BONE CARE INTERNATIONAL INC
Form 10-Q
May 15, 2002

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

FORM 10-Q

(Mark one)

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

For the quarterly period ended March 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	39-1527471
(State of Incorporation)	(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 [X] No [ ]

As of March 31, 2002, 14,151,572 shares of the registrant's common stock, no par value, were outstanding.

BONE CARE INTERNATIONAL, INC.

FORM 10-Q

For the quarterly period ended March 31, 2002

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PART 1. FINANCIAL INFORMATION
ITEM 1. Financial Statements

BONE CARE INTERNATIONAL, INC.
Balance Sheets

ASSETS	March 31,	June 30,

	2002 (Unaudited)	2001 (Audited)
Current Assets:		
Cash and cash equivalents	$ 1,219,277	$ 1,842,838
Marketable securities	19,566,503	15,079,575
Accounts receivable, net of allowance for doubtful accounts of $136,000 and $100,000 for March 31, 2002 and June 30, 2001, respectively	2,913,001	3,347,300
Inventories	2,574,918	1,810,574
Other current assets	676,613	1,085,103
Total current assets	26,950,312	23,165,390
Long-term securities	5,589,096	14,424,490
Property, plant and equipment-at cost:		
Leasehold improvements	588,632	587,632
Furniture and fixtures	449,687	466,200
Machinery and other equipment	2,069,074	1,419,293
	3,107,393	2,473,125
Less accumulated depreciation and amortization	1,358,478	970,120
	1,748,915	1,503,005
Patent fees net of accumulated amortization of $1,018,056 at March 31, 2002 and $988,466 at June 30, 2001	1,167,644	1,025,320
Excess of cost over fair value of net assets acquired, net of accumulated amortization of $1,000,752 at March 31, 2002 and June 30, 2001	359,165	359,165
	$35,815,132	$40,477,370

See the accompanying notes to financial statements.

BONE CARE INTERNATIONAL, INC.
Balance Sheets

Liabilities and Shareholders' Equity	March 31, 2002 (Unaudited)	June 30, 2001 (Audited)
Current liabilities:		
Accounts payable	$ 1,398,514	$ 1,612,543
Accrued liabilities:		

Accrued clinical study and research costs	311,646	147,635
Accrued compensation	307,471	208,930
Due to customers	-	135,102
Other current liabilities	1,099	70,055
Allowance for sales returns	50,000	205,000
Total current liabilities	2,068,730	2,379,265
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 14,151,572 shares at March 31, 2002 and 13,955,372 at June 30, 2001	11,393,883	11,393,883
Additional paid-in capital	62,059,942	61,240,197
Accumulated deficit	(39,787,071)	(34,616,341)
Accumulated other comprehensive income	79,648	80,366
Total shareholders' equity	33,746,402	38,098,105
	$ 35,815,132	$ 40,477,370

See the accompanying notes to financial statements.

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

	Three Months Ended		Nine Months Ended	
	March 31, 2002	March 31, 2001	March 31, 2002	Marc 20
Revenues	$ 3,774,692	$ 2,008,626	$ 10,258,829	$ 3,93
Operating expenses				
Cost of sales	889,957	797,685	2,276,675	1,29
Research and development	1,687,705	1,304,709	4,279,453	3,35
Sales and marketing	2,450,436	1,981,265	7,247,053	5,07
General and administrative	812,975	677,368	2,621,203	1,69
	5,841,073	4,761,027	16,424,384	11,42
Loss from operations	(2,066,381)	(2,752,401)	(6,165,555)	(7,48
Interest income	285,753	531,085	994,825	84

Net loss	$(1,780,628)	$(2,221,316)	$(5,170,730)	$(6,63
Net loss per common share - basic and diluted	$(0.13)	$(0.16)	$(0.37)	$
Weighted average number of common shares	14,124,449	13,929,414	14,061,066	12,53

See the accompanying notes to financial statements.

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

	Nine Months Ended	
	March 31, 2002	March 31, 2001
Cash flows from operating activities		
Net loss	$ (5,170,730)	$ (6,639,797)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of fixed assets	504,268	215,724
Amortization of patents	119,067	147,381
Amortization of goodwill	--	67,086
Loss on disposal of fixed assets	4,890	--
Changes in assets and liabilities:		
Accounts receivable	434,299	(2,006,818)
Inventories	(764,344)	(732,994)
Other current assets	408,490	(645,215)
Accounts payable	(214,029)	111,959
Accrued liabilities	58,494	41,910
Deferred income	--	(63,539)
Allowance for Returns	(155,000)	--
Net cash used in operating activities	(4,774,595)	(9,504,303)
Cash flows from investing activities:		
Sale (purchase) of marketable securities, net	4,347,748	(26,039,917)
Additions to property, plant and equipment	(735,129)	(1,390,452)
Patent fees	(281,330)	(230,219)
Net cash provided by (used in) investing activities	3,331,289	(27,660,588)
Cash flow from financing activities:		
Proceeds from stock option exercises	819,745	87,772
Net proceeds from issuance of common stock	--	35,772,800
Net cash provided by financing activities	819,745	35,860,572
Net decrease in cash and cash equivalents	(623,561)	(1,304,319)
Cash and cash equivalents at beginning of period	1,842,838	4,735,780
Cash and cash equivalents at end of period	$ 1,219,277	$ 3,431,461

See the accompanying notes to financial statements.

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 March 31, 2002 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. The Company's balance sheets included herein reflect an accrual representing the estimated amount of future returns related to Hectorol Capsules and Hectorol Injection of $50,000 at March 31, 2002 and $205,000 at June 30, 2001.

(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:

	March 31, 2002 (Unaudited)	June 30, 2001 (Audited)
Raw materials	$ 134,125	$ 385,834
Work in process	697,200	955,514

Finished goods	1,743,593	469,226
	$2,574,918	$1,810,574

(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 $89,448 in fiscal 2002.

Financial Accounting Standard No. 142 prescribes a two-phase process for impairment testing of goodwill. The first phase, required to be completed by December 31, 2001, screens for impairment; while the second phase (if necessary), required to be completed by June 30, 2002, measures the impairment. The Company completed its first phase impairment analysis during the quarter ended December 31, 2001 and found no instances of impairment. The second testing phase, absent future indicators of impairment, is not necessary during fiscal 2002.

		Three Months Ended	
		March 31, 2002	March 31, 2001
Net Loss:	Reported net loss	$ (1,780,628)	$ (2,221
	Goodwill amortization	-	22
	Adjusted net loss	$ (1,780,628)	$ (2,198

Basic and diluted loss per share:		
Reported loss per share	$ (0.13)	$ (
Goodwill amortization	-	
Adjusted basic and diluted loss per share	$ (0.13)	$ (

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

Results of Operations

Revenues for the quarter ended March 31, 2002 increased to $3,775,000 from $2,009,000 in the quarter ended March 31, 2001. Revenues for the nine months ended March 31, 2002 increased to $10,259,000 from $3,939,000 in the nine months ended March 31, 2001. 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 the implementation of a national reimbursement code effective January 1, 2002. Hectorol Capsules had benefited from a commercial shortage of Rocaltrol(R), a competitive product from Roche Pharmaceuticals, in the quarter ended September 30, 2001. Rocaltrol was again

commercially available by October 1, 2001. In addition, TEVA Pharmaceuticals launched a generic form of Rocaltrol in October 2001. As a result, sales of Hectorol Capsules declined from $1.7 million in the quarter ended December 31, 2001, to $1.1 million in the quarter ended March 31, 2002.

Gross margins for the quarter ended March 31, 2002 were $2,885,000, or 76% of revenues, compared to $1,211,000, or 60% of revenues in the quarter ended March 31, 2001. Gross margins for the nine months ended March 31, 2002, were $7,982,000, or 78% of revenues, compared to $2,645,000, or 67% of revenues, in the nine months ended March 31, 2002. Current quarter and current year 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 $1,688,000 in the quarter ended March 31, 2002, and $1,305,000 in the quarter ended March 31, 2001. Research and development expenses were $4,279,000 in the nine months ended March 31, 2002, and $3,356,000 in the nine months ended March 31, 2001. 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 and attributable to costs associated with a FDA filing for a pre-dialysis dosage.

Sales and marketing expenses increased to $2,450,000 in the quarter ended March 31, 2002, from $1,981,000 in the quarter ended March 31, 2001. Sales and marketing expenses increased to $7,247,000 in the nine months ended March 31, 2002, from $5,079,000 in the nine months ended March 31, 2001. These increases are attributable to increasing the sales force from 29 at March 31, 2001 to 44 by March 31, 2002. The clinical support staff increased from 5 to 7, and the marketing staff increased from 4 to 8 during the same period. 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 $813,000 in the quarter ended March 31, 2002 from $677,000 in the quarter ended March 31, 2001. General and administrative expenses increased to $2,621,000 in the nine months ended March 31, 2002 from $1,697,000 in the nine months ended March 31, 2001. These increases were attributable to an expansion of infrastructure to support Bone Care's increased commercial activities.

Interest income decreased to $286,000 in the quarter ended March 31, 2002, from $531,000 in the quarter ended March 31, 2001. The decrease in the quarter was due to carrying lower cash and marketable security balances in the quarter ended March 31, 2002, as well as lower interest rates. Interest income increased to $995,000 in the nine months ended March 31, 2002, from $847,000 in the nine months ended March 31, 2001. The increase was due to net higher average cash and marketable securities balances during the nine months ended March 31, 2002 as compared to the prior year corresponding period. This was primarily a result of the common stock offering completed in December 2000.

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 proceeds of approximately $35.8 million from the sale.

Net cash used in operating activities was $4,775,000 for the nine months ended March 31, 2002 and $9,504,000 for the nine months ended March 31, 2001. 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 $26,375,000 at March 31, 2002 and $31,347,000 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; 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 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

The sole manufacturer of Hectorol Injection received a warning letter from the FDA in 2000 that identified deviations from the FDA's current Good Manufacturing Practices. This manufacturer received an additional letter from the FDA that identified continuing deviations, some of which related directly to the production of Hectorol Injection. The manufacturer formally responded to the FDA with a plan to implement changes in their manufacturing process which will require a shutdown of Hectorol Injection production until the manufacturing process can be revalidated, which they expect to complete by July 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 corrective actions are adequate or that the FDA will not take further action and, if the FDA is not satisfied with our manufacturer's 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.

Four of the 29 Medicare fiscal intermediaries have proposed "oral first" policies, which would prevent Medicare reimbursement for an intravenous vitamin D unless an oral vitamin-D therapy had first been shown to fail. Dialysis providers who cite experiential and clinical evidence favoring use of the intravenous forms of vitamin D are aggressively challenging these policies.

Three of these four 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 March 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.

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

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:

- 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;
- 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

(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 March 31, 2002.

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: May 10, 2002

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

Date: May 10, 2002

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

BONE CARE INTERNATIONAL, INC.

Exhibit Index

For the Quarterly Period Ended March 31, 2002