

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

BONE CARE INTERNATIONAL INC  
Form 10-Q  
February 11, 2004

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 December 31, 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 January 31, 2004, there were 14,321,179 shares of the registrant's common stock issued and outstanding.

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BONE CARE INTERNATIONAL, INC.

FORM 10-Q

For the quarterly period ended December 31, 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(R) is pending in the European Community Trademark Office, Japan, and selected other countries. Hectorol(R) is the brand name for the active drug substance, doxercalciferol. This filing may also include trademarks of other companies.

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BONE CARE INTERNATIONAL, INC.  
Condensed Balance Sheets  
(unaudited)

ASSETS	December 31, 2003
<hr/>	
Current assets:	
Cash and cash equivalents.....	\$ 2,328,3
Marketable securities.....	8,650,0
Accounts receivable, net .....	3,259,4
Inventory purchased from related party.....	2,570,6
Inventory purchased from others.....	2,611,0
Other current assets.....	1,310,1
	<hr/>
Total current assets.....	20,729,7
Long-term securities.....	910,8
Property, plant and equipment, net .....	1,647,3
Patent fees, net.....	1,485,8
Goodwill.....	359,1
	<hr/>
	\$ 25,133,0
	<hr/> <hr/>
 LIABILITIES AND SHAREHOLDERS' EQUITY  	
<hr/>	
Current liabilities:	
Accounts payable.....	\$ 4,719,0
Accrued compensation payable.....	1,257,8
Accrued clinical study and research costs.....	387,0
Other accrued liabilities.....	164,6
Allowance for sales returns.....	150,0
	<hr/>
Total current liabilities.....	6,678,5
Long-term 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 14,319,679 and 14,218,522 shares as of December 31, 2003 and June 30, 2003, respectively.....	74,232,8
Accumulated deficit.....	(55,778,2)
	<hr/>
Total shareholders' equity.....	18,454,5
	<hr/>
	\$ 25,133,0
	<hr/> <hr/>

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 Operations  
(Unaudited)

	Three Months Ended December 31,		Six Mo
	2003	2002	2003
Product Sales.....	\$ 9,115,485	\$ 3,743,013	\$ 17,24
Cost and expenses			
Cost of product sales from related party...	1,501,201	--	2,85
Cost of product sales from others.....	929,907	1,459,838	1,99
Research and development.....	1,653,228	1,693,892	3,44
Selling, general and administrative.....	5,546,350	4,869.290	11,62
	9,630,686	8,023,020	19,92
Loss from operations.....	(515,201)	(4,280,007)	(2,68
Interest income, net.....	37,176	152,312	10
Net loss.....	\$ (478,025)	.\$ (4,127,695)	\$ (2,58
Net loss per common share -- basic and diluted.....	\$ (0.03)	\$ (0.29)	\$
Shares used in computing basic and diluted net loss per common share.....	14,300,232	14,157,425	14,27

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)

Six

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2003

Cash flows from operating activities:	
Net loss.....	\$ (2,580,07
Adjustments to reconcile net loss to net cash used in operating activities:	
Acceleration of stock option vesting.....	227,50
Depreciation of fixed assets.....	383,52
Amortization of patents.....	81,89
Gain on disposal of fixed assets.....	(7,87
Loss on write-off of patents.....	
Changes in assets and liabilities:	
(Increase) decrease in accounts receivable.....	(444,72
(Increase) decrease in inventory.....	(3,101,16
Increase in other current assets.....	(531,46
Increase in other long-term assets.....	
Increase in accounts payable.....	2,034,16
Increase (decrease) in accrued liabilities.....	(924,89
Increase (decrease) in long-term liabilities.....	(649,88
Increase (decrease) in allowance for sales returns.....	(186,62
	-----
Net cash used in operating activities.....	(5,699,60
	-----
Cash flows from investing activities:	
Maturities of marketable securities, net.....	4,977,33
Proceeds from the sale of property, plant and equipment.....	17,75
Purchase of property, plant and equipment.....	(151,76
Patent fees.....	(245,08
	-----
Net cash provided by investing activities.....	4,598,24
	-----
Cash flow from financing activities:	
Proceeds from exercise of stock options.....	364,51
	-----
Net cash provided by financing activities.....	364,51
	-----
Net increase (decrease) in cash and cash equivalents.....	(736,85
Cash and Cash Equivalents at beginning of period.....	3,065,21
	-----
Cash and Cash Equivalents at end of period.....	\$ 2,328,36
	=====

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

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

#### Description of Business

Bone Care International, Inc. ("Bone Care," "we," or the "Company") is a specialty pharmaceutical company engaged in discovering, developing and commercializing improved vitamin D-hormone therapies to treat secondary hyperparathyroidism in patients with kidney (or renal) disease, and other diseases, including osteoporosis, psoriasis and cancers of the prostate, breast and colon. 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 to manage secondary hyperparathyroidism in kidney dialysis patients. 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. In December 2001 we filed a supplemental New Drug Application with the FDA to treat secondary hyperparathyroidism in chronic kidney disease (CKD) patients. We received an "approvable letter" from the FDA in October 2002, for which we have provided our response. If approved, this would expand the approved indication for Hectorol(R) Capsules.

#### 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 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 with Statement of Financial Accounting Standard (SFAS) No. 48, "Revenue Recognition When Right of Return Exists", Bone Care's December 31, 2003 and June 30, 2003 balance sheets include an accrual of \$150,000 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 \$80,440 and \$111,200 at December 31, 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 consisted of the following:

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	December 31, 2003	June 30, 2003
Raw materials	\$ 1,810,853	\$ 1,293,329
Work in process	528,640	182,998
Finished goods	2,842,271	604,277
	\$ 5,181,764	\$ 2,080,604

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:

	December 31, 2003	June 30, 2003
Leasehold Improvements	\$ 588,632	\$ 588,632
Furniture and Fixtures	516,359	545,547
Machinery and Other Equipment	3,219,757	3,100,108
	4,324,748	4,234,287
Less: Accumulated Depreciation	(2,677,390)	(2,345,287)
	\$ 1,647,358	\$ 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 the expected undiscounted cash flows were less than the carrying value of the asset. Impairment would be measured using fair value. Patent fees are stated net of accumulated amortization of \$1,213,845 and \$1,131,952 at December 31, 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

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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:

	Three Months Ended December 31,		Six De
	2003	2002	2003
Net loss as reported.....	\$ (478,025)	\$ (4,127,695)	\$ (2,580,0
Compensation expense recognized.....	-	-	227,5
Less pro forma compensation expense.....	(779,844)	(396,351)	(1,665,8
Pro forma net loss.....	\$ (1,257,869)	\$ (4,524,046)	\$ (4,018,4
Net loss per share -- basic and diluted			
As reported.....	\$ (0.03)	\$ (0.29)	\$ (0.
Pro forma.....	\$ (0.09)	\$ (0.32)	\$ (0.

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### Reclassifications

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

### (2) COMMITMENTS AND CONTINGENCIES

We have entered into various contractual obligations and commercial commitments. The following table summarizes these contractual obligations as of December 31, 2003:

	Total	Less Than 1 Year	1-3 Ye
Operating Lease Obligations (1).....	\$1,390,400	\$ 685,619	\$ 704,
Purchase Commitment (2).....	1,898,658	1,744,462	154,
Total.....	\$3,289,058	\$2,430,081	\$ 858,

(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.



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### (3) NET LOSS PER SHARE

Net loss per share is based on a weighted average number of shares of common stock of 14,300,232 and 14,270,479 for the three months and six months ended December 31, 2003, respectively, and shares of common stock of 14,157,425 and 14,157,099 for the three months and six months ended December 31, 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 2,117,952 and 1,468,033 for the quarters ended December 31, 2003 and 2002, respectively.

### (4) COMPREHENSIVE INCOME (LOSS)

Total comprehensive loss was \$478,025 and \$4,145,680 for the quarters ended December 31, 2003 and 2002, respectively. Total comprehensive loss was \$2,580,077 and \$5,794,804 for the six months ended December 31, 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.

### OVERVIEW

Bone Care International, Inc. ("Bone Care," "we," or the "Company") is a specialty pharmaceutical company engaged in discovering, developing and commercializing improved vitamin D-hormone therapies to treat secondary hyperparathyroidism in patients with kidney (or renal) disease, and other diseases, including osteoporosis, psoriasis and cancers of the prostate, breast and colon. 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

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received approval for the intravenous formulation to manage secondary hyperparathyroidism in kidney dialysis patients. 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. In December 2001 we filed a supplemental New Drug Application with the FDA to treat secondary hyperparathyroidism in chronic kidney disease (CKD) patients. We received an "approvable letter" from the FDA in October 2002, for which we have provided our response. If approved, this would expand the approved indication for Hectorol(R) Capsules.

### 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. These 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, allowances or 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, allowances or 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,

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percentage of accounts receivable by aging category, and changes if any, 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 been immaterial 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 December 31, 2003 compared with three months ended December 31, 2002

Product sales of Hectorol(R) (Injection and Capsules) were \$9,115,485 for the quarter ended December 31, 2003, an increase of \$5,372,472, or 144%, from the quarter ended December 31, 2002. Sales of Hectorol(R) Injection were \$7,897,288 for the quarter ended December 31, 2003, an increase of \$5,131,419, or 186%, from the same period in 2002. The increase in sales of Hectorol(R) Injection in the second fiscal quarter of 2004 was primarily the result of:

- o Manufacturing constraints in the second quarter of 2003,
- o The efforts of an expanded and more experienced sales force,
- o The implementation of new and effective marketing programs, and
- o A price increase effective July 1, 2003 (approximately \$1.5 million).

Sales of Hectorol(R) Capsules were \$1,218,197 for the quarter ended December 31, 2003, an increase of \$241,053, or 25%, from the same period in 2002 due primarily to the expansion of the sales and marketing efforts and a July 1, 2003 price increase.

Cost of product sales was \$2,431,108 and \$1,459,838 for the quarters ended December 31, 2003 and 2002, respectively, representing approximately 27% and 39%, respectively, of product sales. The increase of cost of product sales of \$971,270 in the second quarter of 2004 versus the same period in 2003 was due to the higher sales volumes in 2004 offset partially by manufacturing validation expenses in the second quarter of 2003 for Hectorol(R) Injection. As a percent of sales, cost of product sales were 12% lower in the second quarter of 2004 from 2003 due to lower manufacturing validation expenses of approximately \$450,000.

Research and development (R&D) expense was \$1,653,228 in the quarter ended December 31, 2003, a decrease of \$40,664, or 2%, from the same quarter in 2002. The decrease in R&D expense was primarily due to a reduction in pre-clinical activities and lower consulting expenses offset partially by higher personnel expenses for the senior R&D management and additions in our regulatory and clinical support groups.

Selling, general and administrative (SG&A) expense was \$5,546,350 in the quarter ended December 31, 2003, an increase of \$677,060, or 14%, from the same quarter in 2002. The increase in SG&A expense was primarily due to marketing promotional programs in support of our sales growth representing approximately \$190,000, consulting expenses related to strategic business activities of approximately \$190,000, expansion of our field sales force representing approximately \$180,000, and professional legal fees of approximately \$110,000 principally related to an increase in contractual, personnel and corporate governance activity.

Six months ended December 31, 2003 compared with six months ended

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December 31, 2002

Product sales of Hectorol(R) (Injection and Capsules) were \$17,240,527 for the six months ended December 31, 2003, an increase of \$8,080,114, or 88%, from the six months ended December 31, 2002. Sales of Hectorol(R) Injection were \$14,933,347 for the six months ended December 31, 2003, an increase of \$7,981,618, or 115%, from the same period in 2002. The increase in sales of Hectorol(R) Injection in the first six months of 2004 was primarily the result of:

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- o Manufacturing constraints in the first and second quarters of 2003,
- o The efforts of an expanded and more experienced sales force,
- o The implementation of new and effective marketing programs, and
- o A price increase effective July 1, 2003 (approximately \$2.3 million)

Sales of Hectorol(R) Capsules were \$2,307,180 for the six months ended December 31, 2003, an increase of \$98,496, or 4%, from the same period in 2002 due primarily to a price increase implemented July 1, 2003.

Cost of product sales was \$4,848,752 and \$2,969,444 for the six months ended December 31, 2003 and 2002, respectively, representing approximately 28% and 32%, respectively, of product sales. The increase of cost of product sales of \$1,879,308 in the first six months of 2004 versus the same period in 2003 was due to the higher sales volumes in 2004 offset partially by manufacturing validation expenses in 2003 for Hectorol(R) Injection. As a percent of sales, cost of product sales were 4% lower in the second quarter of 2004 from 2003 due to lower manufacturing validation expenses of approximately \$355,000.

R&D expense was \$3,446,388 for the six months ended December 31, 2003, an increase of \$75,873, or 2%, from the same period in 2002. The increase in expense was primarily due to higher personnel expenses for the senior R&D management and additions in our regulatory and clinical support groups, partially offset by lower consulting and pre-clinical research expenses.

SG&A expense was \$11,627,549 for the six months ended December 31, 2003, an increase of \$2,681,171, or 30%, from the six months ended December 31, 2002. The increase in SG&A expenses was primarily due to marketing promotional programs representing approximately \$740,000, the expansion of our field sales force representing approximately \$490,000, severance expenses for the former Vice President of Finance of approximately \$393,000, consulting expenses related to strategic business activities of approximately \$280,000, expenses associated with the recruitment, professional legal fees of approximately \$215,000 principally related to an increase in contractual, personnel and corporate governance activity, and hiring and relocation of the new Vice President of Finance of approximately \$213,000.

### LIQUIDITY AND CAPITAL RESOURCES

We require cash to fund our operations, make capital expenditures and for strategic investments. Our cash and cash equivalents, marketable securities and long-term securities balances as of December 31, 2003 were \$2,328,366, \$8,650,000 and \$910,888, respectively, totaling \$11,889,254, a reduction in total of \$5,714,191 from the June 30, 2003 balances. 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 \$5,699,607 for the six months ended December 31, 2003 primarily to fund the net operating loss of \$2,580,077, 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 \$151,764 in cash for the purchase of capital assets, primarily computer and laboratory equipment. Our cash position was enhanced by \$364,512 from stock option proceeds in the six months ended December 31, 2003.

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 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 may 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 December 31, 2003 is adequate to fund our operations at least until our second quarter of fiscal year 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.

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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 us on comparable terms, any change in suppliers could cause a delay in manufacturing and a possible loss of sales, which would adversely affect operating results. We believe that our suppliers have sufficient capacities to meet the currently expected demand for our products from existing and new customers and patients.

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.

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### COMMITMENTS

We have entered into various contractual obligations and commercial commitments. The following table summarizes these contractual obligations as of December 31, 2003:

	Total -----	Less Than 1 Year -----	1-3 Ye -----
Operating Lease Obligations (1).....	\$1,390,400	\$ 685,619	\$ 704,
Purchase Commitment (2).....	1,898,658	1,744,462	154,
	-----	-----	-----
Total.....	\$3,289,058 =====	\$2,430,081 =====	\$ 858, =====

- (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.

### 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 may 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 December 31, 2003, we held \$8,650,000 and \$910,888 in short-term and long-term marketable securities, respectively. 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:

- o short-term investments, which are by their nature less sensitive to interest rate movements, or
- o 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 December 31, 2003, our management, including our 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 our management, including our 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 December 31, 2003 were identified that have materially affected, or are reasonably likely to materially affect, our internal control

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over financial reporting.

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### PART II. OTHER INFORMATION

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

At the Annual Meeting of Shareholders held on November 19, 2003, the following matters were submitted to a vote of security holders:

- (a) Two directors were elected for terms of three years each, as follows:

Director	Votes FOR	Votes WITHHELD
Paul L. Berns	13,896,101	38,550
Edward Staiano, Ph.D.	13,733,197	201,454

- (b) The 2003 Stock Incentive Plan was approved, as follows:

Votes FOR	Votes AGAINST	Votes ABSTAIN	Broker NON-VOTE
9,909,885	447,200	28,637	3,518,929

- (c) The selection of Deloitte & Touche LLP as the Company's independent auditors for fiscal year ending June 30, 2004 was ratified, as follows:

Votes FOR	Votes AGAINST	Votes ABSTAIN	Broker NON-VOTE
13,899,997	31,617	3,037	0

#### 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 October 28, 2003, we filed a Form 8-K under items 7 and 9 (pursuant to item 12) relating to our October 27, 2003 press release announcing our financial results for the quarter ended September 30, 2003.

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SIGNATURES

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Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

BONE CARE INTERNATIONAL, INC.  
(Registrant)

Date: February 10, 2004

/s/Paul L. Berns

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

Date: February 10, 2004

/s/ Brian J. Hayden

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

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BONE CARE INTERNATIONAL, INC.

INDEX TO EXHIBITS

For the Quarterly Period Ended December 31, 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

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