

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

BONE CARE INTERNATIONAL INC  
Form 10-Q  
May 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 March 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, including zip code of  
Registrant's 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 May 1, 2003, 14,215,372 shares of the registrant's common stock, no par value, were outstanding.

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

BONE CARE INTERNATIONAL, INC.

FORM 10-Q

For the quarterly period ended March 31, 2003

## TABLE OF CONTENTS

PART I - FINANCIAL INFORMATION	Page
Item 1 Financial Statements	
Condensed Balance Sheets March 31, 2003 and June 30, 2002, Unaudited	3
Condensed Statements of Operations Quarters and Nine Months Ended March 31, 2003 and 2002, Unaudited	5
Condensed Statements of Cash Flows Nine Months Ended March 31, 2003 and 2002, Unaudited	6
Notes to Condensed Financial Statements, Unaudited	7
Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations	9
Item 3 Quantitative and Qualitative Disclosures About Market Risk	13
Item 4 Controls and Procedures	13
PART II - OTHER INFORMATION	
Item 1 Legal Proceedings	14
Item 2 Changes in Securities and Use of Proceeds	14
Item 3 Defaults Upon Senior Securities	14
Item 4 Submission of Matters to a Vote of Security Holders	14
Item 5 Other Information	14
Item 6 Exhibits and Reports on Form 8-K	15
SIGNATURES	16
Certifications	17
EXHIBIT INDEX	19

PART I. FINANCIAL INFORMATION

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

### ITEM 1. Financial Statements

BONE CARE INTERNATIONAL, INC.  
 Unaudited Condensed Balance Sheets

-----  
 ASSETS  
 -----

	March 31, 2003	June 30, 2002
-----		
Current Assets:		
Cash and cash equivalents	\$ 1,764,362	\$ 2,023,9
Marketable securities	15,178,948	18,436,8
Accounts receivable, net of allowance for doubtful accounts of \$203,009 and \$152,960 at March 31, 2003 and June 30, 2002, respectively	2,468,275	4,285,5
Inventories	2,039,348	2,099,4
Other current assets	980,170	775,5
-----		
Total current assets	22,431,103	27,621,4
-----		
Long-term securities	914,657	3,719,7
Other long-term assets	110,300	
Property, plant and equipment-at cost:		
Leasehold improvements	588,632	588,6
Furniture and fixtures	543,782	452,3
Machinery and other equipment	2,886,485	2,317,4
-----		
Less accumulated depreciation and amortization	4,018,899	3,358,3
	2,119,276	1,573,4
-----		
Patent fees net of accumulated amortization of \$1,099,907 at March 31, 2003 and \$988,026 at June 30, 2002	1,899,623	1,784,8
	1,268,387	1,198,2
Goodwill	359,165	359,1
-----		
	\$26,983,235	\$34,683,5
=====		

See the accompanying notes to condensed financial statements.

BONE CARE INTERNATIONAL, INC.  
 Unaudited Condensed Balance Sheets

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

Liabilities and Shareholders' Equity

	March 31, 2003
Current liabilities:	
Accounts payable	\$ 2,465,8
Accrued liabilities:	
Accrued clinical study and research costs	516,7
Compensation payable	1,257,6
Accrued health and dental costs	56,2
Other current liabilities	3
Allowance for sales returns	299,5
Total current liabilities	4,596,3
Long-term liabilities	676,8
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 14,215,372 shares at March 31, 2003 and 14,156,722 at June 30, 2002	11,393,8
Additional paid-in capital	62,219,9
Accumulated deficit	(51,903,8
Accumulated other comprehensive income	
Total shareholders' equity	21,709,9
	\$ 26,983,2

See the accompanying notes to condensed financial statements.

-4-

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

	Three Months Ended		
	March 31, 2003	March 31, 2002	March 200
Revenues	\$ 3,078,022	\$ 3,774,692	\$ 12,23
Operating expenses:			
Cost of sales	1,527,174	889,957	4,49
Research and development	1,577,120	1,687,705	4,55
Sales and marketing	3,223,289	2,450,436	10,02
General and administrative	1,488,187	812,975	4,02

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

	7,815,770	5,841,073	23,10
Loss from operations	(4,737,748)	(2,066,381)	(10,86
Interest income	112,989	285,753	48
Net loss	\$ (4,624,759)	\$ (1,780,628)	\$ (10,38
Net loss per common share - basic and diluted	\$ (0.33)	\$ (0.13)	\$
Weighted average number of common shares	14,168,652	14,124,449	14,16

See the accompanying notes to condensed financial statements.

-5-

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

	Nine Months Ended	
	March 31, 2003	March 31, 2002
Cash flows from operating activities		
Net loss	\$ (10,383,592)	\$ (5,170,730)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of fixed assets	545,779	504,268
Amortization of patents	115,805	119,067
Loss on disposal of patents	47,853	4,890
Changes in assets and liabilities:		
Accounts receivable	1,817,294	434,299
Inventories	60,121	(764,344)
Other current assets	(204,574)	408,490
Other long-term assets	(110,300)	-
Accounts payable	696,191	(214,029)
Accrued liabilities	1,167,065	58,494
Long-term liabilities	676,868	-
Allowance for sales returns	73,420	(155,000)
Net cash used in operating activities	(5,498,070)	(4,774,595)
Cash flows from investing activities:		
Maturity of marketable securities	6,009,130	4,347,748
Additions to property, plant and equipment	(660,517)	(735,129)
Patent fees	(233,796)	(281,330)
Net cash provided by investing activities	5,114,817	3,331,289
Cash flow from financing activities:		

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

Proceeds from stock option exercises	123,646	819,745
-----	-----	-----
Net cash provided by financing activities	123,646	819,745
-----	-----	-----
Net increase in cash and cash equivalents	(259,607)	(623,561)
Cash and cash equivalents at beginning of period	2,023,969	1,842,838
-----	-----	-----
Cash and cash equivalents at end of period	\$ 1,764,362	\$ 1,219,277
=====	=====	=====

See the accompanying notes to condensed financial statements.

-6-

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

(1) BASIS OF PRESENTATION

The financial statements in this report have been prepared by Bone Care International, Inc. without audit, pursuant to the rules of the Securities and Exchange Commission for quarterly reports on Form 10-Q and do not include all of the information and note disclosures required by accounting principles generally accepted in the United States of America for annual financial statements. These financial statements should be read in conjunction with the financial statements and notes thereto for the year ended June 30, 2002, included in the Company's Form 10-K as filed with the Securities and Exchange Commission on September 30, 2002.

In the opinion of management, information included in this report reflects all adjustments, consisting of normal, recurring adjustments, necessary for a fair presentation of results for these interim periods.

The results of operations for the interim period ended March 31, 2003 are not necessarily indicative of the results to be expected for the entire fiscal year ending June 30, 2003.

(2) REVENUE RECOGNITION POLICY

Bone Care records sales and the related costs of Hectorol Capsules and Hectorol Injection based on shipments to its customers reduced by the estimated future returns. The terms of sale for all product sales are F.O.B. shipping point. 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 March 31, 2003 balance sheet includes a \$299,520 accrual for the estimated amount of future returns related to Hectorol Capsules and Hectorol Injection.

(3) INVENTORIES

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

Inventories are stated at the lower of cost or market; cost is determined principally by the first-in, first-out method. Inventories are comprised of:

	March 31, 2003	June 30, 2002
Raw materials	\$ 1,417,803	\$ 456,548
Work in process	233,751	610,171
Finished goods	387,794	1,032,750
	\$ 2,039,348	\$2,099,469

#### (4) PATENTS

Effective October 1, 2002, the Company revised its estimated useful lives for amortizing patents from 10 years to 17 years. This change in estimated lives was based on the average term patents are enforceable. The impact of this change on the quarter and the nine months ended March 31, 2003 was to decrease the net loss by \$26,300 and \$39,300, respectively.

-7-

#### (5) NET LOSS PER SHARE

Net loss per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period. Options to purchase common stock have been excluded from the calculations of diluted earnings per share as the impact of these options on diluted earnings per share would be anti-dilutive. As of March 31, 2003 and 2002, 1,842,233 and 800,683 options, respectively, have been excluded as the impact would have been anti-dilutive.

#### (6) COMPREHENSIVE INCOME

Total comprehensive loss was \$4,642,745 and \$1,839,254 for the three months ended March 31, 2003 and 2002, respectively. Total comprehensive loss was \$10,437,549 and \$5,171,448 for the nine months ended March 31, 2003 and 2002, respectively. Comprehensive loss is comprised of operating results and changes in unrealized gains and losses on available-for-sale securities.

#### (7) NEW ACCOUNTING PRONOUNCEMENTS

In November 2002, the Financial Accounting Standards Board ("FASB") issued Interpretation ("FIN") No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others." FIN No. 45 requires that a guarantor must recognize, at the inception of a guarantee, a liability for the fair value of the obligation that it has undertaken in issuing a guarantee. FIN No. 45 also addresses the disclosure requirements that a guarantor must include in its financial statements for guarantees issued. The disclosure requirements in this interpretation are effective for financial statements ending after December 15, 2002. The initial recognition and measurement provisions of this interpretation are applicable on a prospective basis to guarantees issued or modified after December 31, 2002. Bone Care has not issued guarantees of indebtedness as of March 31, 2003.

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

On December 31, 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation-Transition and Disclosure." SFAS No. 148 amends SFAS No. 123, "Accounting for Stock-Based Compensation" and provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS 148 amends the disclosure requirements of SFAS No. 123 to require more prominent and more frequent disclosures in financial statements of the effects of stock-based compensation. The interim disclosure requirements of SFAS No. 148 are effective for interim periods beginning after December 15, 2002. 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.

-8-

Pro forma net loss and loss per share had the company elected to adopt the "fair-value based method" of SFAS No. 123 are as follows:

	Quarters Ended		Nine Months
	March 31, 2003	March 31, 2002	March 31, 2003
Net Loss as reported	\$(4,624,759)	\$(1,780,628)	\$(10,383,592)
Deduct: Total stock-based employee compensation expense	(441,877)	(277,691)	(1,150,738)
Pro forma net loss	\$(5,066,636)	\$(2,058,319)	\$(11,534,330)
Net loss per share - basic and diluted			
As reported	\$ (0.33)	\$ (0.13)	\$ (0.73)
Pro forma	\$ (0.36)	\$ (0.15)	\$ (0.81)

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

#### Results of Operations

Total revenues for the quarter ended March 31, 2003 decreased to \$3,078,022 from \$3,774,692 in the quarter ended March 31, 2002. The decrease was the result of a \$757,431 decline in sales of Hectorol Injection, offset by a \$60,761 increase in sales of Hectorol Capsules. Sales of Hectorol Injection were constrained in the quarter ended March 31, 2003 by an inventory shortage resulting from the temporary interruption of supply that began in the prior quarter. From December 16, 2002 to March 12, 2003, the Company was temporarily unable to fill customer orders for Hectorol Injection because of the manufacturing issues described below. Commercial shipments of Hectorol Injection were resumed in mid-March. Total revenues for the nine months ended March 31, 2003 increased to \$12,238,435 from \$10,258,829 in the nine months ended March 31, 2002. The increase was the result of a \$3,025,959 increase in sales of Hectorol Injection, offset by a \$1,046,353 decline in sales of Hectorol

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

Capsules. Hectorol Injection, launched in August 2000, generated revenues of \$1,930,391 and \$2,687,822 during the quarters ended March 31, 2003 and 2002, respectively, and \$8,882,119 and \$5,856,160 during the nine months ended March 31, 2003 and 2002, respectively. Hectorol Capsules generated revenues of \$1,147,631 and \$1,086,870 during the quarters ended March 31, 2003 and 2002, respectively, and \$3,356,316 and \$4,402,669 during the nine months ended March 31, 2003 and 2002, respectively. Hectorol Capsule revenues were adversely impacted by the introduction of a competitive generic form of oral calcitriol, a vitamin D3, in 2002.

Gross margins for the quarter ended March 31, 2003 were \$1,550,848, or 50% of revenues, compared to \$2,884,735, or 76% of revenues, in the quarter ended March 31, 2002. Gross margins for the nine months ended March 31, 2003 were \$7,741,817, or 63% of revenues, compared to \$7,982,154, or 78% of revenues, in the nine months ended March 31, 2002. Gross margins were lower as a percentage of sales due to increased cost of Hectorol Injection by Draxis Pharma Inc. as compared to production of Hectorol by Akorn, Inc., increased spending for quality assurance, and costs associated with the validation activities for the Hectorol Injection manufacturing process at our contract manufacturers. Validation costs were \$416,000 for the quarter ended March 31, 2003 and \$979,000 for the nine months ended March 31, 2003. No validation costs were incurred in the quarter and nine months ended March 31, 2002.

Research and development expenses were \$1,577,120 in the quarter ended March 31, 2003, and \$1,687,705 in the quarter ended March 31, 2002. Research and

-9-

development expenses were \$4,553,280 in the nine months ended March 31, 2003, and \$4,279,453 in the nine months ended March 31, 2002. The increase for the nine months ended March 31, 2003 is attributable to consulting expenses related to validating computer network systems used in operating clinical software, and internal costs to file the supplemental new drug application (SNDA) for 0.5mcg Hectorol Capsules.

Sales and marketing expenses increased \$772,853 to \$3,223,289 in the quarter ended March 31, 2003, from \$2,450,436 in the quarter ended March 31, 2002 and increased \$2,776,946 to \$10,023,999 in the nine months ended March 31, 2003, from \$7,247,053 in the nine months ended March 31, 2002. These increases are attributable to the addition of senior level positions within the sales and marketing departments and increased market research and promotional spending related to the peritoneal dialysis and chronic kidney disease markets.

General and administrative expenses increased \$675,212 to \$1,488,187 in the quarter ended March 31, 2003, from \$812,975 in the quarter ended March 31, 2002. General and administrative expenses increased \$1,407,006 to \$4,028,209 in the nine months ended March 31, 2003, from \$2,621,203 in the nine months ended March 31, 2002. The increase was attributable to costs associated with a higher compensation package for the new President and CEO and to increases in insurance premiums for property, casualty, and liability policies.

Interest income decreased to \$112,989 in the quarter ended March 31, 2003, from \$285,753 in the quarter ended March 31, 2002. Interest income decreased to \$480,079 in the nine months ended March 31, 2003, from \$994,825 in the nine months ended March 31, 2002. The decreases were due to lower average cash and marketable security balances for the current year, as well as lower yields on our investments.

Manufacturing

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

We have entered into a manufacturing agreement with Draxis Pharma Inc., a subsidiary of Draxis Health Inc., to serve as a manufacturer of Hectorol Injection. Draxis has completed production of the validation lots, which have been used as commercial product. On February 6, 2003, the Company submitted to the FDA a CBE-30 (changes being effective in 30 days) to add Draxis as an additional manufacturing site for Hectorol Injection. This submission was accepted by the FDA and allowed commercial distribution to begin in March 2003.

As previously disclosed, Akorn, Inc. (previously the sole manufacturer of Hectorol Injection) agreed to halt production of Hectorol Injection until such time as certain general deviations from the FDA's current Good Manufacturing Practices could be remediated. The FDA's site inspection, which concluded in February 2003, resulted in additional inspectional observations that preclude submission at this time of a CBE-30 with respect to the manufacture and process improvements at Akorn. Although Akorn is not currently producing Hectorol Injection, it has completed production of the validation lots, which could ultimately be used as commercial product.

Management believes that Draxis will have sufficient production capacity to meet the currently expected demand from existing customers and patients and allow the Company to begin to supply new patients and customers by the end of the quarter ending June 30, 2003. Bone Care also intends to seek a backup supplier for Hectorol Injection in addition to Draxis.

-10-

### Liquidity and Capital Resources

Net cash used in operating activities was \$5,498,070 for the nine months ended March 31, 2003 and \$4,774,595 for the nine months ended March 31, 2002. The cash used by operating activities was used primarily to fund marketing and commercialization efforts for Hectorol Capsules and Hectorol Injection as well as research and development.

We have experienced negative cash flows from operations since our inception and do not anticipate generating adequate positive cash flows to fund our operations until we achieve, if ever, sufficient revenues from the sale of Hectorol Capsules and Hectorol Injection. We have expended, and expect to continue to expend in the future, substantial funds for our:

- o research and development programs;
- o pre-clinical and clinical testing;
- o regulatory processes, including completion of FDA post-approval Phase IV commitments for Hectorol Capsules and Hectorol Injection;
- o manufacturing expenses, including validation costs for Hectorol IV at our contract manufacturers;
- o sales and marketing programs; and
- o other operating expenses.

Cash, cash equivalents and short- and long-term marketable securities were \$17,857,967 at March 31, 2003 and \$24,180,661 at June 30, 2002. Cash and cash equivalents are currently invested primarily in short-term investment grade

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

United States government, municipal and corporate debt securities.

Bone Care's capital requirements will depend on numerous factors, including the progress of commercialization and marketing activities; the progress of its research and development programs; the progress of preclinical and clinical testing; the time and cost involved in obtaining regulatory approvals; the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; competing technological and market developments; changes and developments in Bone Care's existing licensing relationships and the terms of any new collaborative, licensing, co-promotion or distribution arrangements that Bone Care may establish; the cost of manufacturing preclinical and clinical products; and other factors not within our control.

Based upon our current plans, we believe that we will have sufficient funds to meet our operating expenses and capital requirements for at least the next year. If necessary, additional capital to fund our operations may be sought through equity or debt offerings or other financings. There is no assurance that such additional funds will be available on acceptable terms, if at all.

At June 30, 2002, we had state tax net operating loss carryforwards of approximately \$38,010,000 and state research and development tax credit carryforwards of approximately \$449,000, which will begin expiring in 2006. We also had federal net operating loss carryforwards of approximately \$39,352,000 and research and development tax credit carryforwards of approximately \$1,741,000, which will begin expiring in 2011.

-11-

### Critical Accounting Policies and Estimates

Our significant accounting policies are described in Note 1 to the Notes to the Financial Statements for the year ended June 30, 2002 included in the Company's Form 10-K as filed with the Securities and Exchange Commission on September 30, 2002. Those financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these 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,

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

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 clinics throughout the United States. 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 an impairment of their ability to make payments, additional allowances may be required. Historically, our actual losses from uncollectible accounts have been immaterial.

### Excess and Obsolete Inventory

Inventories are stated at the lower of cost or market, with cost determined at standard cost which approximates actual cost. 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. Historically, cost of inventories that potentially may not sell prior to expiration or are deemed of no commercial value have been written-off when identified.

-12-

### 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. Because our sales are made in U.S. dollars, a strengthening of the U.S. dollar could make our products less competitive in foreign markets. At March 31, 2003, we did not hold any short- or long-term investments other than high-grade investment securities planned to be held to maturity and, therefore, we do not believe that short-term fluctuations of interest rates would materially affect the value of our investments.

### Item 4. Controls and Procedures

Within the last 90 days, the Company's management, including its chief executive officer and chief financial officer, have conducted an evaluation of effectiveness of disclosure controls and procedures pursuant to Rule 13a-14 of the Securities Exchange Act of 1934. Based on that evaluation, the chief executive officer and chief financial officer concluded that the disclosure controls and procedures are effective in ensuring that all material information required to be filed in this quarterly report has been made known to them in a timely fashion. There have been no significant changes in internal controls, or in factors that could significantly affect internal controls, subsequent to the date the chief executive officer and chief financial officer completed their evaluation.

-13-

PART II - OTHER INFORMATION  
BONE CARE INTERNATIONAL, INC.

Item 1. Legal Proceedings

Bone Care may be a defendant from time to time in actions arising out of our ordinary course of business operations. In the opinion of management, the outcome of pending claims is not likely to have a material adverse effect on our financial statements.

Item 2. Changes in Securities and Use of Proceeds

None

Item 3. Defaults Upon Senior Securities

None

Item 4. Submission of Matters to a Vote of Security Holders

None

Item 5. Other Information

This Quarterly Report on Form 10-Q includes forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends affecting the financial condition of our business. These forward-looking statements are subject to a number of risks, uncertainties and assumptions about us, including, among other things:

- o general economic and business conditions, both nationally and in our markets;
- o our expectations and estimates concerning future financial performance, financing plans and the impact of competition;
- o anticipated trends in our business;
- o existing and future regulations affecting our business;
- o our early stage of development;
- o the uncertainty of our future profitability;
- o our ability to satisfy the FDA's conditions for marketing approval for Hectorol;
- o other risk factors

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

In addition, in this Quarterly Report, the words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect" and similar expressions, as they relate to us, our business or our management, are intended to identify forward-looking statements.

Unless otherwise required by law, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise after the

-14-

date of this Quarterly Report. However, we acknowledge our obligation to disclose material developments related to previously disclosed information. In light of these risks and uncertainties, the forward-looking events and circumstances discussed in the Quarterly Report may not occur and actual results could differ materially from those anticipated or implied in the forward-looking statements.

Hectorol(R) is a registered trademark of Bone Care International, Inc., in the United States, European communities, Japan, and several other countries. Bone Care(R) is a registered trademark of Bone Care International in the United States. HectorolTM is the brand name for the active drug substance of our first product, doxercalciferol. This Quarterly Report also includes trademarks of other companies.

### Item 6. Exhibits and Reports on Form 8-K

#### (a) Exhibits furnished:

(99.1) Certification Pursuant to Section 1350 of Chapter 63 of Title 18 of the United States Code

(99.2) Certification Pursuant to Section 1350 of Chapter 63 of Title 18 of the United States Code

#### (b) Reports on Form 8-K

None

-15-

### 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)

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

Date: May 13, 2003

/S/ PAUL L. BERNS

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

Date: May 13, 2003

/S/ ROBERT A. BECKMAN

-----  
Robert A. Beckman  
Vice President - Finance  
(Principal Financial and Accounting Officer)

-16-

CERTIFICATIONS

I, Paul L. Berns, the President and Chief Executive Officer of Bone Care International, Inc. (the "registrant"), certify that:

1. I have reviewed this quarterly report on Form 10-Q of the registrant;
2. based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. the registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
  - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  - c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. the registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the

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

equivalent functions):

- a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. the registrant's other certifying officer and I have indicated in this quarterly report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 13, 2003

/S/ PAUL L. BERNS

-----  
Paul L. Berns  
President and Chief Executive Officer

-17-

### CERTIFICATIONS

I, Robert A. Beckman, the Vice President-Finance of Bone Care International, Inc. (the "registrant"), certify that:

1. I have reviewed this quarterly report on Form 10-Q of the registrant;
2. based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. the registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
  - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls

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

and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and

- c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date; and
5. the registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
- a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. the registrant's other certifying officer and I have indicated in this quarterly report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 13, 2003

/S/ ROBERT A. BECKMAN  
 -----  
 Robert A. Beckman  
 Vice President-Finance

-18-

BONE CARE INTERNATIONAL, INC.

Exhibit Index

For the Quarterly Period Ended March 31, 2003

No.	Description	Page
99.1	Certification Pursuant to 18 U.S.C. Section 1350, as enacted by section 906 of the Sarbanes-Oxley Act of 2002.....	20
99.2	Certification Pursuant to 18 U.S.C. Section 1350, as enacted by section 906 of the Sarbanes-Oxley Act of 2002.....	21

-19-

