

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

FORM 10-Q

(Mark one)

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

For the quarterly period ended March 31, 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  
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 May 10, 2001, 13,934,918 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, 2001

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PART 1. FINANCIAL INFORMATION

Item 1. Financial Statements

BONE CARE INTERNATIONAL, INC.  
Balance Sheets

ASSETS		
	March 31, 2001 (Unaudited)	June 30, 2000 (Audited)
Current Assets:		
Cash and cash equivalents	\$ 3,431,461	\$ 4,735,780
Marketable securities	10,561,096	4,972,175
Trade receivables	2,036,299	29,481
Inventories	1,372,265	639,271
Other current assets	874,653	229,438
Total current assets	18,275,774	10,606,145
Investments	20,622,615	--
Property, plant and equipment--at cost:		
Leasehold improvements	614,541	115,532
Furniture and fixtures	401,277	102,482
Laboratory and office equipment	1,394,125	920,699
	2,409,943	1,138,713
Less: accumulated depreciation and amortization	789,028	692,525
	1,620,915	446,188
Patent fees, net of accumulated amortization of \$926,131 at March 31, 2001 and \$810,401 at June 30, 2000	1,041,819	958,980
Excess of cost over fair value of net assets acquired, net of accumulated amortization of \$978,390 at March 31, 2001 and \$911,304 at June 30, 2000	381,527	448,613
	\$41,942,650	\$12,459,926

See the accompanying notes to financial statements.

BONE CARE INTERNATIONAL, INC.  
Balance Sheets

Liabilities and Shareholders' Equity		
	March 31, 2001 (Unaudited)	June 30, 2000 (Audited)
Current liabilities:		
Accounts payable	\$ 512,908	\$ 400,949
Accrued liabilities:		
Accrued clinical study and research costs	107,798	213,718
Accrued compensation	105,529	137,261
Due to customers	232,535	409,655
Other current liabilities	508,299	151,617
Deferred income	--	63,539
Total current liabilities	1,467,069	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 13,931,718 shares at March 31, 2001 and 11,456,668 at June 30, 2000	11,393,883	11,393,883
Additional paid-in capital	61,160,526	25,299,954
Accumulated deficit	(32,241,887)	(25,602,090)
Accumulated other comprehensive gain/(loss)	163,059	(8,560)
Total shareholders' equity	40,475,581	11,083,187
	\$41,942,650	\$12,459,926

See the accompanying notes to financial statements.

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

	Three Months Ended		Nine Months Ended	
	March 31, 2001	March 31, 2000	March 31, 2001	March 31, 2000
Revenues	\$ 2,008,626	\$ 59,001	\$ 3,938,550	\$ 265,078
Operating expenses				
Cost of sales	537,685	20,251	1,033,608	30,819
Inventory write-down	260,000	--	260,000	--
Research and development	1,304,709	911,903	3,355,899	2,994,926
Sales and marketing	1,981,265	1,168,272	5,079,315	3,286,420
General and administrative	677,368	533,647	1,696,949	1,281,151
	4,761,027	2,634,073	11,425,771	7,593,316
Loss from operations	(2,752,401)	(2,575,072)	(7,487,221)	(7,328,238)
Interest income	531,085	200,379	847,424	491,737
Loss before income tax	(2,221,316)	(2,374,693)	(6,639,797)	(6,836,501)
Income tax expense	--	--	--	12,500
Net loss	\$(2,221,316)	\$(2,374,693)	\$(6,639,797)	\$(6,849,001)
Net loss per common share - basic and diluted	\$(0.16)	\$(0.21)	\$(0.53)	\$(0.62)
Weighted average number of common shares	13,929,414	11,415,586	12,532,412	10,943,047

See the accompanying notes to financial statements.

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

	Nine Months Ended	
	March 31, 2001	March 31, 2000
Cash flows from operating activities:		
Net loss	\$ (6,639,797)	\$ (6,849,001)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	430,191	383,342
Changes in assets and liabilities:		
Trade receivables	(2,006,818)	(11,621)
Inventories	(732,994)	12,575
Other current assets	(645,215)	(482,532)
Accounts payable	111,959	212,566
Accrued liabilities	41,910	381,234
Deferred income	(63,539)	261,444
Other	--	40,725
Net cash used in operating activities	(9,504,303)	(6,051,268)
Cash flows from investing activities:		
Purchases of marketable securities, net	(5,417,302)	(8,486,096)
Purchase of non-current marketable securities	(20,622,615)	--
Additions to property, plant and equipment	(1,390,452)	(226,946)
Patent fees, net	(230,219)	(364,124)
Net cash used in investing activities	(27,660,588)	(9,077,166)
Cash flows from financing activities:		
Proceeds from exercise of stock options	87,772	199,562
Net proceeds from issuance of common stock	35,772,800	10,975,610
Net cash provided by financing activities	35,860,572	11,175,172
Net decrease in cash and cash equivalents	(1,304,319)	(3,953,262)
Cash and cash equivalents at beginning of period	4,735,780	7,313,551
Cash and cash equivalents at end of period	\$3,431,461	\$3,360,289

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 March 31, 2001, 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 were 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's June 30, 2000 balance sheet includes deferred income of \$63,539. Bone Care has sufficient experience to estimate future product returns. Effective October 1, 2000 Bone Care 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 March 31, 2001 balance sheet includes \$45,600 classified within other current liabilities, representing the estimated amount of future returns related to Hectorol Capsules and Hectorol Injection.

Bone Care began selling Hectorol Injection in late August 2000. Substantially all sales to date of Hectorol Injection have terms which do not allow the customer a right of return; accordingly, an allowance for future returns has not been recorded.

Bone Care's standard sales terms do not allow customers to return products for refunds; however, products may be exchanged. As of March 31, 2001, and June 30, 2000, Bone Care has accrued \$232,535 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:

	March 31, 2001 (Unaudited)	June 30, 2000 (Audited)
Raw materials	\$ 762,248	\$209,979
Work in process	312,855	22,178
Finished goods	297,162	407,114
	<u>\$1,372,265</u>	<u>\$639,271</u>

### (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 January 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 \$2,115,800 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:

	Nine Months Ended	
	March 31, 2001	March 31, 2000
Comprehensive loss:		
Net loss	\$(6,639,797)	\$(6,849,001)
Unrealized gain (loss)		
on marketable securities	171,619	(16,650)
Total comprehensive loss	<u>\$(6,468,178)</u>	<u>\$(6,865,651)</u>
	Unrealized	
	Gain(Loss)	
	on Securities	
Accumulated other comprehensive loss:		
Balance at June 30, 2000	\$ (8,560)	
Change during nine months ended March 31, 2001	171,619	
Balance at March 31, 2001	<u>\$163,059</u>	

### (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.

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 August 2000. Revenues for the quarter ended March 31, 2001 totaled \$2,008,626 compared to \$59,001 for the quarter ended March 31, 2000. Revenues for the nine months ended March 31, 2001 were \$3,938,550 compared to \$265,078 for the nine months ended March 31, 2000. The increases in revenue during fiscal 2001 were primarily a result of the launch of Hectorol Injection in August 2000.

Gross margins on product revenues (excluding the \$260,000 inventory write-down) were \$1,470,941, or 73% of product revenues, for the quarter ended March 31, 2001, and \$2,904,942, or 74% of product revenues, for the nine months ended March 31, 2001.

Bone Care wrote-off \$260,000 of excess inventory in the quarter ended March 31, 2001, which had been manufactured well in advance of the FDA approval. Management determined that the existing inventory exceeded the amounts expected to be sold prior to expiration.

Research and development expenses were \$1,304,709 in the quarter ended March 31, 2001, compared to \$911,903 in the quarter ended March 31, 2000, and were \$3,335,899 in the nine months ended March 31, 2001 compared to \$2,994,926 in the nine months ended March 31, 2000. The primary reason for the increased research and development expenses in the quarter ended March 31, 2001 relate to the validation of a new supplier of Hectorol's active pharmaceutical ingredient.

Sales and marketing expenses increased \$812,993 to \$1,981,265 in the quarter ended March 31, 2001, from \$1,168,272 in the quarter ended March 31, 2000. In the nine months ended March 31, 2001, sales and marketing expenses increased \$1,792,895 to \$5,079,315 from \$3,286,420 in the nine months ended March 31, 2000. The increases were attributable to:

- additional personnel and promotion expenses associated with Hectorol Injection, and
- the development of a marketing research database to analyze dialysis patient data associated with D-hormone treatments. The database project resulted in \$120,000 of expense in the quarter ended March 31, 2001, and \$240,000 of expense in the nine months ended March 31, 2001.

General and administrative expenses increased \$143,721 to \$677,368 in the quarter ended March 31, 2001 from \$533,647 in the quarter ended March 31, 2000. In the nine months ended March 31, 2001, general and administrative expenses increased \$415,798 to \$1,696,949 from \$1,281,151 in the nine months ended March 31, 2000. The increases were attributable to an expansion of infrastructure to support Bone Care's increased commercial activities.

Interest income increased \$330,706 to \$531,085 in the quarter ended March 31, 2001, from \$200,379 in the quarter ended March 31, 2000. In the nine months ended March 31, 2001, interest income increased \$355,687 to \$847,424 from

\$491,737 in the nine months ended March 31, 2000. The increases in interest income were attributable to receipt of net cash proceeds from the sales of common stock of \$2,115,800 in January 2001, \$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, marketable securities and investments increased \$24,907,217 at March 31, 2001 from \$9,707,955 at June 30, 2000. This increase was primarily due to the receipt of net proceeds of \$35,772,800 from the December 2000 and January 2001 sales of common stock. The net cash received from the sales of common stock was offset primarily by the net use of cash in operating activities of \$9,504,303.

We do not anticipate generating sufficient positive cash flows to fund our operations until additional revenues from the sale of Hectorol products are achieved. 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 March 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 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:
  - (11) Statement Regarding Computation of Loss Per Share
- (b) Reports on Form 8-K
  - None

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 15, 2001

/s/ Charles W. Bishop, Ph.D.

Charles W. Bishop, Ph.D.

President and Chief Executive Officer  
(Principal Executive Officer)

Date: May 15, 2001

/s/ Robert A. Beckman

Robert A. Beckman

Acting Vice President - Finance  
(Principal Financial and Accounting  
Officer)

BONE CARE INTERNATIONAL, INC.

Exhibit Index

For the Quarterly Period Ended March 31, 2001

<u>No.</u>	<u>Description</u>
11	Statement Regarding Computation of Loss Per Share