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BONE CARE INTERNATIONAL INC
Form 10-Q
November 09, 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 September 30, 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 November 2, 2001, 14,022,722 shares of the registrant's common stock, no par value, were outstanding.

BONE CARE INTERNATIONAL, INC.

FORM 10-Q

For the quarterly period ended September 30, 2001

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PART 1. FINANCIAL INFORMATION

Item 1. Financial Statements

BONE CARE INTERNATIONAL, INC.
Balance Sheets

ASSETS

September
2001
(Unaudited)

Current Assets:

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| | |
|---|----------|
| Cash and cash equivalents | \$ 1,373 |
| Marketable securities | 18,842 |
| Accounts receivable, net of allowance for doubtful accounts of \$125,000 and \$100,000 for September 30, 2001 and June 30, 2001, respectively | 3,711 |
| Inventories | 2,922 |
| Other current assets | 1,016 |
| <hr/> | |
| Total current assets | 27,866 |
| <hr/> | |
| Long-term securities | 7,939 |
| Property, plant and equipment - at cost: | |
| Leasehold improvements | 588 |
| Furniture and fixtures | 474 |
| Machinery and other equipment | 1,604 |
| <hr/> | |
| | 2,667 |
| Less accumulated depreciation and amortization | 1,106 |
| <hr/> | |
| | 1,560 |
| Patent fees net of accumulated amortization of \$1,037,465 at September 30, 2001 and \$988,466 at June 30, 2001 | 1,014 |
| Excess of cost over fair value of net assets acquired, net of accumulated amortization of \$1,000,752 at September 30, 2001 and June 30, 2001 | 359 |
| <hr/> | |
| | \$38,740 |
| <hr/> | |

See the accompanying notes to financial statements.

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BONE CARE INTERNATIONAL, INC.
Balance Sheets

Liabilities and Shareholders' Equity

September
2001
(Unaudited)

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Current liabilities:

Accounts payable \$ 1,861

Accrued liabilities:

Accrued clinical study and research costs 231

Accrued compensation 250

Due to customers

Other current liabilities

Allowance for sales returns 205

Total current liabilities 2,548

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 14,022,722 shares at September 30, 2001
and 13,955,372 at June 30, 2001 11,393

Additional paid-in capital 61,437

Accumulated deficit (36,752)

Accumulated other comprehensive income 112

Total shareholders' equity 36,191

\$38,740

See the accompanying notes to financial statements.

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

September
2001

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| | |
|---|------------|
| Revenues | \$ 2,652 |
| ----- | |
| Operating expenses | |
| Cost of sales | 592 |
| Research and development | 1,391 |
| Sales and marketing | 2,249 |
| General and administrative | 914 |
| ----- | |
| | 5,149 |
| ----- | |
| Loss from operations | (2,497) |
| Interest income | 361 |
| ----- | |
| Net loss | \$ (2,136) |
| ===== | |
| Net loss per common share - basic and diluted | \$ (|
| ===== | |
| Weighted average number of common shares | 13,987 |
| ===== | |

See the accompanying notes to financial statements.

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

| | |
|---|------------|
| | ----- |
| | September |
| | 2001 |
| ----- | |
| Cash flows from operating activities | |
| Net loss | \$ (2,136) |
| Adjustments to reconcile net loss to net cash used in operating activities: | |
| Depreciation of fixed assets | 138 |
| Amortization of patents | 57 |
| Amortization of goodwill | |
| Loss on disposal of fixed assets | 1 |
| Loss on disposal of patents | 6 |

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Changes in assets and liabilities:

| | |
|--|----------|
| Accounts receivable | (363) |
| Inventories | (1,112) |
| Other current assets | 68 |
| Other non-current assets | |
| Accounts payable | 249 |
| Accrued liabilities | (79) |
| Deferred income | |
| <hr style="border-top: 1px dashed black;"/> | |
| Net cash used in operating activities | (3,171) |
| <hr style="border-top: 1px dashed black;"/> | |
| Cash flows from investing activities: | |
| Sale of marketable securities | 2,753 |
| Additions to property, plant and equipment | (193) |
| Patent fees | (55) |
| <hr style="border-top: 1px dashed black;"/> | |
| Net cash provided by investing activities | 2,504 |
| <hr style="border-top: 1px dashed black;"/> | |
| Cash flow from financing activities: | |
| Proceeds from stock option exercises | 197 |
| <hr style="border-top: 1px dashed black;"/> | |
| Net cash provided by financing activities | 197 |
| <hr style="border-top: 1px dashed black;"/> | |
| Net decrease in cash and cash equivalents | (46) |
| Cash and cash equivalents at beginning of period | 1,842 |
| <hr style="border-top: 1px dashed black;"/> | |
| Cash and cash equivalents at end of period | \$ 1,373 |
| <hr style="border-top: 3px double black;"/> | |

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

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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 September 30, 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 \$205,000, 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:

| | September 30, 2001 (Unaudited) | June 30, 2001 (Audited) |
|-----------------|--------------------------------------|-------------------------------|
| Raw materials | \$ 266,348 | \$ 385,834 |
| Work in process | 1,031,107 | 955,514 |
| Finished goods | 1,625,139 | 469,226 |
| | ----- | ----- |
| | \$2,922,594 | \$1,810,574 |
| | ===== | ===== |

(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 \$16.00 per share. Bone Care received proceeds of \$2,115,800 from the sale, net of offering expenses.

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(5) NET LOSS PER SHARE

Net loss per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period. Options to purchase common stock have been excluded from the calculations of diluted earnings per share as the impact of these options on diluted earnings per share would be anti-dilutive.

(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

Total revenues for the first quarter ended September 30, 2001 increased to \$2,652,140 from \$1,362,833 in the quarter ended September 30, 2000. The increase was primarily the result of increased sales of Hectorol(R) Capsules, which benefited from the continuing commercial shortage on Rocaltrol(R), a competitive product from Roche Pharmaceuticals.

Gross margins for the quarter ended September 30, 2001, were \$2,059,234, or 78% of revenues compared to \$1,021,617, or 75% of revenues in the quarter ended September 30, 2000. Current quarter margins improved because the cost of inventory previously written off is being recovered since the FDA agreed to extend the shelf life of Hectorol Capsules from three to four years.

Research and development expenses were \$1,391,717 in the quarter ended September 30, 2001, and \$981,266 in the quarter ended September 30, 2000. The increase is attributable to more work being done in preclinical studies to evaluate compounds in the treatment of psoriasis and prostate, breast, and colon cancers.

Sales and marketing expenses increased \$796,918 to \$2,249,835 in the quarter ended September 30, 2001, from \$1,452,917 in the quarter ended September 30, 2000. The increase is attributable to increasing the sales force from 30 to 39 and related marketing expenses in preparation of a national J-code that becomes effective January 1, 2002. This code is issued by the Centers for Medicare and Medicaid Services (CMS) for reimbursement of D-hormone therapies administered intravenously during hemodialysis.

General and administrative expenses increased \$461,715 to \$914,934 in the quarter ended September 30, 2001 from \$453,219 in the quarter ended September 30, 2000. The increase was attributable to an expansion of infrastructure to support Bone Care's increased commercial activities.

Interest income increased \$223,761 to \$361,053 in the quarter ended September 30, 2001, from \$137,292 in the quarter ended September 30, 2000. The increase was due to net higher average cash and marketable securities balances during the quarter ended September 30, 2001.

Liquidity and Capital Resources

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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. 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

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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 \$3,171,914 for the quarter ended September 30, 2001 and \$3,169,289 for the quarter ended September 30, 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 \$28,155,849 at September 30, 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; 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

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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.

Reimbursement Code

On November 5, 2001 Bone Care announced that the Centers for Medicare and Medicaid Services (CMS) has issued a nationwide J-code for Hectorol Injection to

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become effective January 1, 2002. The J-code serves to identify standardized treatments within the CMS centralized billing system and will be used for reimbursement of D-hormone therapies administered intravenously during hemodialysis.

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 September 30, 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.

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PART II - OTHER INFORMATION BONE CARE INTERNATIONAL, INC.

Item 1. Legal Proceedings

Bone Care may be a defendant from time to time in actions arising out of our ordinary course of business operations. In the opinion of management, the outcome of pending claims is not likely to have a material adverse effect on our financial 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

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None

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

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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
- (27) Financial Data Schedule

(b) Reports on Form 8-K

No reports on Form 8-K were filed by the Company during the quarter ended September 30, 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: November 2, 2001 /s/ Richard B. Mazess, Ph.D.
Richard B. Mazess, Ph.D.
Acting President, Chief Executive Officer,
Chairman, and Director
(Principal Executive Officer)

Date: November 2, 2001 /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 September 30, 2001

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