

Edgar Filing: BONE CARE INTERNATIONAL INC - Form 10-Q

BONE CARE INTERNATIONAL INC
Form 10-Q
November 14, 2003

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended September 30, 2003

OR

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

From the transition period from to

Commission File Number: 0-27854

BONE CARE INTERNATIONAL, INC.
(Exact name of registrant as specified in its charter)

Wisconsin
(State of Incorporation)

39-1527471
(IRS Employer
Identification No.)

1600 Aspen Commons, Suite 300
Middleton, Wisconsin 53562
(Address of Principal Executive Offices)

608-662-7800
(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes No

As of October 8, 2003, there were 14,289,795 shares of the registrant's common stock issued and outstanding.

BONE CARE INTERNATIONAL, INC.

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FORM 10-Q

For the quarterly period ended September 30, 2003

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Bone Care(R) and Hectorol(R) are registered trademarks of Bone Care International, Inc., in the U.S. A community trademark application for Hectorol is pending in the European Community Trademark Office, Japan, and selected other countries. Hectorol is the brand name for the active drug substance, doxercalciferol. This filing may also include trademarks of other companies.

BONE CARE INTERNATIONAL, INC.
Condensed Balance Sheets

ASSETS

September 30,
2003

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| | |
|--|---------------|
| Current Assets: | (unaudited) |
| Cash and cash equivalents | \$ 1,958,417 |
| Marketable securities | 11,334,313 |
| Accounts receivable, net | 3,343,632 |
| Inventory purchased from related party | 1,196,308 |
| Inventory purchased from others | 1,544,659 |
| Other current assets | 966,692 |
| | ----- |
| Total current assets | 20,344,021 |
| Long-term securities | 912,145 |
| Property, plant and equipment, net | 1,792,946 |
| Patent fees, net | 1,381,629 |
| Goodwill | 359,165 |
| | ----- |
| | \$ 24,789,906 |
| | ===== |

LIABILITIES AND SHAREHOLDERS' EQUITY

| | |
|---|---------------|
| Current liabilities: | |
| Accounts payable | \$ 4,530,121 |
| Accrued compensation payable | 666,013 |
| Accrued clinical study and research costs | 461,497 |
| Accrued other | 130,041 |
| Allowance for sales returns | 199,020 |
| | ----- |
| Total current liabilities | 5,986,692 |
| Other liabilities | - |
| Commitments and Contingencies (Note 2) | |
| Shareholders' equity: | |
| Preferred stock-authorized 2,000,000 shares of \$.001 par value; none issued | - |
| Common stock-authorized 28,000,000 shares of no par value; issued and outstanding 14,283,129 and 14,218,522 shares as of September 30, 2003 and June 30, 2003, respectively | 74,103,475 |
| Accumulated deficit | (55,300,261) |
| | ----- |
| Total shareholders' equity | 18,803,214 |
| | ----- |
| | \$ 24,789,906 |
| | ===== |

The accompanying notes to the condensed financial statements are an integral part of these statements.

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| | | |
|--|----------------|---------|
| Product Sales | \$ 8,125,042 | \$ 5,4 |
| Operating expenses | | |
| Cost of product sales from related party | 1,353,064 | |
| Cost of product sales from others | 1,064,580 | 1,5 |
| Research and development | 1,793,160 | 1,6 |
| Selling, general and administrative | 6,081,199 | 4,0 |
| | ----- | ----- |
| | 10,292,003 | 7,2 |
| | ----- | ----- |
| Loss from operations | (2,166,961) | (1,8 |
| Interest income | 64,909 | 2 |
| | ----- | ----- |
| Loss before income taxes | (2,102,052) | (1,6 |
| Income taxes | - | |
| | ----- | ----- |
| Net loss | \$ (2,102,052) | \$ (1,6 |
| | ===== | ===== |
| Net loss per common share - basic and diluted | \$ (0.15) | \$ |
| | ===== | ===== |
| Shares used in computing basic and diluted net loss per common share | 14,240,725 | 14,1 |

The accompanying notes to the condensed financial statements are an integral part of these statements.

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BONE CARE INTERNATIONAL, INC.
Condensed Statements of Cash Flows
(Unaudited)

| | |
|---|------------|
| | Three Mo |
| | 2003 |
| | ----- |
| Cash flows from operating activities | |
| Net loss | \$ (2,102, |
| Adjustments to reconcile net loss to net cash used in operating activities: | |
| Acceleration of stock option vesting | 227, |
| Depreciation of fixed assets | 185, |
| Amortization of patents | 39, |
| Gain on disposal of fixed assets | (7, |
| Changes in assets and liabilities: | |
| (Increase) decrease in accounts receivable | (528, |
| (Increase) decrease in inventory | (660, |
| Increase in other current assets | (187, |
| Increase in other long-term assets | |
| Increase (decrease) in accounts payable | 1,845, |
| Increase (decrease) in accrued liabilities | (1,476, |
| Decrease in other liabilities | (649, |
| Increase (decrease) in allowance for sales returns | (137, |
| | ----- |

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| | |
|---|-----------|
| Net cash used in operating activities | (3,453, |
| ----- | |
| Cash flows from investing activities: | |
| Maturities of marketable securities, net | 2,291, |
| Proceeds from the sale of property, plant and equipment | 17, |
| Purchases of property, plant and equipment | (99, |
| Patent fees | (98, |
| ----- | |
| Net cash provided by investing activities | 2,111, |
| ----- | |
| Cash flow from financing activities: | |
| Proceeds from stock option exercises | 235, |
| ----- | |
| Net cash provided by financing activities | 235, |
| ----- | |
| Net increase (decrease) in cash and cash equivalents | (1,106, |
| Cash and cash equivalents at beginning of period | 3,065, |
| ----- | |
| Cash and cash equivalents at end of period | \$ 1,958, |
| ===== | |

The accompanying notes to the condensed financial statements are an integral part of these statements.

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BONE CARE INTERNATIONAL, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(Unaudited)

(1) BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

Bone Care International, Inc. ("Bone Care" or the "Company") is engaged in discovering, developing and commercializing improved D-hormone therapies. In June 1999, Bone Care received approval from the U.S. Food and Drug Administration for an oral formulation of Hectorol(R), and in May 2000, Bone Care received approval for the intravenous formulation. Hectorol(R) Injection has not been approved for sale outside of the U.S. and Hectorol(R) Capsules are approved for sale only in the U.S. and Canada. Hectorol(R) is a synthetic D-hormone analog to manage secondary hyperparathyroidism in kidney dialysis patients.

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared from the books and records of Bone Care in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnote disclosures required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a

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fair presentation have been included. Interim results are not necessarily indicative of the results that may be expected for the year. These financial statements should be read in conjunction with the financial statements and footnotes thereto for the year ended June 30, 2003 included in the Company's Form 10-K as filed with the Securities and Exchange Commission.

Revenue Recognition Policy

Bone Care records sales and the related costs of Hectorol(R) Capsules and Hectorol(R) Injection based on shipments to its customers reduced by the estimated future returns and allowances. Revenue is recognized at the time of shipment as risk of loss has transferred to the customer, delivery has occurred, and collectibility is reasonably certain. Customers have a right to return product if they are unable to sell it prior to the expiration date. In accordance to Statement of Financial Accounting Standard (SFAS) No. 48, "Revenue Recognition When Right of Return Exists", Bone Care's September 30, 2003 and June 30, 2003 balance sheets include an accrual of \$199,020 and \$336,620, respectively, for the estimated amount of future returns, based on historical experience, related to Hectorol(R) Capsules and Hectorol(R) Injection.

Accounts Receivable

Accounts receivable is stated net of allowance for doubtful accounts of \$88,730 and \$111,200 at September 30, 2003 and June 30, 2003, respectively.

Inventory

Inventory is stated at the lower of cost or market; cost is determined by the first-in, first-out method. Inventory consists of the following:

| | ----- September 30, 2003 | June 30, 2003 ----- |
|-----------------|-----------------------------|---------------------------|
| Raw materials | \$ 1,050,893 | \$ 1,293,329 |
| Work in process | 221,836 | 182,998 |
| Finished goods | 1,468,238 | 604,277 |
| | ----- \$ 2,740,967 | \$ 2,080,604 ----- |

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Property, Plant and Equipment

Bone Care periodically evaluates the carrying value of property and equipment in accordance with SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. If the expected future undiscounted cash flows are less than the carrying amount of the asset, a loss is recognized for the differences between the fair value and the carrying value of the asset. Property, plant and equipment consisted of the following:

| | ----- September 30, 2003 | June 30, 2003 ----- |
|------------------------|--------------------------------|---------------------------|
| Leasehold Improvements | \$ 588,632 | \$ 588,632 |

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| | | |
|--------------------------------|--------------|--------------|
| Furniture and Fixtures | 512,314 | 545,547 |
| Machinery and Other Equipment | 3,171,625 | 3,100,108 |
| | ----- | ----- |
| | 4,272,571 | 4,234,287 |
| Less: Accumulated Depreciation | (2,479,625) | (2,345,287) |
| | ----- | ----- |
| | \$ 1,792,946 | \$ 1,889,000 |
| | ===== | ===== |

Patent Fees

Legal costs incurred to register patents are amortized on a straight line basis over the life of the patent. Bone Care continuously evaluates whether events and circumstances have occurred that indicate the remaining estimated useful life of intangibles may warrant revision or that the remaining balance of intangibles may not be recoverable. When factors indicate that intangibles should be evaluated for possible impairment, Bone Care assesses recoverability from expected future operations using undiscounted cash flows. Impairment would be recognized in operating results if a permanent diminution in value occurred. Impairment would be measured using fair value. Patent fees are stated net of accumulated amortization of \$1,171,324 and \$1,131,952 at September 30, 2003 and June 30, 2003, respectively.

Stock Based Compensation

Bone Care's stock-based compensation related to employees and non-employee directors is recognized using the intrinsic value method in accordance with Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and thus there is no compensation expense for options granted with exercise prices equal to the fair value of Bone Care's common stock on the date of the grant. Pro forma net loss and loss per share had Bone Care elected to adopt the "fair-value based method" of SFAS No. 123 are as follows:

| | Quarters Ended September 30, | |
|---|------------------------------|----------------|
| | 2003 | 2002 |
| Net loss as reported | \$ (2,102,052) | \$ (1,631,138) |
| Compensation expense recognized | 227,500 | - |
| Less pro forma compensation expense ... | (885,996) | (312,510) |
| | ----- | ----- |
| Pro forma net loss | \$ (2,760,548) | \$ (1,943,648) |
| | ===== | ===== |
| Net loss per share - basic and diluted | | |
| As reported | \$ (0.15) | \$ (0.12) |
| Pro forma | \$ (0.19) | \$ (0.14) |

Reclassifications

Certain prior period amounts in the condensed financial statements and the notes have been reclassified to conform to the fiscal 2004 presentation.

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(2) COMMITMENTS AND CONTINGENCIES

We have entered into various contractual obligations and commercial commitments. The following table summarizes these contractual obligations as of

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September 30, 2003:

| | Total | Less Than 1 Year | 1-3 Years |
|-------------------------------------|-------------|---------------------|-------------|
| | ----- | ----- | ----- |
| Operating Lease Obligations (1) ... | \$1,557,590 | \$ 681,329 | \$ 876,261 |
| Purchase Commitment (2) | 2,440,793 | 2,209,499 | 231,294 |
| | ----- | ----- | ----- |
| Total | \$3,998,383 | \$2,890,828 | \$1,107,555 |
| | ===== | ===== | ===== |

- (1) Represents office and laboratory facilities in Middleton, WI.
 (2) Purchase commitment for: active pharmaceutical ingredients used in Hectorol(R) production and pre-clinical research and prescriber data for market research.

(3) NET LOSS PER SHARE

Net loss per share is based on a weighted average number of shares of common stock of 14,240,725 and 14,156,772 for the quarters ended September 30, 2003 and 2002, respectively. Options to purchase common stock have been excluded from the calculation of diluted earnings per share as the impact of these options on diluted earnings per share would be anti-dilutive. The excluded options totaled 2,143,420 and 1,520,633 for the quarters ended September 30, 2003 and 2002, respectively.

(4) COMPREHENSIVE INCOME (LOSS)

Total comprehensive loss was \$2,102,052 and \$1,649,124 for the quarters ended September 30, 2003 and 2002, respectively. Comprehensive loss is comprised of net loss and changes in unrealized gains and losses on available-for-sale securities.

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

The following discussion should be read in conjunction with our audited financial statements, including the related footnotes, presented in our Annual Report on Form 10-K for the year ended June 30, 2003.

Statements included in this Form 10-Q which do not relate solely to historical matters are intended to be, and are hereby identified as, forward looking statements for purposes of the safe harbor provisions of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward looking statements may be identified by words including "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "plan," "expect" and similar expressions. Forward looking statements, including without limitation those relating to our future business prospects, sales, cost of sales, profitability, financial resources or products and production schedules, are subject to risks and uncertainties that could cause actual results to differ materially from those indicated in the forward looking statements due to important risks and factors, including those identified herein or identified from time to time in our filings with the Securities and Exchange Commission. We disclaim any obligation to update any such risks or factors or to publicly announce any revisions to any of the forward-looking statements contained herein, unless otherwise required by law.

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OVERVIEW

Bone Care International, Inc. (Bone Care) is engaged in discovering, developing and commercializing improved D-hormone therapies. In June 1999, Bone Care received approval from the U.S. Food and Drug Administration for an oral formulation of Hectorol(R), and in May 2000, Bone Care received approval for the intravenous formulation. Hectorol(R) Injection has not been approved for sale outside of the U.S. and Hectorol(R) Capsules are approved for sale only in the U.S. and Canada. Hectorol(R) is a synthetic D-hormone analog to manage secondary hyperparathyroidism in kidney dialysis patients.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our significant accounting policies are described in Note 1 to the Notes to the Financial Statements in the Company's Form 10-K for the year ended June 30, 2003. Those condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these condensed financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent liabilities. On an on-going basis, we evaluate our estimates, including those related to our provision for sales returns and allowances, allowance for doubtful accounts, and our estimate of excess and obsolete inventory. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis of judgments regarding the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Sales Returns and Allowances

When revenue is recognized, Bone Care simultaneously records an estimate of various costs, which reduce product sales. These costs include estimates for product returns, chargebacks, rebates, and discounts. Estimates are based on a variety of factors including historical return experience, rebate and chargeback agreements, inventory levels at our wholesale customers, and estimated sales by our wholesale customers to other third parties who have contracts with us. Actual experience associated with any of these items may differ materially from our estimates. Factors are reviewed that influence our estimates and, if necessary, adjustments are made when we believe that actual product returns, chargebacks, rebates, and discounts may differ from established reserves.

Allowance for Doubtful Accounts

An allowance is maintained for estimated losses resulting from the inability of customers to make required payments. Credit terms are extended on an uncollateralized basis primarily to wholesale drug distributors and independent dialysis clinics throughout the U.S. Management specifically analyzes accounts receivable, historical bad debts, customer credit-worthiness, percentage of accounts receivable by aging category, and changes in customer payment terms when evaluating the adequacy of the allowance for doubtful accounts. If the financial condition of our customers were to deteriorate, resulting in impairment in their ability to make payments, additional allowances may be required. Our actual losses from uncollectible accounts have not been material to-date.

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Excess and Obsolete Inventory

Inventories are stated at the lower of cost or market, with cost determined on the first-in, first-out method. In evaluating whether inventory is stated at the lower of cost or market, management considers such factors as the amount of inventory on hand, expiration dates, and the estimated time to sell such inventory. As appropriate, provisions are made to reduce inventories to their net realizable value. Cost of inventories that potentially may not sell prior to expiration or are deemed of no commercial value have been written-off when identified.

RESULTS OF OPERATIONS

Three months ended September 30, 2003 compared to three months ended September 30, 2002

Product sales of Hectorol(R) were \$8,125,042 for the quarter ended September 30, 2003, an increase of \$2,707,642, or 50.0% from the quarter ended September 30, 2002. Sales of Hectorol(R) Injection were \$7,036,059 for the quarter ended September 30, 2003, an increase of \$2,850,200 or 68.1% from the same period in 2002. The increase was the result of higher demand due in part to an expansion of our sales force and marketing efforts and a price increase of approximately 20.0% effective July 1, 2003. Sales of Hectorol(R) Capsules were \$1,088,983 for the quarter ended September 30, 2003, a decrease of \$142,558, or 11.6% from the same period in 2002. The reduction in demand was partially offset by a price increase of approximately 5.0% effective July 1, 2003.

Cost of product sales was \$2,417,644 and \$1,509,606 for the quarters ended September 30, 2003 and 2002, respectively, representing approximately 30.0% and 28.0%, respectively, of net product sales. The higher cost as a percent of sales for the quarter ended September 30, 2003 was primarily due to manufacturing expenses incurred in the production of Hectorol(R) Capsules for validation purposes, which inventory is not saleable and was therefore written off in the quarter ended September 30, 2003.

Research and development expense was \$1,793,160 in the quarter ended September 30, 2003, an increase of \$116,536, or 7.0% from the same quarter in 2002. The increase in expense was primarily due to higher personnel expenses of approximately \$240,000 related to the hiring of our new Vice President of Research and Development and additions in our regulatory group, offset by lower consulting and research expenses of approximately \$100,000 and \$50,000, respectively.

Selling, general and administrative expense was \$6,081,199 in the quarter ended September 30, 2003, an increase of \$2,004,111, or 49.2% from the same quarter in 2002. Sales and marketing costs increased \$1,206,775 primarily as a result of the expansion of our field sales force representing approximately \$430,000, additional promotional programs for our products representing approximately \$550,000, and personnel recruitment expenses of approximately \$150,000. General and administrative expense increased \$797,336 primarily due to severance expenses for the former Vice President of Finance of approximately \$393,000, expenses associated with the recruitment, hiring and relocation of the new Vice President of Finance of approximately \$213,000 and an increase in professional legal fees of approximately \$105,000 principally related to an increase in contractual, personnel and corporate governance activity.

LIQUIDITY AND CAPITAL RESOURCES

We require cash to fund our operations, make capital expenditures and for strategic investments. Our cash, cash equivalents, marketable securities and long-term securities balance as of September 30, 2003 was \$14,204,875, a reduction of \$3,398,570 from the June 30, 2003 balance. Our cash is invested in

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highly liquid, interest-bearing, investment grade and government securities in order to preserve principal.

Cash used in operating activities was \$3,453,579 for the three months ended September 30, 2003. Cash was used to fund the net operating loss of \$2,102,052, for inventory purchases in anticipation of increased future demand for our products and to pay for accrued liabilities, principally management bonus compensation related to fiscal year end June 30, 2003.

We used \$99,587 in cash for the purchase of capital assets, primarily computer and laboratory equipment. Our cash position was enhanced by \$235,174 from stock option proceeds in the first quarter of fiscal 2004.

Our cash and investments to-date have been used to fund our operations and capital needs. We anticipate that annual expenditures for our active pharmaceutical ingredient, contract manufacturing, research projects, development of our current

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and planned products, regulatory activity, growth of our sales force, expansion of our marketing programs and development of the infrastructures to accommodate the planned growth and development, will increase in future years. Profits from product sales, if any, may not be sufficient to support these activities. There can be no assurance that we will be able to achieve profitability or positive cash flow from operations. We anticipate that we will require additional financing in the future to finance our anticipated growth and development largely through equity or debt financing and/or strategic or corporate alliances. We believe that our existing cash position as of September 30, 2003 is adequate to fund our operations at least until our second fiscal quarter of 2005. However, there can be no assurance that we will not require additional capital prior to that time. There can be no assurance that additional equity or debt financing or corporate collaborations will be available on terms acceptable to us, if at all. The failure of the Company to achieve profitability or to raise capital on acceptable terms if and when needed would have a material adverse effect on our business, financial condition and results of operations.

We currently have no internal manufacturing capabilities. We rely on third party contractors to produce our active pharmaceutical ingredient and for the subsequent manufacturing and packaging of finished injection and capsule products. We rely on one supplier to formulate and package Hectorol(R) Injection, one supplier to formulate Hectorol(R) Capsules and one supplier to package Hectorol(R) Capsules. Although other suppliers, formulators and vendors are available and could provide these goods and services to Bone Care on comparable terms, any change in suppliers could cause a delay in manufacturing and a possible loss of sales, which would affect operating results adversely. We believe that our suppliers have sufficient capacities to meet the currently expected demand for our products from existing and new customers and patients. We believe our relationships with our suppliers are good.

At June 30, 2003, we had state tax net operating loss carryforwards of approximately \$44,337,000 and state research and development tax credit carryforwards of approximately \$621,000, which will begin expiring in 2006 and 2011, respectively. We also had federal net operating loss carryforwards of approximately \$48,770,000 and research and development tax credit carryforwards of approximately \$2,040,000, which will begin expiring in 2011 and 2012, respectively.

COMMITMENTS

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We have entered into various contractual obligations and commercial commitments. The following table summarizes these contractual obligations as of September 30, 2003:

| | Total | Less Than 1 Year | 1-3 Years |
|-------------------------------------|-------------|---------------------|-------------|
| | ----- | ----- | ----- |
| Operating Lease Obligations (1) ... | \$1,557,590 | \$ 681,329 | \$ 876,261 |
| Purchase Commitment (2) | 2,440,793 | 2,209,499 | 231,294 |
| | ----- | ----- | ----- |
| Total | \$3,998,383 | \$2,890,828 | \$1,107,555 |
| | ===== | ===== | ===== |

(1) Represents office and laboratory facilities in Middleton, WI.

(2) Purchase commitment for: active pharmaceutical ingredients used in Hectorol production and pre-clinical research and prescriber data for market research.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our sales from inception to date have been made to U.S. customers and, as a result, we have not had any exposure to factors such as changes in foreign currency exchange rates or weak economic conditions in foreign markets. However, in future periods, we expect to sell in foreign markets, including Europe and Asia. As our sales are made in U.S. dollars, a strengthening of the U.S. dollar at that time could make our products less competitive in foreign markets.

As of September 30, 2003, we held \$11,334,313 of short-term marketable securities and \$912,145 of long-term marketable securities. The investments have been made for investment (as opposed to trading) purposes. Interest rate risk with respect to our investments is not significant as all such investments are in U.S. dollar cash equivalents and are:

- short-term investments, which are by their nature less sensitive to interest rate movements, or
- have maturities in excess of one year and are expected to be held to maturity, thereby eliminating the risks associated with interest rate changes.

ITEM 4. CONTROLS AND PROCEDURES

As of September 30, 2003, Bone Care's management, including its Chief Executive Officer and Chief Financial Officer, have conducted an evaluation of the effectiveness of disclosure controls and procedures, pursuant to Rule 13a-15 of the Securities Exchange Act of 1934, as amended. Based on that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective in ensuring that all material information required to be filed in this report has been made known to them in a timely fashion.

In connection with the evaluation by Bone Care's management, including the Chief Executive Officer and Chief Financial Officer, of our internal control over financial reporting, pursuant to Exchange Act Rule 13a-15(d), no changes during the quarter ended September 30, 2003 were identified that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits furnished:

- 31.1 Rule 13a-14(a) certification of President and Chief Executive Officer
- 31.2 Rule 13a-14(a) certification of Vice President and Chief Financial Officer
- 32.1 Certification Pursuant to Section 1350 of Chapter 63 of Title 18 of the United States Code
- 32.2 Certification Pursuant to Section 1350 of Chapter 63 of Title 18 of the United States Code

(b) Reports on Form 8-K

On July 28, 2003, we filed a Form 8-K under items 7 and 9 (pursuant to item 12) relating to our July 28, 2003 press release setting forth our year-ended June 30, 2003 financial results.

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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.

BONE CARE INTERNATIONAL, INC.
(Registrant)

Date: November 14, 2003

/s/ Paul L. Berns

Paul L. Berns
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 14, 2003

/s/ Brian J. Hayden

Brian J. Hayden
Vice President - Finance and Chief Financial
Officer
(Principal Financial and Accounting Officer)

BONE CARE INTERNATIONAL, INC.

INDEX TO EXHIBITS

For the Quarterly Period Ended September 30, 2003

| No. | Description |
|------|--|
| 31.1 | Rule 13a-14(a) certification of President and Chief Executive Officer..... |
| 31.2 | Rule 13a-14(a) certification of Vice President and Chief Financial Officer..... |
| 32.1 | Certification Pursuant to Section 1350 of Chapter 63 of Title 18 of the United States Co |
| 32.2 | Certification Pursuant to Section 1350 of Chapter 63 of Title 18 of the United States Co |