

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

BONE CARE INTERNATIONAL INC

Form 10-Q

February 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 December 31, 2002

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 February 11, 2003, 14,157,772 shares of the registrant's common stock, no par value, were outstanding.

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BONE CARE INTERNATIONAL, INC.

FORM 10-Q

For the quarterly period ended December 31, 2002

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PART 1. FINANCIAL INFORMATION  
ITEM 1. Financial Statements

BONE CARE INTERNATIONAL, INC.  
Unaudited Condensed Balance Sheets

ASSETS

	December 31, 2002 -----	June 30, 2002 -----
Current Assets:		
Cash and cash equivalents	\$ 2,252,745	\$ 2,023,969
Marketable securities	16,685,097	18,436,896
Accounts receivable, net of allowance for doubtful accounts of \$152,819 and \$152,960 at December 31, 2002 and June 30, 2002, respectively	3,233,158	4,285,569
Inventories	1,756,831	2,099,469
Other current assets	1,261,260	775,596
	-----	-----
Total current assets	25,189,091	27,621,499
	-----	-----
Long-term securities	1,939,232	3,719,796
Other long-term assets	110,300	-
Property, plant and equipment-at cost:		
Leasehold improvements	588,632	588,632
Furniture and fixtures	479,600	452,345
Machinery and other equipment	2,703,822	2,317,405
	-----	-----
	3,772,054	3,358,382
Less accumulated depreciation and amortization	1,909,257	1,573,497
	-----	-----
	1,862,797	1,784,885
Patent fees net of accumulated amortization of \$1,070,827 at December 31, 2002 and \$998,027 at June 30, 2002	1,246,339	1,198,249
Goodwill	359,165	359,165
	-----	-----
	\$30,706,924	\$34,683,594
	=====	=====

See the accompanying notes to financial statements.

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BONE CARE INTERNATIONAL, INC.  
Unaudited Condensed Balance Sheets

Liabilities and Shareholders' Equity

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	December 31, 2002
	-----
Current liabilities:	
Accounts payable	\$ 2,218,715
Accrued liabilities:	
Accrued clinical study and research costs	363,273
Compensation payable	1,155,930
Other current liabilities	613
Allowance for sales returns	299,520
	-----
Total current liabilities	4,038,051
	437,691
Long-term liabilities	
Shareholders' equity:	
Preferred stock-authorized 2,000,000 shares of \$.001 par value; none issued	0
Common stock-authorized 28,000,000 shares of no par value; issued and outstanding 14,157,722 shares at December 31, 2002 and 14,156,722 at June 30, 2002	11,393,883
Additional paid-in capital	62,098,382
Accumulated deficit	(47,279,069)
Accumulated other comprehensive income	17,986
	-----
Total shareholders' equity	26,231,182
	-----
	\$ 30,706,924
	=====

See the accompanying notes to financial statements.

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

	Three Months Ended		Six
	December 31, 2002	December 31, 2001	December 3 2002
	-----	-----	-----
Revenues	\$ 3,743,013	\$ 3,831,997	\$ 9,160,4
Operating expenses			
Cost of sales	1,459,838	793,812	2,969,4
Research and development	1,527,725	1,200,031	2,976,1
Sales and marketing	3,775,761	2,546,782	6,800,7
General and administrative	1,259,696	893,294	2,540,0
	-----	-----	-----
	8,023,020	5,433,919	15,286,3

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Loss from operations	(4,280,007)	(1,601,922)	(6,125,9
Interest income	152,312	348,019	367,0
Net loss	\$ (4,127,695)	\$ (1,253,903)	\$ (5,758,8
Net loss per common share - basic and diluted	\$ (0.29)	\$ (0.09)	\$ (0.
Weighted average number of common shares	14,157,425	14,072,551	14,157,0

See the accompanying notes to financial statements.

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

	Six Mo December 31, 2002 -----
Cash flows from operating activities	
Net loss	\$ (5,758,833)
Adjustments to reconcile net loss to net cash used in operating activities:	
Depreciation of fixed assets	335,760
Amortization of patents	80,814
Loss on disposal of patents	29,106
Changes in assets and liabilities:	
Accounts receivable	1,052,411
Inventories	342,638
Other current assets	(485,664)
Other long-term assets	(110,300)
Accounts payable	449,050
Accrued liabilities	855,863
Long-term liabilities	437,691
Allowance for sales returns	73,420
Net cash used in operating activities	(2,698,044) -----
Cash flows from investing activities:	
Maturity of marketable securities	3,496,392
Additions to property, plant and equipment	(413,672)
Patent fees	(158,010)
Net cash provided by investing activities	2,924,710 -----
Cash flow from financing activities:	
Proceeds from stock option exercises	2,110
Net cash provided by financing activities	2,110 -----

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Net increase in cash and cash equivalents	228,776
Cash and cash equivalents at beginning of period	2,023,969
	-----
Cash and cash equivalents at end of period	\$ 2,252,745
	=====

See the accompanying notes to financial statements.

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### BONE CARE INTERNATIONAL, INC. NOTES TO 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 December 31, 2002, 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 December 31, 2002 balance sheet includes a \$299,520 accrual for the estimated amount of future returns related to Hectorol Capsules and Hectorol Injection.

#### (3) INVENTORIES

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:

December 31,

June 30,

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	2002 -----	2002 -----
Raw materials	\$ 1,304,393	\$ 456,548
Work in process	47,073	610,171
Finished goods	405,365	1,032,750
	-----	-----
	\$ 1,756,831	\$ 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 ended December 31, 2002 was to decrease the net loss by \$13,000.

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(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 December 31, 2002 and 2001, 1,468,033 and 909,483 options respectively, have been excluded as the impact would have been anti-dilutive.

(6) COMPREHENSIVE INCOME

Total comprehensive loss was \$4,145,680 and \$1,228,285 for the three months ended December 31, 2002 and 2001, respectively. Total comprehensive loss was \$5,794,804 and \$3,332,194 for the six months ended December 31, 2002 and 2001, respectively. Comprehensive income is comprised of operating results and 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 December 31, 2002.

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

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the disclosure requirements of SFAS 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.

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

#### Results of Operations

Total revenues for the quarter ended December 31, 2002 decreased to \$3,743,013 from \$3,831,997 in the quarter ended December 31, 2001. The decrease was the result of a \$709,572 decline in sales of Hectorol Capsules, offset by a \$620,588 increase in sales of Hectorol Injection. Sales of Hectorol Injection were constrained in the quarter ended December 31, 2002 by an inventory shortage. Bone Care cannot resume shipments of Hectorol Injection until one of its suppliers gains FDA clearance. On December 16, 2002, the Company announced that it is temporarily unable to fill customer orders for Hectorol Injection because of the manufacturing issues described below. Total revenues for the six months ended December 31, 2002 increased to \$9,160,413 from \$6,484,137 in the six months ended December 31, 2001. The increase was the result of a \$3,783,391 increase in sales of Hectorol Injection, offset by a \$1,107,115 decline in sales of Hectorol Capsules. Hectorol Capsule revenues were adversely impacted by the introduction of a generic form of oral calcitriol, a vitamin D3, in 2002. Hectorol Injection, launched in August 2000, generated revenues of \$2,765,870 and \$2,145,282 during the quarters ended December 31, 2002 and 2001, respectively and \$6,951,729 and \$3,168,338 during the six months ended December 31, 2002 and 2001, respectively. Hectorol Capsules generated revenues of \$977,143 and \$1,686,715 during the quarters ended December 31, 2002 and 2001, respectively and \$2,208,684 and \$3,315,799 during the six months ended December 31, 2002 and 2001, respectively.

Gross margins for the quarter ended December 31, 2002 were \$2,283,175, or 61% of revenues, compared to \$3,038,185, or 79% of revenues, in the quarter ended December 31, 2001. Gross margins for the six months ended December 31, 2002 were \$6,190,969, or 68% of revenues, compared to \$5,097,419, or 79% of revenues, in the six months ended December 31, 2001. Margins were lower as a percentage of sales due to increased spending for quality assurance overhead and costs associated with validating Hectorol Injection manufacturing at our contract manufacturers. Validation costs were \$455,000 for the quarter ended December 31, 2002 and \$551,000 for the six months ended December 31, 2002.

Research and development expenses were \$1,527,724 in the quarter ended December 31, 2002, and \$1,200,031 in the quarter ended December 31, 2001. Research and development expenses were \$2,976,160 in the six months ended December 31, 2002, and \$2,591,748 in the six months ended December 31, 2001. These increases are attributable to consulting expenses related to validating computer network systems, and internal costs to file the SNDA for 0.5mcg Hectorol Capsules.



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Sales and marketing expenses increased \$1,228,979 to \$3,775,761 in the quarter ended December 31, 2002, from \$2,546,782 in the quarter ended December 31, 2001 and increased \$2,004,094 to \$6,800,711 in the six months ended December 31, 2002, from \$4,796,617 in the six months ended December 31, 2001. 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 \$366,402 to \$1,259,696 in the quarter ended December 31, 2002, from \$893,294 in the quarter ended December 31, 2001. General and administrative expenses increased \$731,794 to \$2,540,022 in the six months ended December 31, 2002, from \$1,808,228 in the quarter ended December 31, 2001. The increase was attributable to costs associated with hiring the President and CEO and to increases in insurance premiums for property, casualty, and liability policies.

Interest income decreased \$195,707 to \$152,312 in the quarter ended December 31, 2002, from \$348,019 in the quarter ended December 31, 2001. Interest income decreased \$341,981 to \$367,091 in the six months ended December 31, 2002, from \$709,072 in the six months ended December 31, 2001. The decreases were due to lower average cash and marketable security balances for the current year, as well as a decline in yield on our investments.

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### Manufacturing

Akorn, Inc., currently the sole manufacturer of Hectorol Injection, received a warning letter from the FDA in September 2000 identifying general deviations from the FDA's current Good Manufacturing Practices (c-GMP) regarding manufacturing procedures, records and training. They received another letter from the FDA in December 2001 identifying additional deviations from c-GMP pursuant to a follow-up inspection of their facility. In response to this second FDA letter, Akorn agreed to halt production of Hectorol Injection until such time as these deviations could be remediated. Akorn has completed production of the validation lots, which could ultimately be used as commercial product. If the FDA's site inspection of Akorn determines that Akorn is in acceptable compliance with c-GMP, the Company intends to submit a CBE-30 (changes being effective in 30 days) with respect to the manufacture and process improvements at Akorn.

In addition, we have entered into a manufacturing agreement with Draxis Pharma Inc., a subsidiary of Draxis Health Inc., to serve as an additional manufacturer of Hectorol Injection. Draxis has completed production of the validation lots, which could ultimately be used as commercial product. On February 6, 2003, the Company submitted to the FDA a CBE-30 to add Draxis as an additional manufacturing site for Hectorol Injection. If the FDA accepts our submission for Draxis under an accelerated review process, commercial shipments of Hectorol Injection could commence in approximately 30 days after filing.

### Liquidity and Capital Resources

Net cash used in operating activities was \$2,698,044 for the six months ended December 31, 2002 and \$2,884,476 for the six months ended December 31, 2001. 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.

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We have experienced negative cash flows from operations since our inception and do not anticipate generating sufficient positive cash flows to fund our operations until we achieve, if ever, significant 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:

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

Cash, cash equivalents and short- and long-term marketable securities were \$20,877,074 at December 31, 2002 and \$24,180,661 at June 30, 2002. Cash and cash equivalents are currently invested primarily in short-term investment grade United States government, municipal and corporate debt securities.

Bone Care's capital requirements will depend on numerous factors, including the timing of the resumption of sales of Hectorol Injection; 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;

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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 assuming remediation and validation of Hectorol Injection manufacturing by March 31, 2003. If Hectorol Injection manufacturing has not resumed by this date, cost reduction initiatives will be implemented. 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. Should our plans not be consummated, we may have to seek alternative sources of capital.

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.

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### 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, respectively. 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 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

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their ability to make payments, additional allowances may be required. Historically, our actual losses from uncollectible accounts have been insignificant.

#### Excess and Obsolete Inventory

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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.

### 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 December 31, 2002, 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.

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## 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

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### Item 3. Defaults Upon Senior Securities

None

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

The 2002 Annual Meeting of Shareholders of Bone Care was held on November 15, 2002. The total number of shares of Bone Care's common stock, no par value per share, outstanding as of October 11, 2002, the record date of the annual meeting, was 14,156,772. Management of Bone Care solicited proxies for the annual meeting pursuant to Section 14 of the Securities Exchange Act of 1934, as amended, and Regulation 14A promulgated thereunder. Two directors, Martin Barkin, M.D. and Charles R. Klimkowksi, were elected to serve until the 2005 Annual Meeting of Shareholders. Both nominees were elected by a vote of 13,627,719 votes "FOR"; 300 votes "AGAINST"; and 54,598 "ABSTAIN".

In addition, at the Annual Meeting, the Bone Care International, Inc. Stock Incentive Plan was approved by a vote of 9,530,898 votes "FOR"; 480,607 votes "AGAINST"; 14,672 votes "ABSTAIN"; and 3,656,440 "BROKER NON VOTE".

In addition, at the Annual Meeting, the selection of Deloitte & Touche LLP as independent auditors for the fiscal year ended June 30, 2003 was ratified by a vote of 13,644,190 votes "FOR"; 36,125 votes "AGAINST"; and 2,302 votes "ABSTAIN".

### 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:

- general economic and business conditions, both nationally and in our markets;
- our expectations and estimates concerning future financial performance, financing plans and the impact of competition;
- anticipated trends in our business;
- existing and future regulations affecting our business;
- our early stage of development;

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- the uncertainty of our future profitability;
- our ability to satisfy the FDA's conditions for marketing approval for Hectorol;

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- other risk factors

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 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. Hectorol(TM) 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:

- (11) Statement Regarding Computation of Loss Per Share
- (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

No reports on Form 8-K were filed by the Company during the quarter ended December 31, 2002.

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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: February 13, 2003

/s/ PAUL L. BERNS  
-----

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

Date: February 13, 2003

/S/ ROBERT A. BECKMAN

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

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### 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 or 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 equivalent functions):
  - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the

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- 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: February 13, 2003

/S/ PAUL L. BERNS

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Paul L. Berns  
President and Chief Executive Officer

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### 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 or 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



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- 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: February 13, 2003

/S/ ROBERT A. BECKMAN

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Robert A. Beckman  
Vice President-Finance

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BONE CARE INTERNATIONAL, INC.

Exhibit Index

For the Quarterly Period Ended December 31, 2002

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