

BONE CARE INTERNATIONAL INC
Form 10-Q
February 14, 2001

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, 2000

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
Middleton, Wisconsin 53562
(Address, including zip code of
Registrant's principal executive offices)

608-662-7800
(Registrant's telephone number, including area code)

One Science Court
Madison, Wisconsin 53711
(Former address, including zip code, of
Registrant's principal executive offices)

608-236-2500
(Former telephone number, including area code, of Registrant)

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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 14, 2001, 13,928,268 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, 2000

TABLE OF CONTENTS

	<u>Page</u>	
PART I	FINANCIAL INFORMATION	
Item 1	Financial Statements	
	Balance Sheets December 31, 2000 and June 30, 2000	3
	Statements of Operations Quarter and Six Months Ended December 31, 2000 and 1999	5
	Statements of Cash Flows Six Months Ended December 31, 2000 and 1999	6
	Notes to Financial Statements	7
Item 2	Management's Discussion and Analysis of Financial Condition and Results of Operations	9
	. . .	
Item 3	Quantitative and Qualitative Disclosures About Market Risk	10

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PART II	OTHER INFORMATION	
Item 1	Legal Proceedings	11
	. . .	
Item 4	Submission of Matters to a Vote of Security Holders	11
	. . .	
Item 5	Other Information	11
	. . .	
Item 6	Exhibits and Reports on Form 8-K	12
	. . .	
SIGNATURES		13
EXHIBIT INDEX		14

PART 1. FINANCIAL INFORMATION

Item 1. Financial Statements

BONE CARE INTERNATIONAL, INC.

Balance Sheets

ASSETS

	December 31, 2000 (Unaudited)	June 30, 2000 (Audited)
Current Assets:		
Cash and cash equivalents	\$30,142,321	\$ 4,735,780
Marketable securities	2,993,423	4,972,175
Accounts receivable	1,609,975	29,481
Inventories	835,384	639,271
Other current assets	774,649	229,438
Total current assets	36,355,752	10,606,145
Long-term marketable securities	3,438,110	--
Property, plant and equipment at cost:		
Leasehold improvements	435,808	115,532
Furniture and fixtures	204,502	102,482
Laboratory and office equipment	1,110,417	920,699
	1,750,727	1,138,713
Less: accumulated depreciation and amortization	809,855	692,525
	940,872	446,188
Patent fees, net of accumulated amortization of \$889,888 at December 31, 2000 and	996,190	958,980

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\$810,401 at June 30, 2000		
Excess of cost over fair value of net assets acquired, net of accumulated amortization of \$956,028 at December 31, 2000 and \$911,304 at June 30, 2000	403,889	448,613
	\$42,134,813	\$12,459,926

See the accompanying notes to financial statements.

BONE CARE INTERNATIONAL, INC.

Balance Sheets

Liabilities and Shareholders Equity	December 31, 2000 (Unaudited)	June 30, 2000 (Audited)
Current liabilities:		
Accounts payable	\$ 507,938	\$ 400,949
Accrued liabilities:		
Accrued clinical study and research costs	152,122	213,718
Accrued compensation	167,697	137,261
Due to customers	355,667	409,655
Other current liabilities	551,985	151,617
Deferred income	9,098	63,539
Total current liabilities	1,744,507	1,376,739
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 13,783,168 shares at December 31, 2000 and 11,456,668 at June 30, 2000	11,393,883	11,393,883
Additional paid-in capital	59,021,654	25,299,954
Accumulated deficit	(30,020,572)	(25,602,090)
Accumulated other comprehensive loss	(4,659)	(8,560)
Total shareholders equity	40,390,306	11,083,187
	\$42,134,813	\$12,459,926

See the accompanying notes to financial statements.

BONE CARE INTERNATIONAL, INC.

Statements of Operations

(Unaudited)

Three Months Ended

Six Months Ended

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	December 31, 2000	December 31, 1999	December 31, 2000	December 31, 1999
Revenues	\$ 567,091	\$ 206,077	\$ 1,929,924	\$ 206,077
Operating expenses				
Cost of sales	154,707	10,568	495,923	10,568
Research and development	1,069,924	1,090,015	2,051,190	2,083,023
Sales and marketing	1,645,133	1,337,810	3,098,050	2,118,148
General and administrative	566,363	448,696	1,019,582	747,504
	3,436,127	2,887,089	6,664,745	4,959,243
Loss from operations	(2,869,036)	(2,681,012)	(4,734,821)	(4,753,166)
Interest income	179,047	202,184	316,339	291,358
Loss before income tax	(2,689,989)	(2,478,828)	(4,418,482)	(4,461,808)
Income tax expense	--	12,500	--	12,500
Net loss	\$(2,689,989)	\$(2,491,328)	\$(4,418,482)	\$(4,474,308)
Net loss per common share basic and diluted	\$(0.22)	\$(0.22)	\$(0.37)	\$(0.41)
Weighted average number of common shares	12,241,524	11,245,295	11,849,096	10,709,346

See the accompanying notes to financial statements.

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

	Six Months Ended	
	December 31, 2000	December 31, 1999
Cash flows from operating activities:		
Net loss	\$ (4,418,482)	\$ (4,474,308)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	267,055	237,092
Changes in assets and liabilities:		
Accounts receivable	(1,580,494)	(543,688)
Inventories	(196,113)	5,457
Other current assets	(545,211)	(409,875)
Accounts payable	106,989	150,962
Accrued liabilities	315,220	269,196
Deferred income	(54,441)	421,152
Other	--	31,316
Net cash used in operating activities	(6,105,477)	\$ (4,312,696)
Cash flows from investing activities:		

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Proceeds from sales (purchases) of marketable securities, net	1,982,653	(7,000,928)
Purchase of non-current marketable securities	(3,438,110)	--
Additions to property, plant and equipment	(612,015)	(146,842)
Patent fees, net	(142,210)	(293,820)
Net cash provided by (used in) investing activities	\$ (2,209,682)	\$ (7,441,590)
Cash flows from financing activities:		
Proceeds from exercise of stock options	64,700	37,500
Net proceeds from issuance of common stock	33,657,000	10,975,610
Net cash provided by (used in) financing activities	33,721,700	\$ 11,013,110
Net increase (decrease) in cash and cash equivalents	25,406,541	(741,176)
Cash and cash equivalents at beginning of period	4,735,780	7,313,551
Cash and cash equivalents at end of period	\$ 30,142,321	\$ 6,572,375

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, 2000, 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, 2000, included in the Company's Form 10-K/A as filed with the Securities and Exchange Commission on December 8, 2000.

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, 2000, are not necessarily indicative of the results to be expected for the entire fiscal year ending June 30, 2001.

(2) REVENUE RECOGNITION POLICY

Bone Care began selling Hectorol Capsules in October 1999. Because Hectorol Capsules was Bone Care's first product, Bone Care did not 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 were included in the Statement of Operations at the time the product was sold by these wholesalers to retail users of the product. Bone Care now has sufficient experience to estimate future product returns. Effective October 1, 2000 Bone Care began recording sales and the related costs of Hectorol Capsules based on shipments to its customers reduced by the estimated future returns. Bone Care's December 31, 2000 and June 30, 2000 balance sheets include deferred income of \$9,098 and \$63,539, respectively, related to

Hectorol Capsule sales.

Bone Care began selling Hectorol Injection in late August 2000. Bone Care's terms for these sales to date do not allow the customer a right of return; accordingly, no revenues have been deferred.

Bone Care's standard sales terms do not allow customers to return products for refunds; however, products may be exchanged. As of December 31, 2000, and June 30, 2000 Bone Care has accrued \$355,667 and \$409,655, respectively, as credits due to customers for returned products which may be applied against future purchases.

(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, 2000 (Unaudited)	June 30, 2000 (Audited)
Raw materials	\$129,005	\$209,979
Work in process	345,232	22,178
Finished goods	361,147	407,114
	\$835,384	\$639,271

(4) COMMON STOCK

In December 2000, Bone Care completed a public offering of 2,300,000 shares of common stock at a price of \$16.00 per share. Bone Care received proceeds of \$33,657,000 from the sale, net of offering expenses.

In October 1999, Bone Care completed a directed public offering of 1,229,058 shares of common stock at a price of \$9.02 per share. Bone Care received proceeds of \$10,975,610 from the sale, net of offering expenses.

(5) OTHER COMPREHENSIVE LOSS

The following tables display other comprehensive loss and the components of accumulated other comprehensive loss:

	Six Months Ended	
	12/31/2000	12/31/1999
Comprehensive loss:		
Net loss	\$ (4,418,482)	\$ (4,474,308)
Unrealized gain (loss) on marketable securities	3,901	(11,470)
Total comprehensive loss	\$ (4,414,581)	\$ (4,485,778)

Unrealized Gain(Loss) on Securities

Accumulated other comprehensive loss:	
Balance at June 30, 2000	\$ (8,560)
Change during six months ended December 31, 2000	3,901
Balance at December 31, 2000	\$ (4,659)

(6) 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.

(7) SUBSEQUENT EVENT

On January 11, 2001 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 per share. Bone Care received proceeds of \$2,122,800, net of offering expenses.

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

Results of Operations

Bone Care launched its first product, Hectorol Capsules, in October 1999, and its second product Hectorol Injection in late August 2000. Revenues for the quarter ended December 31, 2000 totaled \$567,091 compared to \$206,077 for the quarter ended December 31, 1999. Revenues for the six months ended December 31, 2000 were \$1,929,924 compared to \$206,077 for the six months ended December 31, 1999. Revenues for the three and sixth month periods ended December 31, 2000 have increased from the three and sixth month periods ended December 31, 1999 as a result of the launch of Hectorol Injection in August 2000.

Margins on product revenues were \$412,384, or 73% of product revenues for the quarter ended December 31, 2000, and \$1,434,001, or 74% of product revenues for the six months ended December 31, 2000 compared to \$281,903, or 73% of product revenues for the year ended June 30, 2000. Margins on product revenues have improved due to the increase in sales volume.

Research and development expenses were \$1,069,924 in the quarter ended December 31, 2000, compared to \$1,090,015 in the quarter ended December 31, 1999, and were \$2,051,190 in the six months ended December 31, 2000 compared to \$2,083,023 in the six months ended December 31, 1999.

Sales and marketing expenses increased \$307,323 to \$1,645,133 in the quarter ended December 31, 2000, from \$1,337,810 in the quarter ended December 31, 1999. In the six months ended December 31, 2000, sales and marketing expenses increased \$979,902 to \$3,098,050 from \$2,118,148 in the six months ended December 31, 1999. The increases are attributable to:

- additional personnel and promotion expenses associated with the launch of Hectorol Injection, and
- the development of a marketing research data base to analyze dialysis patient data associated with D-hormone treatments. The data base project resulted in \$120,000 of expense in the quarter ended December 31, 2000.

General and administrative expenses increased \$117,667 to \$566,363 in the quarter ended December 31, 2000 from \$448,696 in the quarter ended December 31, 1999. In the six months ended December 31, 2000, general and administrative expenses increased \$272,078 to \$1,019,582 from \$747,504 in the six months ended December 31, 1999. The increase was attributable to an expansion of infrastructure to support Bone Care's increased commercial activities.

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Interest income decreased \$23,137 to \$179,047 in the quarter ended December 31, 2000, from \$202,184 in the quarter ended December 31, 1999. In the six months ended December 31, 2000, interest income increased \$24,981 to \$316,339 from \$291,358 in the six months ended December 31, 1999. The changes in interest income are attributable to receipt of net cash proceeds from the sales of common stock of \$33,657,000 in December 2000 and \$10,975,610 in September 1999, offset by the use of cash in expanded operating activities.

Liquidity and Capital Resources

Cash, cash equivalents and marketable securities totaled \$36,573,854 at December 31, 2000 and \$9,707,955 at June 30, 2000. The increase was primarily due to the receipt of net proceeds of \$33,657,000 from the December 2000 common stock offering. The net cash received from the sale of common stock was offset by the net use of cash in operating, investing, and other financial activities of \$8,250,459, resulting in a net increase of \$25,406,541 to cash, cash equivalents and marketable securities.

On November 17, 2000, Bone Care entered into a line of credit agreement with a bank. Effective with completion of the common stock offering in December 2000, Bone Care terminated the agreement.

We do not anticipate generating sufficient positive cash flows to fund our operations until we achieve significant revenues from the sale of Hectorol products. We have expended, and expect to continue to expend in the future, substantial funds for:

- 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

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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our sales from inception to date have been made to United States 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 United States dollars, a strengthening of the United States dollar could make our products less competitive in foreign markets. At December 31, 2000, we did not hold any short- or long-term investments other than short-term investment grade securities and, therefore, we do not believe that short-term fluctuations of interest rates would materially affect the value of our investments. Therefore, no quantitative tabular disclosures are required.

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 4. Submission of Matters to a Vote of Security Holders

The 2000 Annual Meeting of Shareholders of Bone Care was held on November 15, 2000. The total number of shares of Bone Care's common stock, no par value per share, outstanding as of October 6, 2000, the record date of the annual meeting, was 11,457,468. 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, Robert A. Beckman and Charles W. Bishop, Ph.D., were elected to serve until the 2003 Annual Meeting of Shareholders. Charles W. Bishop, Ph.D., was elected by a vote of 10,947,904 votes "FOR"; no votes "AGAINST"; and 188,353 "WITHHELD AUTHORITY." Robert A. Beckman was elected by a vote of 10,883,515 votes "FOR"; no votes "AGAINST"; and 224,115 "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 1,000,000 to 1,600,000 shares was approved. The amendment was approved by a vote of 8,488,657 votes "FOR"; 2,590,548 votes "AGAINST"; and 28,425 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;
- 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.

Item 6. Exhibits and Reports on Form 8-K

- | | | |
|-----|---------------------|---|
| (a) | Exhibits furnished: | |
| | (4) | Bone Care International, Inc., 1996 Stock Option Plan, as amended |
| | (11) | Statement Regarding Computation of Loss Per Share |
| (b) | Reports on Form 8-K | |
| | | Bone Care filed a Form 8-K on December 15, 2000 |

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 14, 2001

/s/ Charles W. Bishop, Ph.D.
Charles W. Bishop, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: February 14, 2001

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

BONE CARE INTERNATIONAL, INC.

Exhibit Index

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For the Quarterly Period Ended December 31, 2000

<u>No.</u>	<u>Description</u>
4	Bone Care International, Inc., Stock Option Plan, as amended
11	Statement Regarding Computation of Loss Per Share