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BONE CARE INTERNATIONAL INC

Form 10-Q

February 13, 2002

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, 2001

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

As of February 8, 2002, 14,127,572 shares of the registrant's common stock, no par value, were outstanding.

BONE CARE INTERNATIONAL, INC.

FORM 10-Q

For the quarterly period ended December 31, 2001

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PART 1. FINANCIAL INFORMATION
 ITEM 1. Financial Statements

BONE CARE INTERNATIONAL, INC.
 Balance Sheets

 ASSETS

December 31, 2001 (Unaudited)	June 30, 2001 (Audited)
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Current Assets:		
Cash and cash equivalents	\$ 3,314,720	\$ 1,842,838
Marketable securities	19,184,773	15,079,575
Accounts receivable, net of allowance for doubtful accounts of \$166,141 and \$100,000 for December 31, 2001 and June 30, 2001, respectively	2,451,060	3,347,300
Inventories	3,526,015	1,810,574
Other current assets	719,351	1,085,103

Total current assets	29,195,919	23,165,390

Long-term securities	5,972,083	14,424,490
Property, plant and equipment-at cost:		
Leasehold improvements	588,632	587,632
Furniture and fixtures	479,798	466,200
Machinery and other equipment	1,869,671	1,419,293

	2,938,101	2,473,125
Less accumulated depreciation and amortization	1,274,554	970,120

	1,663,547	1,503,005
Patent fees net of accumulated amortization of \$1,043,795 at December 31, 2001 and \$988,466 at June 30, 2001	1,103,840	1,025,320
Excess of cost over fair value of net assets acquired, net of accumulated amortization of \$1,000,752 at December 31, 2001 and June 30, 2001	359,165	359,165

	\$38,294,554	\$40,477,370
=====		

See the accompanying notes to financial statements.

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BONE CARE INTERNATIONAL, INC.
Balance Sheets

Liabilities and Shareholders' Equity

	December 31, 2001 (Unaudited)	June 30, 2001 (Audited)

Current liabilities:		
Accounts payable	\$ 1,903,713	\$ 1,612,543
Accrued liabilities:		

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Accrued clinical study and research costs	221,697	147,635
Accrued compensation	627,020	208,930
Due to customers	0	135,102
Other current liabilities	612	70,055
Allowance for sales returns	205,000	205,000

Total current liabilities	2,958,042	2,379,265
Shareholders' equity:		
Preferred stock-authorized 2,000,000 shares of \$.001 par value; none issued	0	0
Common stock-authorized 28,000,000 shares of no par value; issued and outstanding 14,112,672 shares at December 31, 2001 and 13,955,372 at June 30, 2001	11,393,883	11,393,883
Additional paid-in capital	61,810,798	61,240,197
Accumulated deficit	(38,006,443)	(34,616,341)
Accumulated other comprehensive income	138,274	80,366

Total shareholders' equity	35,336,512	38,098,105

	\$ 38,294,554	\$ 40,477,370
=====		

See the accompanying notes to financial statements.

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

	Three Months Ended		Six Months Ended	
	December 31, 2001	December 31, 2000	December 31, 2001	December 31, 2000
Revenues	\$ 3,831,997	\$ 567,091	\$ 6,484,137	\$ 1,997,000
Operating expenses				
Cost of sales	793,812	154,707	1,386,718	4,411,000
Research and development	1,200,031	1,069,924	2,591,748	2,000,000
Sales and marketing	2,546,782	1,645,133	4,796,617	3,000,000
General and administrative	893,294	566,363	1,808,228	1,000,000
	5,433,919	3,436,127	10,583,311	6,611,000
Loss from operations	(1,601,922)	(2,869,036)	(4,099,174)	(4,714,000)
Interest income	348,019	179,047	709,072	300,000
Net loss	\$ (1,253,903)	\$ (2,689,989)	\$ (3,390,102)	\$ (4,414,000)
Net loss per common share				
- basic and diluted	\$ (0.09)	\$ (0.22)	\$ (0.24)	\$ (0.24)
Weighted average number of common shares	14,072,551	12,241,524	14,030,063	11,800,000

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See the accompanying notes to financial statements.

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

	Six Months Ended	
	December 31, 2001	December 31, 2000

Cash flows from operating activities		
Net loss	\$ (3,390,102)	\$ (4,418,482)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of fixed assets	307,085	117,330
Amortization of patents	63,330	105,000
Amortization of goodwill	0	44,725
Loss on disposal of fixed assets	0	0
Loss on disposal of patents	9,883	0
Changes in assets and liabilities:		
Accounts receivable	896,240	(1,580,494)
Inventories	(1,715,441)	(196,113)
Other current assets	365,752	(545,211)
Accounts payable	291,170	106,989
Accrued liabilities	287,607	315,220
Deferred income	0	(54,441)
Net cash used in operating activities	(2,884,476)	(6,105,477)

Cash flows from investing activities:		
Sale of marketable securities	10,655,117	1,982,653
Purchase of marketable securities	(6,250,000)	(3,438,110)
Additions to property, plant and equipment	(467,627)	(612,015)
Patent fees	(151,733)	(142,210)
Net cash provided by (used in) investing activities	3,785,757	(2,209,682)

Cash flow from financing activities:		
Proceeds from stock option exercises	570,601	64,700
Net proceeds from issuance of common stock	0	33,657,000
Net cash provided by financing activities	570,601	33,721,700

Net increase in cash and cash equivalents	1,471,882	25,406,541
Cash and cash equivalents at beginning of period	1,842,838	4,735,780

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Cash and cash equivalents at end of period \$ 3,314,720 \$ 30,142,321
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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, except for balance sheet information at June 30, 2001, 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 generally accepted accounting principles 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, 2001, included in the Company's Form 10-K as filed with the Securities and Exchange Commission on September 28, 2001.

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, 2001, are not necessarily indicative of the results to be expected for the entire fiscal year ending June 30, 2002.

(2) REVENUE RECOGNITION POLICY

Bone Care began selling Hectorol Capsules in October 1999. Because Hectorol Capsules were Bone Care's first product, Bone Care did not initially have historical data to estimate returns and exchanges in accordance with SFAS No. 48, "Revenue Recognition When Right of Return Exists." Revenues from shipments of Hectorol Capsules and the related costs were deferred at the time of shipment to wholesalers and included in the Statement of Operations at the time the product was sold by these wholesalers to retail users of the product. Effective October 1, 2000, Bone Care had sufficient experience to estimate future product returns and began recording sales and the related costs of Hectorol Capsules and Hectorol Injection based on shipments to its customers reduced by the estimated future returns. Bone Care's September 30, 2001 and June 30, 2001 balance sheets include a \$205,000 accrual, representing 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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	2001 (Unaudited)	2001 (Audited)
Raw materials	\$ 598,455	\$ 385,834
Work in process	1,263,281	955,514
Finished goods	1,664,279	469,226
	-----	-----
	\$ 3,526,015	\$1,810,574
	=====	=====

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(4) COMMON STOCK

Bone Care completed a public offering of 2,300,000 shares of common stock at a price of \$16.00 per share in December 2000. Bone Care received proceeds of \$33,657,000 from the sale, net of offering expenses. The underwriters of the Company's December 2000 common stock offering exercised their over-allotment option to acquire 145,000 additional shares of common stock at a price of \$16.00 per share in January 2001. Bone Care received proceeds of \$2,115,800 from the sale, net of offering expenses.

(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.

(6) INTANGIBLE ASSETS

On June 30, 2001, the Financial Accounting Standards Board (FASB) finalized Statement of Financial Accounting Standard No. 142, "Goodwill and Other Intangible Assets." Under Statement No. 142, existing goodwill at June 30, 2001, will no longer be amortized. Instead, an assessment of fair value will be used to test for impairment of goodwill on an annual basis or when circumstances indicate a possible impairment. On July 1, 2001, the company adopted SFAS No. 142. Application of the non-amortization provision of SFAS No 142 is expected to result in an increase in income of approximately \$89,448 in fiscal 2002.

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

Results of Operations

Revenues for the quarter ended December 31, 2001 increased to \$3,832,000 from \$567,000 in the quarter ended December 31, 2000. Revenues for the six months ended December 31, 2001 increased to \$6,484,000 from \$1,930,000 in the six months ended December 31, 2000. These increases were the result of increased sales of both Hectorol Injection and Hectorol Capsules. Hectorol Injection has been gaining market acceptance, which has been facilitated by some of the fiscal intermediaries that implemented local Medicare billing codes in advance of a national reimbursement code effective January 1, 2002. Hectorol Capsules benefited from a commercial shortage of Rocaltrol(R), a competitive

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product from Roche Pharmaceuticals, in the quarter ended September 30, 2001. Although Rocaltrol was commercially available by October 1, 2001 and TEVA Pharmaceuticals launched a generic form of Rocaltrol in October, 2001, sales of Hectorol Capsules were higher in the quarter ended December 31, 2001 as compared to the quarter ended December 31, 2000.

Gross margins for the quarter ended December 31, 2001, were \$3,038,000, or 79% of revenues compared to \$412,000, or 73% of revenues in the quarter ended December 31, 2000. Gross margins for the six months ended December 31, 2001, were \$5,097,000, or 79% of revenues compared to \$1,434,000, or 74% of revenues in the six months ended December 31, 2000. Current quarter margins improved because inventory previously written off can now be sold as a result of an FDA approval to extend the shelf life of Hectorol Capsules from three to four years.

Research and development expenses were \$1,200,000 in the quarter ended December 31, 2001, and \$1,070,000 in the quarter ended December 30, 2000. Research and development expenses were \$2,592,000 in the six months ended December 31, 2001, and \$2,051,000 in the six months ended December 30, 2000. These increases are attributable to expanded preclinical studies designed to evaluate early stage compounds in the treatment of psoriasis and prostate, breast, and colon cancers.

Sales and marketing expenses increased to \$2,547,000 in the quarter ended December 31, 2001, from \$1,645,000 in the quarter ended December 31, 2000. Sales and marketing expenses increased to \$4,797,000 in the six months ended December 31, 2001, from \$3,098,000 in the six months ended December 31, 2000.

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These increases are attributable to increasing the sales force from 30 at December 31, 2000 to 40 by December 31, 2001. The clinical support staff increased from 3 to 7, and the marketing staff increased from 4 to 9 during calendar 2001. We implemented these headcount increases in anticipation of a national J-code that became effective January 1, 2002. This code was issued by the Centers for Medicare and Medicaid Services (CMS) for reimbursement of Hectorol Injection during hemodialysis.

General and administrative expenses increased to \$893,000 in the quarter ended December 31, 2001 from \$566,000 in the quarter ended December 31, 2000. General and administrative expenses increased \$789,000 to \$1,808,000 in the six months ended December 31, 2001 from \$1,020,000 in the six months ended December 31, 2000. These increases were attributable to an expansion of infrastructure to support Bone Care's increased commercial activities.

Interest income increased to \$348,000 in the quarter ended December 31, 2001, from \$179,000 in the quarter ended December 31, 2000. Interest income increased to \$709,000 in the six months ended December 31, 2001, from \$316,000 in the six months ended December 31, 2000. These increases were due to net higher average cash and marketable securities balances during the quarter and six months ended December 31, 2001 as compared the prior year corresponding periods.

Liquidity and Capital Resources

In December 2000 and January 2001 we completed a public offering of 2,445,000 shares of common stock at a price of \$16.00 per share. We received net

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proceeds of approximately \$35.8 million from the sale. In October 1999, we completed a directed public offering of 1,229,058 shares of newly issued common stock at a price of \$9.02 per share. We received net proceeds of approximately \$11.0 million from the sale. In July 1998, we completed a directed public offering of 1,326,000 shares of common stock at a price of \$8.00 per share. We received net proceeds of approximately \$10.3 million from the sale.

Net cash used in operating activities was \$2,884,475 for the six months ended December 31, 2001 and \$6,105,477 for the six months ended December 31, 2000. The cash used by operating activities was used primarily to fund research and development as well as marketing and commercialization efforts for Hectorol Capsules and Hectorol Injection.

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;
- sales and marketing programs; and
- other operating expenses.

Cash, cash equivalents and short- and long-term marketable securities were \$28,471,576 at December 31, 2001 and \$31,346,903 at June 30, 2001. 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 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;

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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 two years. Thereafter, we may need to raise additional capital to fund our operations; however, we do not have any specific plans to raise additional capital. If we seek additional funds, equity offerings or other sources would be considered. There is no assurance that such additional funds will be available

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on acceptable terms, if at all. Should our plans not be consummated, we may have to seek alternative sources of capital.

At June 30, 2001, we had state tax net operating loss carryforwards of approximately \$33,972,000 and state research and development tax credit carryforwards of approximately \$262,000 which will begin expiring in 2009. We also had federal net operating loss carryforwards of approximately \$30,922,000 and research and development tax credit carryforwards of approximately \$1,245,000, which will begin expiring in 2012.

Manufacturing

As previously disclosed, the sole manufacturer of Hectorol Injection received a warning letter from the FDA that identified deviations from the FDA's current Good Manufacturing Practices. This manufacturer has informed us that a recent FDA inspection identified continuing deviations, some of which related directly to Hectorol Injection. The manufacturer has advised us that they intend to implement changes in the manufacturing process in response to the FDA notification which will require a shutdown of Hectorol Injection production until the manufacturing process can be revalidated, which they expect to complete by June 2002. Bone Care has adequate inventory to meet the expected demand for Hectorol Injection beyond this planned shutdown period, although no assurance can be given that the revalidation process will be completed by that time. Bone Care believes the existing inventory is safe and effective, in spite of the manufacturing deviations. There can be no assurance that the FDA will find that our manufacturer's responses and proposed corrective actions are adequate or that the FDA will not take further action and, if the FDA is not satisfied with our manufacturer's responses and proposed corrective action, the FDA could take regulatory actions including seizure of products, injunction against further manufacture, recall or other actions that could further interrupt production and sales of Hectorol Injection.

Reimbursement

The Centers for Medicare and Medicaid Services (CMS) issued a nationwide J-code for Hectorol Injection effective for services delivered after January 1, 2002. Prior to January 1, use of Hectorol Injection was limited in scope because it was not universally reimbursed or the claims required additional documentation for reimbursement. While we believe the issuance of this J-code will eventually provide nationwide reimbursement of claims for Hectorol Injection, there will be delays in implementation by payers processing Medicare, Medicaid, and private insurance claims.

Three of the approximately 30 Medicare fiscal intermediaries have recently proposed an "oral first" policy, which would prevent Medicare reimbursement for an intravenous vitamin D unless an oral vitamin-D therapy had been shown to fail prior to initiating the intravenous form. Dialysis providers who cite experiential and clinical evidence favoring use of the intravenous forms of vitamin D are aggressively challenging these policies.

These three fiscal intermediaries have also proposed a "least-cost alternative" (LCA) policy which would reduce the reimbursement for all intravenous vitamin-D therapies to a fixed payment per administration irrespective of the cost of therapy. In an LCA environment, providers would be motivated to use therapy with the lowest acquisition cost rather than prescribing products with the highest reimbursement value. One intermediary that processes Medicare claims successfully implemented an LCA policy in 2001 citing an absence of clear clinical evidence differentiating the three available intravenous vitamin D products.

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, 2001, 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.

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 position or results of operations.

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

The 2001 Annual Meeting of Shareholders of Bone Care was held on November 15, 2001. The total number of shares of Bone Care's common stock, no par value per share, outstanding as of October 11, 2001, the record date of the annual meeting, was 14,022,722. Management of Bone Care solicited proxies pursuant to Section 14 of the Securities Exchange Act of 1934, as amended, and Regulation 14A promulgated thereunder for the Annual Meeting. Two directors, Richard B. Mazess, Ph.D. and Gary E. Nei, were elected to serve until the 2004 Annual Meeting of Shareholders. Both nominees were elected by a vote of 13,417,891 votes "FOR"; no votes "AGAINST"; and 232,553 "WITHHELD AUTHORITY".

Amendment of the Bone Care International, Inc. 1996 Stock Option Plan to increase the number of shares of common stock available for grant under the Plan from 1,600,000 to 2,300,000 shares was approved. The amendment was approved by a vote of 12,884,286 votes "FOR";

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710,929 votes "AGAINST"; and 55,229 votes "ABSTAIN".

Item 5. Other Information - Recent Developments

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;
- the uncertainty of our future profitability;

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- our ability to satisfy the FDA's conditions for marketing approval for Hectorol;
- 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. 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

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- (a) Exhibits furnished:
 - (11) Statement Regarding Computation of Loss Per Share
- (b) Reports on Form 8-K
No reports on Form 8-K were filed by the Company during the quarter ended December 31, 2001.

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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, 2002 /s/ Richard B. Mazess, Ph.D.
Richard B. Mazess, Ph.D.
Acting President, Chief Executive Officer,
Chairman, and Director
(Principal Executive Officer)

Date: February 13, 2002 /s/ Robert A. Beckman
Robert A. Beckman
Vice President - Finance and Director
(Principal Financial and
Accounting Officer)

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BONE CARE INTERNATIONAL, INC.

Exhibit Index

For the Quarterly Period Ended December 31, 2001

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