has established a reserve equal to the receivable. Harshbarger filed a Motion for Relief From Judgment in September 1999, alleging among other things that he was not provided notice of the August 24, 1998 jury trial. Discovery is ongoing and a hearing has been set for November 27, 2001 to determine the merits of Harshbarger's claims. In the opinion of management, the outcome is expected to have no adverse material effect on the consolidated financial statements of the Company.

RECLASSIFICATIONS:

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

NEW ACCOUNTING PRONOUNCEMENTS:

Statement of Financial Accounting Standards (SFAS) No. 133 "Accounting for Derivative Instruments and Hedging Activities" was issued in June 1998 and establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts (collectively referred to as derivatives) and for hedging activities. It requires that an entity recognize all derivatives as either assets or liabilities in the balance sheet and measure these instruments at fair value. The accounting for changes in the fair value of a derivative (that is, gains and losses) depends upon the intended use of the derivative and resulting designation if used as a hedge. The Company adopted SFAS No. 133, as amended, on January 1, 2001. The adoption of SFAS No. 133 did not have any impact on the Company's consolidated financial statements.

On June 29, 2001, SFAS No. 141, "Business Combinations" was approved by the Financial Accounting Standards Board (FASB). SFAS No. 141 requires that the purchase method of accounting be used for all business combinations initiated after June 30, 2001. Goodwill and certain intangible assets will remain on the balance sheet and not be amortized. On an annual basis, and when there is reason to suspect that their values have been diminished or impaired, these assets must be tested for impairment, and write-downs may be necessary. The Company implemented SFAS No. 141 on July 1, 2001. The adoption of SFAS No. 141 did not have any impact on the Company's consolidated financial statements.

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On June 29, 2001, SFAS No. 142, "Goodwill and Other Intangible Assets" was approved by the FASB. SFAS No. 142 changes the accounting for goodwill from an amortization method to an impairment-only approach. Amortization of goodwill, including goodwill recorded in past business combinations, will cease upon adoption of this statement. The Company is required to implement SFAS No. 142 on January 1, 2002 and it has not determined the impact, if any, that this statement will have on its consolidated financial statements.

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BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES
MANAGEMENT'S DISCUSSION AND ANALYSIS OF
FINANCIAL CONDITION AND RESULTS OF OPERATIONS

RESULTS OF OPERATIONS:

Three Months Ended September 30, 2001 versus Three Months Ended September 30, 2000

The Company reported net sales of $6,316,000 and a net loss of $149,000 or $.01 per basic and diluted common share for the three months ended September 30, 2001 compared to net sales of $3,626,000 and a net loss of $419,000 or $.03 per basic and diluted common share for the same period in the prior year.

The Company's Spanish subsidiaries, Laboratorios Belmac S.A. and Laboratorios Davur S.L., reported an increase in net sales of 79% in local currency for the three months ended September 30, 2001 compared to the same period of the prior year; however, a 2% decline in the value of the Spanish Peseta and related Euro negatively impacted net sales by $92,000, resulting in net sales generated in Spain of $6,316,000, or an increase of 76% over the prior year, when expressed in U.S. dollars. The Company anticipated the opportunities that the emerging generic drug market in Spain present and began taking measures over three years ago to enter the Spanish generic drug market. The Company, through its wholly-owned subsidiaries, began to register, market and distribute generic pharmaceutical products in Spain and began aligning its 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 the Company as a leader in the Spanish generic drug market. The increase in net sales is primarily attributable to this effort. Sales of the product, Controlvas(R), which accounted for approximately $513,000 of third quarter 2000 net sales, were eliminated in the third quarter of 2001 as a result of the Company's divestiture of the related drug license during the first quarter of 2001. Net sales for the three months ended September 30, 2000 included $40,000 related to research and formulation activities performed in the United States.

Gross margins for the three months ended September 30, 2001 decreased to 57%

compared to gross margins of 59% in the same period of the prior year, primarily as a result of the mix of products sold as well as higher depreciation charges resulting from the Company's recent renovations and improvements at its manufacturing facility. Approximately 35% of the Company's net sales during the three months ended September 30, 2001 were generic product sales, which typically have lower sales prices and gross margins than branded products. In comparison, the Company sold no generic drug products during the third quarter of the prior year. As generic product sales become more significant in the future, gross margins may continue to decrease. The Ministry of Health and the Pharma Industry in Spain had entered into a two-year agreement that expired in December 1999 whereby pharmaceutical companies in Spain, including the Company's Spanish subsidiaries, were taxed on their growth as a vehicle for funding rising health care costs in Spain. A new agreement was reached in March 2001, which also had the effect of reducing gross margins by approximately $45,000, or one percentage point, for the three months ended September 30, 2001.

The Company entered into a strategic alliance with Teva Pharmaceutical Industries, Ltd. in July 2000, whereby the Company, through its Spanish subsidiaries, has received the right to register and market in Spain more than 75 of Teva's products. The products are comprised of both branded and generic forms. Sales from the products are expected to begin gradually, but will progress over the next two to three years. An investment in additional sales representatives will be required, along with an increase in regulatory activities, both of which may create a short term decrease in the Company's earnings. The Company, through its subsidiary Laboratorios Davur, has also submitted registrations to the Spanish Ministry of Health for generic versions of various products, in response to growing interest in generic drug products in Spain. The Company believes that resulting gross margins may be lower on sales of such products. The Company's decision to enter the generic drug market was based on its objectives to remain competitive, grow sales and market share, and ultimately achieve profitability.

Selling, general and administrative expenses increased by $667,000 or 30%, to $2,910,000 for the three months ended September 30, 2001 compared to $2,243,000 for the same period of the prior year. Selling, general and administrative expenses, as a percentage of net sales, decreased from 62% of third quarter 2000 net sales to 46% of third quarter 2001 net sales. A significant portion (70% or $2,030,000) of these third quarter 2001 expenses are selling and marketing expenses, which are necessary for the Company to maintain and grow sales and market share in Spain. Selling and marketing expenses increased by $534,000, or 36%, over the same period of the prior year, and as a percent of net sales, decreased from 41% in the third quarter of 2000 to 32% in the third quarter of 2001, primarily as a result of sales and marketing programs designed to introduce the Company's new generic drug products and support the launches of such products in an attempt to promote product awareness and market share. The 2% decline in the value of the Spanish peseta and related Euro, in relation to the U.S. dollar, during the period, had the effect of reducing selling and marketing expenses by $30,000 for the three months ended September 30, 2001. General and administrative expenses increased by 18% from $747,000 in the third quarter of 2000 to $880,000 in the third quarter of 2001, decreasing from 21% of third quarter 2000 net sales to 14% of third quarter 2001 net sales. The 2% decline in the value of the Spanish peseta and related Euro, in relation to the U.S. dollar, during the period, had the effect of reducing general and administrative expenses by $7,000 for the quarter ended September 30, 2001. The Company intends to continue its efforts to carefully manage general and administrative expenses.

The Company reported research and development expenses of $468,000 for the three months ended September 30, 2001, which are slightly more than double the research and development expenses of $233,000 for the same period of the prior year. The increase in the Company's costs for research and development is primarily the result of costs associated with ongoing Phase I Clinical Studies (treatment of nail fungal infections), pre-clinical programs underway in collaboration with universities and with product formulation and testing efforts being performed in the laboratory in the Company's U.S. headquarters, located in New Hampshire, and at the Company's facility in Zaragoza, Spain. The U.S. laboratory is being used by the Company to develop potential product applications using its permeation enhancement technology. The limited expenditures in research and development reflect the Company's direction of its resources toward projects that are necessary for expansion of its portfolio of marketed products and clinical trials involving its drug delivery technology, the results of which should assist

potential collaborators in the evaluation process. The Company intends to continue to carefully manage its research and development expenditures in order to ensure that its development programs are efficient and cost effective and seeks funding of certain of its research and development by collaborative partners, however, the Company does expect that its future expenditures for research and development activities will continue to increase as a result of research and development programs that are necessary to advance its technology in an effort to achieve commercial viability.

Depreciation and amortization expenses totaled $223,000 for the quarter ended September 30, 2001, compared to $143,000 for the same period of the prior year. The 56% increase was primarily due to higher amortization charges with respect to recently acquired drug licenses and technologies, including Codeisan(R), and to a lesser extent, higher depreciation charges with respect to recent asset additions, partially offset by the effect of fluctuations in foreign currency exchange rates. Depreciation and amortization charges are expected to continue to be higher than in the prior year as a result of these acquisitions.

Laboratorios Belmac S.A., a subsidiary of the Company, completed the sale of the trademark, registration rights and dossier for its branded pharmaceutical product, Amantadine(R), to a third party during the quarter ended September 30, 2001, for 30 million Spanish pesetas (approximately $153,000). The Company received a deposit of 11 million Spanish pesetas (approximately $56,000) from the purchaser in June 2001, which was reflected as Deferred income in the Consolidated Balance Sheets as of June 30, 2001. The Company received a second payment of 11 million Spanish pesetas upon approval of the transfer of the rights to the purchaser by the Spanish Ministry of Health, which occurred during the quarter ended September 30, 2001. The resulting gain of approximately $113,000 has been recognized in the Consolidated Statement of Operations for the quarter ended September 30, 2001. The remaining 8 million Spanish pesetas (approximately $41,000) is payable over the next five years, in the form of a royalty arrangement.

Interest income totaled $30,000 for the three months ended September 30, 2001 compared to $85,000 for the same period of the prior year primarily as a result of lower short-term interest bearing investment balances and lower interest rates on the investment balances during the three months ended September 30, 2001 compared to the same period of 2000.

Interest expense totaled $61,000 for the three months ended September 30, 2001 compared to $46,000 for the same period of the prior year. Interest expense

incurred during the third quarter of 2001 resulted primarily from the outstanding balances on lines of credit used for operating purposes and lines of credit and borrowings used to finance the purchase of the product Codeisan(R) and capital equipment and improvements, in Spain.

The Company recorded a provision for foreign income taxes totaling $245,000 for the three months ended September 30, 2001 as a result of reporting taxable income for tax purposes in Spain, compared to the benefit for foreign income taxes of $18,000 as a result of reporting a loss for tax purposes in Spain in the same period of the prior year. The provision for foreign income taxes would have been $3,000 higher than reported, absent the 2% decline in the value of the Spanish peseta and related Euro in relation to the U.S. dollar during the period. The Company generated additional U.S. federal net

operating loss carry-forwards during the quarter ended September 30, 2001. However, since the Company has not yet achieved profitable domestic operations, it has recorded a valuation allowance for any future benefit of such losses.

Including the $113,000 gain on sale of the Amantadine(R) drug license, the Company reported income from operations of $120,000 for the three months ended September 30, 2001 compared to a loss from operations of $476,000 in the same period of the prior year. The impact of income from operations and the non-operating items, primarily the provision for income taxes of $245,000, resulted in a net loss of $149,000, or $.01 per basic and diluted common share on 14,308,000 weighted average common shares outstanding for the three months ended September 30, 2001, compared to a net loss in the same period of the prior year of $419,000, or $.03 per basic and diluted common share on 13,662,000 weighted average common shares outstanding.

Nine Months Ended September 30, 2001 versus Nine Months Ended September 30, 2000

The Company reported net sales of $18,255,000 and recognized gains of $5,090,000 from the sale of its Controlvas(R) and Amantadine(R) drug licenses which, together, resulted in net income of $1,924,000 or $.14 per basic common share ($.12 per diluted common share) for the nine months ended September 30, 2001 compared to net sales of $13,305,000 and a net loss of $560,000 or $.04 per basic and diluted common share for the same nine month period in the prior year.

The Company's Spanish subsidiaries, Laboratorios Belmac S.A. and Laboratorios Davur S.L., reported an increase in net sales of 46% in local currency for the nine months ended September 30, 2001 compared to the same period of the prior year; however, a 5% decline in the value of the Spanish Peseta and related Euro negatively impacted net sales by $813,000, resulting in net sales generated in Spain of $18,255,000, or an increase of 38% over the same nine month period of the prior year, when expressed in U.S. dollars. The Company anticipated the opportunities that the emerging generic drug market in Spain present and began taking measures over three years ago to enter the Spanish generic drug market. The Company, through its wholly-owned subsidiaries, began to register, market and distribute generic pharmaceutical products in Spain and began aligning its 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 the Company as a leader in the Spanish generic drug market. The increase in net sales is partially attributable to this effort. Sales of the product Controlvas(R), which accounted for approximately $1,708,000 of net sales

in the first nine months of 2000, were reduced to approximately $60,000 in the first nine months of 2001 as a result of the Company's divestiture of the related drug license during the first quarter of 2001. Also negatively impacting net sales was a decision by the Spanish Ministry of Health to suspend from commercialization a class of drugs that included Finedal, a product previously marketed by the Company. The Company's net sales for the nine months ended September 30, 2000 included sales of Finedal totaling approximately $200,000, while net sales for the nine months ended September 30, 2001 included no sales of Finedal. The Company does not anticipate any future sales of this product nor does it anticipate incurring any future costs with respect to this product. Net sales for the nine months ended September 30, 2000 included $65,000 related to

research and licensing agreements and fees from research and product formulation activities performed in the United States.

Gross margins for the nine months ended September 30, 2001 decreased to 57% compared to gross margins of 61% in the same period of the prior year, primarily as a result of the mix of products sold as well as higher depreciation charges resulting from the Company's recent renovations and improvements at its manufacturing facility. Approximately 27% of the Company's net sales during the nine months ended September 30, 2001 were generic product sales, which typically have lower sales prices and gross margins than branded products. In comparison, the Company sold no generic drug products during the first three quarters of the prior year. As generic product sales become more significant in the future, gross margins may continue to decrease. The Ministry of Health and the Pharma Industry in Spain had entered into a two-year agreement that expired in December 1999 whereby pharmaceutical companies in Spain, including the Company's Spanish subsidiaries, were taxed on their growth as a vehicle for funding rising health care costs in Spain. A new agreement was reached in March 2001, which also had the effect of reducing gross margins by approximately $166,000, or one percentage point, for the nine months ended September 30, 2001.

The Company entered into a strategic alliance with Teva Pharmaceutical Industries, Ltd. in July 2000, whereby the Company, through its Spanish subsidiaries, has received the right to register and market in Spain more than 75 of Teva's products. The products are comprised of both branded and generic forms. Sales from the products are expected to begin gradually, but will progress over the next two to three years. An investment in additional sales representatives will be required, along with an increase in regulatory activities, both of which may create a short term decrease in the Company's earnings. The Company, through its subsidiary Laboratorios Davur, has also submitted registrations to the Spanish Ministry of Health for generic versions of various products, in response to growing interest in generic drug products in Spain. The Company believes that resulting gross margins may be lower on sales of such products. The Company's decision to enter the generic drug market was based on its objectives to remain competitive, grow sales and market share, and ultimately achieve profitability.

Selling, general and administrative expenses increased by $2,006,000 or 28%, to $9,215,000 for the nine months ended September 30, 2001 compared to $7,209,000 for the same period of the prior year. Selling, general and administrative expenses, as a percentage of net sales, decreased from 54% of net sales during the first nine months of 2000 to 50% of net sales during the first nine months of 2001. A significant portion (70% or $6,472,000) of these expenses in the first three quarters of 2001 are selling and marketing expenses, which are necessary for the Company to maintain and grow sales and market share in Spain. Selling and marketing expenses increased by $1,838,000, or 40%, over the same

period of the prior year, and as a percent of net sales, remained constant at 35% in the first nine months of 2001 compared to the first nine months of 2000, primarily as a result of sales and marketing programs designed to introduce the Company's new generic drug products and support the launches of such products in an attempt to promote product awareness and market share. The 5% decline in the value of the Spanish peseta and related Euro, in relation to the U.S. dollar, during the period, had the effect of reducing selling and marketing expenses by $297,000 for the nine months ended September 30, 2001. General and administrative expenses increased 7% to $2,743,000 during the first nine months of 2001 compared to $2,575,000 during the first nine months of 2000, decreasing from 19% of net sales

during the first nine months of 2000 to 15% of net sales during the first nine months of 2001. The 5% decline in the value of the Spanish peseta and related Euro, in relation to the U.S. dollar, during the period, had the effect of reducing general and administrative expenses by $58,000 for the nine months ended September 30, 2001. The Company intends to continue its efforts to carefully manage general and administrative expenses.

The Company reported research and development expenses of $1,352,000 for the nine months ended September 30, 2001, which more than doubled when compared to $608,000 for the same period of the prior year. However, prior year first quarter research and development expenses of $238,000 were offset by $161,000 as a result of a negotiated reduction in an amount previously accrued for research and development expenses. The increase in the Company's costs for research and development is primarily the result of costs associated with Phase I Clinical Studies (treatment of nail fungal infections), pre-clinical programs underway in collaboration with universities and with product formulation and testing efforts being performed in the laboratory in the Company's U.S. headquarters, located in New Hampshire, and at the Company's facility in Zaragoza, Spain. The U.S. laboratory is being used by the Company to develop potential product applications using its permeation enhancement technology. The limited expenditures in research and development reflect the Company's direction of its resources toward projects that are necessary for expansion of its portfolio of marketed products and clinical trials involving its drug delivery technology, the results of which should assist potential collaborators in the evaluation process. The Company intends to continue to carefully manage its research and development expenditures in order to ensure that its development programs are efficient and cost effective and seeks funding of certain of its research and development by collaborative partners, however, the Company does expect that its future expenditures for research and development activities will continue to increase as a result of research and development programs that are necessary to advance its technology in an effort to achieve commercial viability.

Depreciation and amortization expenses totaled $670,000 for the nine months ended September 30, 2001, compared to $420,000 for the same period of the prior year. The 60% increase was primarily due to higher amortization charges with respect to recently acquired drug licenses and technologies, including Codeisan(R), and to a lesser extent, higher depreciation charges with respect to recent asset additions, partially offset by the effect of fluctuations in foreign currency exchange rates. Depreciation and amortization charges are expected to continue to be higher than in the prior year as a result of these acquisitions.

Laboratorios Belmac, S.A., a subsidiary of the Company, sold the trademark, registration rights and dossier for its branded pharmaceutical product, Controlvas(R), for approximately $5,148,000 during the nine months ended

September 30, 2001. The Company entered into an agreement to sell Controlvas(R) and received a 50% deposit from the purchaser in November 2000, which was reflected as Deferred income in the Consolidated Balance Sheet as of December 31, 2000. The resulting gain of approximately $4,977,000 has been recognized in the Consolidated Statement of Operations for the nine months ended September 30, 2001.

Laboratorios Belmac S.A., a subsidiary of the Company, completed the sale of the trademark, registration rights and dossier for its branded pharmaceutical product, Amantadine(R), to a third party

during the quarter ended September 30, 2001, for 30 million Spanish pesetas (approximately $153,000). The Company received a deposit of 11 million Spanish pesetas (approximately $56,000) from the purchaser in June 2001, which was reflected as Deferred income in the Consolidated Balance Sheets as of June 30, 2001. The Company received a second payment of 11 million Spanish pesetas upon approval of the transfer of the rights to the purchaser by the Spanish Ministry of Health, which occurred during the quarter ended September 30, 2001. The resulting gain of approximately $113,000 has been recognized in the Consolidated Statement of Operations for the nine months ended September 30, 2001. The remaining 8 million Spanish pesetas (approximately $41,000) is payable over the next five years, in the form of a royalty arrangement.

Interest income totaled $121,000 for the nine months ended September 30, 2001 compared to $269,000 for the same period of the prior year primarily as a result of lower short-term interest bearing investment balances and lower interest rates on the investment balances during the nine months ended September 30, 2001 compared to the same period of 2000.

Interest expense totaled $184,000 for the nine months ended September 30, 2001 compared to $342,000 for the same period of the prior year. The Company incurred first quarter 2000 interest expense of approximately $233,000 related to its Debentures, which was eliminated beginning with the second quarter of 2000 as a result of the conversion of all outstanding Debentures into shares of Common Stock. Interest expense incurred during the first three quarters of 2001 resulted primarily from the outstanding balances on lines of credit used for operating purposes and lines of credit and borrowings used to finance the purchase of the product Codeisan(R) and capital equipment and improvements, in Spain.

The Company recorded a provision for foreign income taxes totaling $2,298,000 for the nine months ended September 30, 2001 as a result of reporting taxable income for tax purposes in Spain and for capital gains tax arising from the sale of Controlvas(R) and Amantadine(R), compared to the provision for foreign income taxes of $378,000 in the same period of the prior year, as a result of taxable income earned in Spain. The provision for foreign income taxes would have been $113,000 higher than reported, absent the 5% decline in the value of the Spanish peseta and related Euro in relation to the U.S. dollar during the period. The Company generated additional U.S. federal net operating loss carry-forwards during the nine months ended September 30, 2001. However, since the Company has not yet achieved profitable domestic operations, it has recorded a valuation allowance for any future benefit of such losses.

Including the $5,090,000 gain on sale of drug licenses, the Company reported income from operations of $4,264,000 for the nine months ended September 30, 2001 compared to a loss from operations of $109,000 in the same period of the prior year. Excluding the $5,090,000 pre-tax gain from the sale of the

Controlvas(R) and Amantadine(R) drug licenses, the loss from operations for the first nine months of 2001 would have totaled $826,000. The combination of income from operations and the non-operating items, primarily the provision for income taxes of $2,298,000, resulted in net income of $1,924,000, or $.14 per basic common share ($.12 per diluted common share) on 14,064,000 weighted average basic common shares outstanding (15,594,000 weighted average diluted common shares outstanding) for the nine months ended September 30, 2001, compared to a net loss in the same period of the prior year of $560,000, or $.04 per basic and diluted common share on 12,672,000 weighted average common shares outstanding.

LIQUIDITY AND CAPITAL RESOURCES:

Total assets increased from $28,877,000 at December 31, 2000 to $29,884,000 at September 30, 2001, while Stockholders' Equity increased from $17,816,000 at December 31, 2000 to $21,292,000 at September 30, 2001. The increase in Stockholders' Equity reflects primarily the net income of $1,924,000 for the nine months ended September 30, 2001, and net proceeds from the exercise of stock options and warrants totaling $1,827,000, partially offset by the negative impact of the fluctuation of the Spanish peseta (and related Euro) exchange rate of $500,000 for the nine months ended September 30, 2001.

The Company's working capital increased from $3,742,000 at December 31, 2000 to $7,087,000 at September 30, 2001, primarily as a result of collection of the remainder of the cash due upon the sale of the product Controlvas(R) (approximately $2,676,000), most of which was used to reduce short-term and long-term borrowings, the recognition of deferred income of approximately $2,564,000 related to the sale of Controlvas(R), and net proceeds received from the exercise of stock options and warrants totaling $1,827,000 during the nine months ended September 30, 2001.

Cash and cash equivalents decreased from $4,816,000 at December 31, 2000 to $4,689,000 at September 30, 2001, primarily as a result of using cash to repay net borrowings (approximately $3,447,000) and additions to fixed assets of approximately $1,196,000 during the nine month period, partially offset by cash generated by operating activities of $1,267,000, which included the sale of the Controlvas(R) drug license and proceeds from the exercise of stock options and warrants (approximately $1,827,000). Included in cash and cash equivalents at September 30, 2001 are approximately $3,610,000 of short-term investments considered to be cash equivalents.

Accounts receivable increased from $5,135,000 at December 31, 2000 to $5,882,000 at September 30, 2001 as a result of sales growth. Trade receivables increased by approximately $901,000 in local currency, but fluctuations in foreign currency exchange rates offset the increase by approximately $75,000. The Company has not experienced any material delinquent accounts on its trade receivables. Inventories increased from $1,827,000 at December 31, 2000 to $2,504,000 at September 30, 2001 primarily as a result of raw materials purchases in anticipation of demand for the Company's generic products.

The combined total of accounts payable and accrued expenses increased from $3,613,000 at December 31, 2000 to $4,576,000 at September 30, 2001, primarily due to accruals for social security taxes payable, salaries payable and taxes payable, as well as for inventory purchases, partially offset by the effect of fluctuations in foreign currency exchange rates.

Short-term borrowings and current portion of long-term debt decreased from $3,185,000 at December 31, 2000 to $2,047,000 at September 30, 2001, as a result of utilizing proceeds from the sale of the

product, Controlvas(R), to reduce balances outstanding, combined with the effect of fluctuations in foreign currency exchange rates, partially offset by additional borrowings during the quarter ended September 30, 2001 to finance capital expenditures at the Company's manufacturing plant in Spain. The weighted average interest rate on the Company's short-term borrowings is 5.8%.

Receivables from related parties represent loans totaling $440,000 made to executive officers of the Company in March 2000. Proceeds from the loans were used to pay the income taxes on stock-based compensation provided to such officers in the prior year. The loans, in the form of promissory notes, are secured by an aggregate of 50,000 shares of Common Stock owned by the officers and bear interest at 6.59% annually. Accrued interest payable totaling $44,000 is included in the amounts receivable at September 30, 2001.

Long-term debt, which totaled $623,000 at December 31, 2000, was reduced to zero at September 30, 2001, using proceeds from the sale of Controlvas(R).

Investing activities, primarily the proceeds from the sale of investments, offset by additions to machinery and equipment and capital improvements to the manufacturing facility in Spain and the U.S. and the purchase of investments used net cash of $1,493,000 during the nine months ended September 30, 2001. Financing activities, primarily proceeds from borrowings and from the exercise of stock options and warrants, offset by repayments of borrowings provided net cash of $164,000. Operating activities for the nine months ended September 30, 2001 provided net cash of $1,267,000.

Seasonality. In the past, the Company has experienced lower sales in the third calendar quarter and higher sales in the fourth calendar quarter due to seasonality. As the Company markets 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 the Company's net sales or income from operations for the periods presented.

Given the Company's current liquidity and cash balances and considering its future strategic plans (including its budgeted capital improvements and planned equipment purchases), the Company should have sufficient liquidity to fund operations for the next twelve months, which should be a sufficient time frame for the Company to advance its strategic objectives and generate sufficient revenues and cash flow to support the Company's operating cash flow needs. As mentioned above, the Company has cash and cash equivalents of approximately $4,689,000 as of September 30, 2001. These resources, combined with available lines of credit, should be adequate to satisfy the Company's capital and operating requirements, as stated above. The Company also has stock purchase warrants, including its publicly traded Class B Warrants, outstanding at September 30, 2001, to purchase approximately 3,424,000 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, the Company would receive aggregate cash proceeds of approximately $16,018,000. The expiration date of the Class B Warrants has been extended to December 31, 2002. Two Class B Redeemable Warrants, together, entitle a holder, until December 31, 2002, to purchase one share of

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Common Stock at a price of $5.00 per share. There can be no assurance, however, that changes in the Company's research and development plans or other events affecting the Company's revenues or operating expenses will not result in the earlier depletion of the Company's funds. The Company continues to explore alternative sources for financing its business activities. In appropriate situations, that will be strategically determined, the Company 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.

NEW ACCOUNTING PRONOUNCEMENTS

SFAS No. 133 "Accounting for Derivative Instruments and Hedging Activities" was issued in June 1998 and establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts (collectively referred to as derivatives) and for hedging activities. It requires that an entity recognize all derivatives as either assets or liabilities in the balance sheet and measure these instruments at fair value. The accounting for changes in the fair value of a derivative (that is, gains and losses) depends upon the intended use of the derivative and resulting designation if used as a hedge. The Company adopted SFAS No. 133, as amended, on January 1, 2001. The adoption of SFAS No. 133 did not have any impact on the Company's consolidated financial statements.

On June 29, 2001, SFAS No. 141, "Business Combinations" was approved by the Financial Accounting Standards Board (FASB). SFAS No. 141 requires that the purchase method of accounting be used for all business combinations initiated after June 30, 2001. Goodwill and certain intangible assets will remain on the balance sheet and not be amortized. On an annual basis, and when there is reason to suspect that their values have been diminished or impaired, these assets must be tested for impairment, and write-downs may be necessary. The Company implemented SFAS No. 141 on July 1, 2001. The adoption of SFAS No. 141 did not have any impact on the Company's consolidated financial statements.

On June 29, 2001, SFAS No. 142, "Goodwill and Other Intangible Assets" was approved by the FASB. SFAS No. 142 changes the accounting for goodwill from an amortization method to an impairment-only approach. Amortization of goodwill, including goodwill recorded in past business combinations, will cease upon adoption of this statement. The Company is required to implement SFAS No. 142 on January 1, 2002 and it has not determined the impact, if any, that this statement will have on its consolidated financial position or results of operations.

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QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Foreign Currency. A substantial amount of the Company's business is conducted in Europe and is therefore influenced by the extent to which there are fluctuations in the dollar's value against other currencies, specifically the euro and the

peseta. On January 1, 1999, the euro became the official currency of European Union (EU) member states with a fixed conversion rate against their national currencies. The value of the euro against the dollar and all other currencies, including the EU member states that are not participating in the euro zone, will fluctuate according to market conditions. Although euro notes and coins will not appear until January 1, 2002, the new currency has been used by consumers, retailers, companies and public administrations since January 1, 1999, in the form of "written money," i.e. by means of checks, traveler's checks, bank transfers, credit card transactions, etc. The permanent value of one euro in Spain is fixed at 166.39 pesetas. The exchange rate at September 30, 2001 and December 31, 2000 was 182.54 and 178.02 pesetas per U.S. dollar, respectively. The weighted average exchange rate for the three months ended September 30, 2001 and 2000 was 186.84 and 184.16 pesetas per U.S. dollar, respectively; the weighted average exchange rate for the nine months ended September 30, 2001 and 2000 was 185.93 and 177.05 pesetas per U.S. dollar, respectively. The effect of foreign currency fluctuations on long lived assets for the nine months ended September 30, 2001 was a decrease of $501,000 and the cumulative historical effect was a decrease of $3,129,000, as reflected in the Company's Consolidated Balance Sheets in the "Liabilities and Stockholders' Equity" section. Although exchange rates fluctuated significantly in recent years, and in particular, the weakening of the euro in relation to the U.S. dollar in 1999, 2000 and the first six months of 2001, the Company does not believe that the effect of foreign currency fluctuation is material to the Company's results of operations as the expenses related to much of the Company's 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, the Company does not plan to modify its business practices. The Company has relied primarily upon financing activities to fund the operations of the Company in the United States. In the event that the Company is required to fund United States operations or cash needs with funds generated in Spain, currency rate fluctuations in the future could have a significant impact on the Company. However, at the present time, the Company does not anticipate altering its business plans and practices to compensate for future currency fluctuations.

Interest Rates. The weighted average interest rate on the Company's short-term borrowings is 5.8% and the balance outstanding is $2,047,000 as of September 30, 2001. The effect of an increase in the interest rate of one hundred basis points, to 6.8%, would have the effect of increasing interest expense by approximately $20,000 annually.

CAUTIONARY STATEMENTS FOR PURPOSES OF THE "SAFE HARBOR" PROVISIONS OF THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

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, Inc. ("Bentley"), the occurrence of which involve certain risks and uncertainties that could cause Bentley's actual results to differ materially from those expected by Bentley, including the risk that we could be required to cut back or stop operations if we are unable to raise or obtain needed funding; that we have a history of losses and if we do not achieve profitability we may not be able to continue our business in the future; that we may be restricted from using our net operating loss carry forwards due to a change in equity ownership and a change in our tax year; that successful development of current and future products is uncertain; that clinical trial results may result in failure to obtain regulatory approval and inability to sell products; that we will rely on third parties to commercialize our products in the United States; that our products are early stage and may not be

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successful; that we could be materially harmed if our agreements were terminated; that our failure to develop additional product candidates will impair our ability to grow; that our patent position is uncertain and our success depends on our proprietary rights; that we may have to lower prices or spend more money to effectively compete against companies with greater resources than us, which could result in lower revenues and/or profits; that rapid technological change may result in our products becoming obsolete before we recoup a significant portion of related costs; that pharmaceutical pricing is uncertain and may result in a negative effect on our profitability; that we depend on key personnel and must continue to attract and retain key employees; that we face product liability risks; that we may be affected by changes in pharmaceutical pricing and reimbursement; that we face risks when doing business outside of the United States; that your percentage of ownership, voting power and price of Bentley common stock may decrease as a result of events which increase the number of shares of our outstanding common stock; that our stock is volatile; that obligations in connection with warrants and options may hinder our ability to obtain future financing; that your interest in Bentley may be diluted by the issuance of preferred stock with greater rights than the common stock, which we can sell or issue at any time; that we have not paid dividends on our common stock and do not intend to pay dividends in the foreseeable future; that certain laws and provisions in our certificate of incorporation and by laws make it more difficult or discourage third parties from attempting to control Bentley, and other uncertainties detailed in Bentley's Annual Report on Form 10-K (SEC File No. 1-10581) for the year ended December 31, 2000.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On January 22, 2001, the Company settled a legal dispute, by paying $140,000 to Creative Technologies, Inc. and Creative Technologies, Inc. agreed to the dismissal of the related suit with prejudice. Creative Technologies had asserted that it was due a brokerage or finder's fee with respect to the Company's 1999 acquisition of permeation enhancement technology. The Company included the accrual for the $140,000 charge in the Consolidated Balance Sheet as of December 31, 2000 and included the $140,000 charge and related legal costs of approximately $55,000 in operating expenses in the Consolidated Statements of Operations for the year ended December 31, 2000.

The Company was awarded a judgment of approximately $2,130,000 in the Circuit Court of the Thirteenth Judicial Circuit, State of Florida, Hillsborough County Civil Division during the year ended December 31, 1998, relating to the Company's claims of civil theft and breach of employment agreement filed against its former President and Chief Executive Officer, Michael M. Harshbarger. The judgment included treble damages totaling $418,000 related to its civil theft claim and $1,712,000 related to its breach of employment agreement claim. Harshbarger originally filed suit against the Company in November 1993, alleging wrongful termination, seeking monetary damages in excess of $1,400,000. In addition to establishing a receivable on its books, the Company has established a reserve equal to the receivable, as the Company is of the opinion that

Harshbarger does not have the financial resources to satisfy the judgment.

Harshbarger filed a Motion for Relief From Judgment in September 1999, alleging among other things that he was not provided notice of the August 24, 1998 jury trial. Discovery is ongoing and a hearing has been set for November 27, 2001 to determine the merits of Harshbarger's claims. In the opinion of management, the outcome is expected to have no material effect on the financial position, results of operations or cash flows of the Company.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits:
None.

(b) Reports on Form 8-K filed during the quarter ended September 30, 2001:
None.

The Company has not filed any reports on Form 8-K subsequent to September 30, 2001.

All other items required in Part II have been previously filed or are not applicable for the quarter ended September 30, 2001.

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 1, 2001 By: /s/ James R. Murphy
James R. Murphy
Chairman, President and Chief Executive Officer
(principal executive officer)

November 1, 2001 By: /s/ Michael D. Price
Michael D. Price
Vice President, Chief Financial Officer,
Treasurer and Secretary (principal financial

and accounting officer)